Health Industry Business
Communications Council

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LETTER OF TRANSMITTAL

January 24, 2019

To The European Commission,

HIBCC is pleased to submit to the European Commission our enclosed application to be designated as a UDI Issuing Entity. The application includes supporting attachments and material that is numbered to correspond with the information requested in your Call for Applications.

We look forward to working with the Commission as it launches this important initiative.

Please contact me if additional information or clarification is needed.

Sincerely,

President & CEO

1. Name, address, and phone number of the applicant;

Name: Health Industry Business Communications Council Global Office
Address: 2525 E. Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016
Phone Number: +1 (602) 381-1091

2. Detailed information regarding the applicant's organisation, including the description of any financial or other relationship between the applicant and any manufacturer or governmental institutions or organisation;

HIBCC was established in 1984 by a consortium of healthcare supply chain trade associations for the purpose of creating a bar code (auto-ID) labeling standard for medical devices. The HIBC Supplier Labeling Standard (SLS) (Attachment 1) was successfully implemented and was followed by a series of related standards for auto –ID labeling, electronic data interchange, provider identification, and other supply chain processes. Over time these have evolved with changing technologies and user requirements. The HIBCC office was created to serve as the global secretariat and accredited standards development organization (SDO) for the SLS and our other standards. We were thereafter accredited by the American National Standards Institute (ANSI) (Attachment 4), recognized as part of the International Organization for Standardization (ISO) network (Attachment 2), the Committee for European Normalization (CEN), etc. We are also a designated Issuing Agency for the US Food and Drug Administration (FDA) UDI regulation.

HIBCC is registered and structured as a 501(c)6 non-profit corporation under US law by the US Internal Revenue Service (Federal EIN 36-3313052). In addition to registering companies and organizations with company identifiers (known as Labeler Identification Codes) for UDI and product labeling, HIBCC also provides fee-based database services to companies and government agencies that utilize our Health Industry Number (HIN) System of healthcare provider identifiers. In some cases, HIN users and licensees may also be HIBC SLS product labelers; however HIN services do not relate to the UDI system or our LIC application process.

HIBCC standards are maintained in conformance with standard operation procedures, and are designed to assure conformity, patient safety, and supply chain efficiency. Various companies, healthcare institutions, and other organizations, including government agencies, participate in our technical committees. All participants are required to comply with HIBCC's Antitrust Policy (Attachment 7) and HIBCC's Conflict of Interest Policy (Attachment 8).

HIBCC supports a network of affiliated organizations, such as the European Health Industry Business Council (EHIBCC) and others, to provide technical support to our labelers. However, changes and/or maintenance to the standard, as well as policy, oversight and registration maintenance are the responsibility of HIBCC.

3. Detailed description of its system for the assignment of UDIs, including description of any standard or criteria applied;

The HIBC Supplier Labeling Standard (SLS) (Attachment 1) is accredited by ANSI, and in conformance with the EU MDR and FDA UDI rule. Labelers using the HIBC SLS are required to strictly adhere to the standard in order to be in conformance with all UDI regulations from which they will derive their device and production identifiers. In order to become a labeler, the interested party will register with HIBCC to obtain a Labeler Identification Code (LIC). HIBCC will then assign a unique 4-digit, alphanumeric code (such as B123) to identify the registrant. The LIC code is never duplicated or reassigned and thus is distinctly unique to that registrant/labeler. HIBCC maintains the LIC assignments in an internal database.

The HIBC Supplier Labeling Standard (SLS) is the guideline from which a labeler will derive their UDI data. The HIBC SLS specifies the type of information that should be encoded and the method of doing so.

For instance, the primary data string requires a “+” flag character, the 4-character LIC, a 1-18 character product or catalog identifier, a one-digit unit of measure and a single-digit check characters. Elements of this data string become the device identifier.

Secondary information such as lot/batch number, serial number, expiry date an/or date of manufacture are prescribed as well, and will provide the method for developing the production identifier. (Please reference the attached HIBC SLS for specific encoding requirements.)

Because the LIC assignment is unique to the individual labeler and never reassigned to a different labeler, when attached to their own product code it inherently creates a unique data string. No two UDIs could be alike because of the uniqueness of the LIC assignment. And because the HIBC SLS is variable length, and alphanumeric there are virtually limitless numbers of possible UDIs.

Attached are the American National Standard Institute (ANSI) approved HIBCC Standard Operating Procedures, which document the required process for updating a standard (Attachment 9). All updates to the HIBC Supplier Labeling Standard are made in an effort to support the EU MDR requirements and provide additional clarification surrounding any common areas of confusion. All versions of the standard are backward compatible to ensure that any UDI created in a previous version maintains compliance.

All new versions of the HIBC Supplier Labeling Standard (SLS) are approved by ANSI and subsequently published in their publication "Standards Action". HIBCC posts all new versions of the standard on our website and sends an email notification describing any updates to all HIBCC labelers. Additionally, HIBCC works with labelers one-on-one to review all changes as requested.

4. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to manufacturers who plan to use the applicant's system for the assignment of UDIs. Where those materials are still under preparation, the applicant shall provide a detailed plan for adoption of those materials;

All labelers receive a welcome letter (Attachment 15) upon registering with HIBCC, which confirms the 4-character LIC assignment. Labelers are also given the latest copy of the Supplier Labeling Standard (Attachment 1) and the relevant technical guidance documents (Attachment 11, 12, 5, and 6). All guidance documents are created and/or updated constantly. HIBCC plans to release EU MDR specific guidance documents once the MDR guidelines are finalized.

5. Detailed description of the applicant's policies and procedures for determining whether manufacturers may use the applicant's system;

The HIBC Supplier Labeling Standard is an open standard and available to all parties that elect to use it.

The HIBCC organization is the sole assigner of the Labeler Identification Code (LIC). An application form (Attachment 14) and payment of a one-time fee (Attachment 10) is required for assignment of an LIC. HIBCC released a Clarification on LIC Fees (Attachment 18) in 2016 to ensure the process maintained clear and transparent for all parties.

6. Description of the applicant's policies/procedures for dealing with manufacturers' deficiencies in using correctly the system for the assignment of UDIs, including for monitoring corrections;

HIBCC will notify labelers of deficiencies in the use of the HIBC Supplier Labeling Standard by letter (Attachment 3). This notice requires the organization to take corrective action within 30 days of receiving the letter. The most common action would be to update an existing LIC or apply for a new LIC.

In the case of an organization using an LIC that is not registered to them, HIBCC would issue a cease and desist letter. Additionally, HIBCC will notify all regulatory bodies including the European Commission and the U.S. FDA, in the event that an organization is using an unregistered HIBCC prefix.

7. Description of business model and fee system, with an explanation and rationale of any fee waiver or reduction available;

HIBCC has been registering labelers for 30 years, and will further enhance processes to meet EU MDR requirements. The registration process requires a new labeler to pay a one-time application to HIBCC for assignment of the Labeler Identification Code (LIC). Thereafter, there are no reoccurring fees to the labeler to maintain their LIC. HIBCC continues to provide technical support and guidance to labelers at their request. The assigned LIC is applied globally, and can be used for the labeling of a registrant's entire product line.

There are no fees for individual product code assignments. Additionally, because of the variable-length, alphanumeric structure of the HIBC Supplier Labeling Standard, there are virtually limitless possible combinations to create a UDI compliant data string.

The LIC registration fee is based upon a progressive fee-schedule that is tied the labelers gross annual sales in its immediate prior fiscal year. LIC registration fees are extremely modest and because of their progressive schedule to do not impose a burden on small companies. We estimate that the vast majority of the medium to large companies already have a HIBC LIC or GTIN, therefore we believe the majority of new applicants will be at low-end of the fee schedule. (See Attachment 14 and 10 for application and fee schedule.)

8. Detailed description of the applicant's electronic data management system;

HIBCC currently maintains numerous databases for the health care industry and routinely distributes the data via various mediums including hard format, Electronic Data Interchange (EDI) and web-based services. These data distribution processes occur daily, weekly and quarterly. As such HIBCC is well positioned in terms of experience and infrastructure to provide electronic data in a format compatible with European Union data systems.

The draft guidance on the Eudamed database is currently being reviewed by HIBCC so that it can plan for the development of compatible systems when the final specification is released.

9. Description of the tools or services made available by the applicant allowing to check data quality in the EU database (Eudamed);

The "HIBCC UDI and Bar Code Generator" (Attachment 19) is a free utility available on the HIBCC website that allows labelers to generate sample UDIs and barcodes to the specifications in the HIBC standard. The utility currently creates the UDI Device Identifier in the correct format for GUDID submissions to assist labelers in achieving UDI compliance .The utility is updated in conjunction with the HIBC standard. HIBCC will make updates and enhancements to this utility to conform with the Eudamed database requirements.

HIBCC has recently launched a modification to its existing online UDI Generator Utility, which will compare LICs entered by labelers to our database in order to confirm that the LIC is valid (Attachment 19). This process will provide the labeler with a mechanism to confirm that they are using their assigned LIC.

HIBCC plans to offer a certification service beginning in 2019 which will examine sample labels and UDIs for compliance to the HIBCC Standard. The certification service will be voluntary and offered to all HIBCC labelers.

The "HIBCC UDI Decoder" (Attachment 20) is a free mobile application for iOS and Android platforms that scans and parses the information in a HIBC auto-ID symbol. This application is not intended to replace any barcode verification process. It is meant as a tool to help anyone become more familiar with the HIBC standard.

10. The form "Applicant's undertakings", signed by the applicant organisation's legal representative in the European Union;

Per our call with EC staff on January 17, 2019, HIBCC will be opening an additional administrative in Brussels to support the EU MDR. HIBCC will continue to utilize affiliate organizations in Europe, i.e. EHIBCC, for technical support. HIBCC will keep the EC updated on the progress of the administrative office and of any changes in the legal representative. Please see Attachment 21 for the signed "Applicant's Undertakings" document.

11. Detailed information and, if available, market studies on the readability of UDI carriers which are compliant with the applicant's technical specification by the readers generally available to economic operators and healthcare institutions within the EU.

When the Health Industry Supplier Labeling Standard (HIBC SLS) was developed in 1984, the specification specifically stated that Auto-ID symbols and specifications for the standard were to be in conformance with universally approved and accepted symbologies, as well as printing, encoding, and scanning specifications. As the standard evolved to include small-package and two-dimensional symbols the standard has continued to adhere to those requirements. These specifications are as required by internationally recognized governance bodies such as ISO, AIM International, etc. Thus, HIBCC has never encountered an instance in which our standards specification did not conformed to these norms.

ANSI/HIBC 2.6

THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (UDI)

An American National Standard (ANS)

AMERICAN NATIONAL STANDARD

Approval of an American National Standard requires verification by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgment of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made toward their resolution.

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The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

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THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD: FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (HIBC / SLS / UDI)

SECRETARIAT:
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HIBCC Standards are supported globally. HIBCC Standards are developed in accordance with the procedures of the American National Standards Institute (ANSI) and in consultation with our affiliates and other interested parties. For additional information and support options, contact HIBCC via email at info@hibcc.org or by calling 602.381.1091 (use country code '001' if calling from outside of the United States).

Contents

Foreword

Automatic identification technology is continually evolving. As technological advances prove applicable to the health care industry, they will be incorporated into revisions of this standard, wherever possible. However, every attempt will be made to maintain the existing data structures, thereby allowing new technology to be introduced into systems in a non-disruptive manner. HIBCC recognizes that this standard is a technology driven solution to improvement of health care delivery. As new technology becomes widely available, the standard will be modified to incorporate the advantages of the new technologies.

1.0 Scope

This document describes the voluntary HIBC Supplier Labeling Standard for products distributed within the health care industry. Labelers (manufacturers) of health care products are strongly encouraged to identify their products with consistently readable symbols in accordance with the standards described herein.

1.1 Symbol Quality Compliance and Printing Assistance

Printed bar code symbols must meet or exceed the quality requirements of Section 5 and be easily scannable by standard bar code scanners at the point of use. Labelers having questions about or problems meeting the requirements of this standard should contact HIBCC in Phoenix at (602) 381-1091.

2.0 Supplier Labeling Data Structures

It is intended that all health care products be labeled with a Primary Symbol, which identifies the labeler in an internationally consistent and unique manner, the product code, and the unit of measure. Secondary information is useful to distributors and providers and, at the discretion of the labeler, should be added.

2.1 Primary Data Structure (Device Identifier)

The primary data structure contains an indication of the labeler of the item, the item, the packaging level, and a Check Character. Once constructed from these four elements, these structures should not be parsed. The labeler identification is a data element that is controlled by the Health Industry Business Communications Council (HIBCC). A labeler that chooses to utilize the HIBC Labeler Identification Code (LIC) should follow the HIBC LIC data and symbology format.

2.1.1 HIBC LIC Primary Data Structure (Device Identifier)

The HIBC LIC Primary Data Structure format encodes a "+" data identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single Check Character (C).

The format for the Primary Data Structure format follows (for illustration purposes, the product identifier, or PCN, is shown at its maximum length, 18 characters, therefore the maximum symbol length is 25 characters): See Table 1

+ I I I I P P P P P P P P P P P P P P P P U C

where: (see below)

Table 1

Field Descriptor	Field Length	(F)ixed Length (V)ariable Length	Field Description
+	1	F	HIBC Supplier Labeling Flag Character "+"
I	4	F	Labeler Identification Code (LIC) an alphanumeric number, with the first character always being alphabetic.
P	1-18	V	Labelers Product or Catalog Number (PCN). Alphanumeric data
U	1	F	Unit of Measure ID, Numeric value only, 0 through 9, where 0 always represents a single unit.1 to 8 are used to indicate different packaging levels above the unit of use. The value 9 is used for variable quantity containers when manual key entry or scan of a secondary will be used to collect specific quantity data. The labeler should ensure consistency in this field within their packaging process.
C	1	F	Check Character calculated from the above characters. (see Appendix B2)

The Labeler Identification Code (LIC) is assigned and maintained by HIBCC. The first character of this field will always be an alphabetic character. The LIC may identify a labeler to the point of separate subsidiaries and divisions within a parent organization.

The Product or Catalog Number (PCN) shall be compressed to eliminate embedded spaces and special characters. Special characters shall not be used in this field. The allowed characters are A through Z and 0 through 9. Examples of this compression follow:

655-9 ..... would become 6559
24-86-2S ..... would become 24862S
84/XPG ..... would become 84XPG
MP 15 86-G…….would become MP1586G
92.885*BK ..... would become 92885BK

This compression impacts only the machine-readable representations of the PCN and its associated human readable interpretations. Other external package markings and catalog listings covered by this standard remain the prerogative of the individual labeler.

The Unit of Measure Identifier (U/M) is a numeric representation of the relative level of packaging (0 to 9) with 0 being the lowest level or "unit-of-use". For example, a labeler might pack unit-of-use items in a box, boxes in a carton, and cartons in a case. One way of labeling this example would be, unit-of-use = 0; Box = 1; Carton = 3; and Case = 5. It may be that a unit-of-use is packaged, however, in a box. For instance, individual cotton swabs would be considered the unit-of-use and may go unmarked. Consequently, the box in which the cotton swabs were packaged would be marked with the HIBC Supplier Primary Data Structure with a 1 or greater in the U/M field. Note that U/M identifiers are arbitrarily assigned by each labeler and must be internally consistent.

2.1.2 Primary Data Structure in Electronic Data Interchange

For information about communicating Primary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.1.3 Reuse of HIBC Primary Identifier

A HIBC Primary Identifier shall not be reissued to any other item, even if the item to which it has been assigned has been discontinued, or superseded by another product.

2.1.4 Definition of the HIBCC Universal Product Number (UPN)

The HIBCC UPN is the Primary Identifier excluding the "+" character and the Check Character.

2.2 Secondary Data Structure (Production Identifier)

Optional secondary data elements are used in conjunction with primary data elements, for example to encode expiry date and/or Lot/Batch/Serial Number. Appendices E and F describe the secondary data fields in detail.

2.2.1 HIBC LIC Secondary Data Structure

The format for the HIBC Secondary Data Structure is shown in Table 2.

Table 2

Field Descriptor	Field Length	Field Description
+	1	Internationally recognized, unique, HIBC Supplier Labeling Data Identifier Flag Character, "+"
R	1, 2 , 3, or 5	Date/Lot or Serial Number Reference Identifier Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No Lot/Batch or Serial Number is present (See Note 2) $: If the first character is a "$" and the second character is alphanumeric, then the Date fields are not used. $+: If the first two characters are "$+" and the third character is alphanumeric then a serial number only follows. This format is included for backward compatibility only. It is recommended that "$$+7" be used to indicate a serial number follows. $$: If the first two characters are "$$" followed by a digit, then the digit specifies the Date Field format. For use with lot numbers, not serial numbers. $$+: If the first three characters are "$$+" followed by digit, then the digit specifies the date field format. For use with serial numbers, not lot numbers. See Appendix E1.2 If the first character is a number then the 5-digit Julian Date format follows. This format is included for backward compatibility only. It is recommended that "$$7" be used to indicate a lot/batch.
D	0 or 4-9	Expiry Date Field, for use after the Reference Identifier (includes the date field format indicator).
B	0-18	Lot/Batch **or** Serial Number Field, Alphanumeric field. See Appendix E1.2
L	1	Link Character (Check Character from primary data field.) (See 2.2.1.1 for concatenation rule).
C	1	Modulo 43 Check Character (calculated from the above characters) See Appendix B2.0.

Note 1: The HIBC Secondary Data Structure is distinguished from the Primary Data Structure in that the Primary Data Structure has an alphabetic character following the HIBC Supplier Labeling Flag Character "+",while the Secondary Data Structure has a numeric character or a "$" following the HIBC Supplier Labeling Flag Character. See Appendices E and F for more information.

Note 2: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5"."

Note 3: Quantity is no longer included in the Secondary Data Structure as it had been in previous versions of the standard, but can be included as Supplemental Data. For more information on how to include Quantity as Supplemental Data see section 2.3.2.4.

2.2.1.1 Combining Primary and Secondary Codes in One Symbol when Using the HIBC LIC Format

When combining the Primary and Secondary Code into a single symbol (known as concatenation), a forward slash (/) is used as a delimiter between the primary and secondary data. In addition, the primary data Link Character, the plus (+) at the start of the secondary data, and the secondary data Link Character are omitted. Only one Check Character at the end of the symbol will be used which will check the entire data string.

For example:
+ A 9 9 9 1 2 3 4 5 / $ $ 5 200 0 1 5 1 0 X 3 3
Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
3	3 is the Check Character

2.2.2 Secondary Data Structure in Electronic Data Interchange

For information about communicating Secondary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.3 Additional Supplemental Data

Additional Supplemental Data can be added to the Secondary data string. It is strongly recommended that Additional Supplemental Data be used in the concatenated format and with 2D symbologies to reduce the risk of creating a linear bar code that may be too long for practical use. Additional Supplemental Data can be used when a manufacturer wishes to encode both lot number and serial number in the same symbol, date of manufacture, expiry date in the YYYYMMDD format, and/or quantity. Quantity must be the last field in supplemental data when used in conjunction with other supplemental data.

2.3.1 Data syntax

The Secondary Supplemental Data field is constructed with a "/" character followed by a Data Identifier (DI), followed by data. Multiple Secondary Supplemental data fields are possible. The Secondary Supplemental Data will always follow the Secondary data, and the check character will be inserted at the end of the total string.

2.3.2 Data usage

2.3.2.1 Serial number when Lot number is used

For example, when serial number is encoded with the DI "S" using the following format.

Field Length - an1 + an18 S Serial number or code assigned by the Supplier to an entity for its lifetime, (e.g., computer serial number, traceability number, contract tool identification)

2.3.2.2 Date of Manufacture

Date of Manufacture is encoded with DI “16D” using the following format.

Field Length - an3+n8 16D Production Date (YYYYMMDD) – Date of manufacture

2.3.2 Example of HIBC data string with Secondary Supplemental Data

Following is an example with both a Date of Manufacture and a serial number added to a HIBC Primary and Secondary symbol containing a lot number and an expiry date.

+A99912345/$$52001510X3/16D20111212/S77DEFG457

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111212	December 12, 2011
/	Secondary Supplemental Data delimiter
S	Serial Number Data Identifier
77DEFG45	serial Number
7	7 is the Mod 43 Check Character

2.3.2.3 Expiry date formatted as YYYYMMDD

Where a manufacturer wishes to use an expiry date with the format YYYYMMDD, which is not one of the available options in the secondary data formats, the manufacturer can instead use the supplemental data option for expiry date.

When using the supplemental data option the expiry date is encoded with DI “14D” using the following format.

Field Length - an3+n8 14D Expiry Date (YYYYMMDD) – Date of expiry

Following is an example with both a Date of Manufacture and the expiry date are added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/$10X3/16D20111231/14D202001313

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
3	3 is the Mod 43 Check Character

2.3.2.4 Quantity

Where a manufacturer wishes to include quantity they shall use the supplemental data option for quantity.*

When using the supplemental data option the quantity is encoded with DI “Q” using the following format.

Field Length - an1+n1...n5 Q Quantity

Following is an example with a Date of Manufacture, YYYYMMDD expiry date, and quantity added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/$10X3/16D20111231/14D20200131/Q500V

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
9	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
/	Secondary Supplemental Data delimiter
Q	Quantity Identifier
500	Quantity
Z	Z is the Mod 43 Check Character

*Note: Quantity is an optional field and should only be used with the Unit of Measure "9" for packages containing variable quantities.

3.0 Label Symbologies

It is possible for a Primary (or a Primary and Secondary) Label to be encoded in one of two possible linear bar code symbologies, or alternatively in one of the approved 2D symbologies.

No special characters (-, ., $, /, +, %, and space) are used in the Primary data structure other than the use of the flag characters, "+" and "$", in the beginning of the HIBC LIC symbols. The use of the special characters "." and "-" are permitted in the Secondary data structure. Note that the generated Check Character may, however, be one of these special characters, including space. In addition, when combining both Primary and Secondary information in a single barcode, the "/" character is used as a concatenation character. (See section 2.2.1.1 for use).

The data structure and human-readable interpretation is identical regardless of symbology used.

See Appendix C for detailed printing information.

Specifications for these symbologies are available http://www.ansi.org and http://www.iso.org .

3.1 HIBC LIC Primary and/or Secondary Data – Linear Symbologies

Where a labeler decides to use a linear symbology, the labeler may use either of the linear symbologies in this section as directed.

- **Code 128:** HIBC primary and secondary data should be printed in separate Code 128 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification.*

- **Code 39**: HIBC primary and secondary data should be printed in separate Code 39 symbols but may be concatenated if space allows. More information on this symbology may be obtained *from ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification.*

If Code 39 is used, the Regular setting (not Full ASCII) should be used. In addition, the full ASCII function shall be disabled in the reader. The wide to narrow ratio should be 3:1, the inter-character gap should be equal to the nominal narrow element dimension (X-dimension) and the optional Mod 43 symbology Check Character is used.

3.2 HIBC LIC Primary and/or Secondary Data – 2D Symbologies

Where a labeler decides to use a 2D symbology, the labeler may use any one of the 2D symbologies in this section. When using a 2D symbol, a single 2D code should be used to carry all Primary, secondary and supplemental HIBC data as required. For example, those requiring the use of Primary and Secondary data structures should concatenate both into a single 2D symbol (See section 2.2.1.1 for concatenation mechanism).

- **Aztec Code:** HIBC data should be printed in a single Aztec Code symbol. More information on this symbology may be obtained from *ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification.*

- **Data Matrix ECC200:** HIBC data should be printed in a single Data Matrix ECC200 symbol. More information on this symbology may be obtained from *ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification,*

- **QR Code:** HIBC data should be printed in a single QR Code symbol. More information on this symbology may be obtained *from ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification*

4.0 Label Features

HIBC Guidelines provide information on printing techniques, symbol placement, and symbol orientation.

See Section 5 for print quality requirements and Appendix C for specific 2D symbol rules, guidance and examples

4.1 Human-Readable Interpretation

References are made to the Human Readable Interpretation of the bar code or auto-ID symbol in this standard. This refers to the text representation of the data in the bar code or auto-ID symbol that can be displayed underneath the bar code or auto-ID symbol. For example:

+83278F8G9H0J2G%

On product labels or packaging for medical devices, the generally accepted convention for displaying “plain-text” information is by using the symbols as shown in the example below:

2016-09-30 (to indicate the expiry date of September 30, 2016)

2010-09-30 (to indicate the manufacture date)

16390082 (to indicate the lot number)

All product marking including marking required by law shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

The following are meant as guidance, and in no case are to be meant to replace appropriate regulations.

The preferred human-readable interpretation of a HIBC Supplier Labeling linear Symbol is a line of characters, preferably directly underneath the bar code symbol, representing all encoded characters. The human-readable interpretation is intended to be used for human recognition only, and not as a method of machine readability addressed in this standard.

It is the recommendation of HIBCC that the human-readable interpretation of zero be represented as “Ø”. The Check Character or Link Character in the symbol will sometimes be a space character. In this case, the human-readable interpretation shall use an “underscore” to represent the space character. See Appendix B.2.1 for further guidance.

While the asterisk, “*” is not encoded within the barcode symbols, the human-readable interpretation for both HIBC LIC Primary and Secondary linear symbols should be bounded in the beginning and at the end of the data string by an asterisk, “*”.

The recommended human-readable format for the linear HIBC LIC Primary and Secondary Symbol should always enclose the human-readable data with the “*” regardless of symbology and should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

4.2 Label Placement

Transport package labels should be placed no closer than 1.25 inches (3.2 cm) from any package edge, and the bottom edge of the label should be within the range of 1.25 inches to 3.0 inches (3.2 cm to 7.6 cm) from the natural bottom of the package.

4.3 Bar Code Symbol Examples

Examples of formats and printed symbols are shown below

4.3.1 HIBC LIC Primary Data Structure

Shown below are examples of the symbols for the HIBC LIC Primary Data Structure.

Figure 1. Code 128
Note: the figures in this document are here as examples only, and due to the nature of the document their resolution may not conform to the specifications that are needed when using these symbols in a working environment

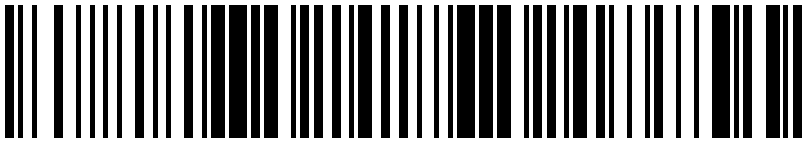
Figure 2. Code 39

+A123BJC5D6E71G

Figure 3 Data Matrix

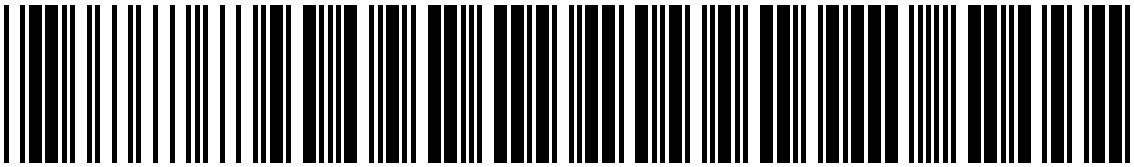
4.3.2 HIBC LIC Secondary Data Structure

Shown below are examples of the symbols for the HIBC LIC Secondary Code Data Structure. They are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is G, and the Check character in the example below is D.



+$$52001510X3GD

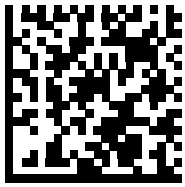
Figure 5. Code 128



+$$52001510X3GD

Figure 6. Code 39

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol



***+A123BJC5D6E71/**
$$52001510X3C*

Note: the 2D concatenated symbol does not contain either check character of the primary symbols but rather has a new check character for the entire data string. The link character is not included in the concatenated symbol.

5.0 Print Quality

5.1 Code 128 or Code 39

The bar code symbol quality for a Code 128 or Code 39 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.010 inches (0.25 mm). Those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm) providing the print quality requirements are met.

Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

5.2 Aztec Code, Data Matrix or QR Code

The bar code symbol quality for an Aztec Code, Data Matrix or QR Code symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.015 inches (0.37 mm). Any X-dimension greater than 0.010 (0.25mm) inches is allowable if the print quality requirement is met.

6.0 Radio Frequency Identification (RFID)

HIBCC has produced a Guideline for RFID – *Using HIBC Standards with RFID: An Implementation Guideline,* which is a specification of the coding schemas required for RFID tagging using the HIBCC standards. This guideline is available from HIBCC, and can be downloaded from the HIBCC website www.hibcc.org.

Appendix A – Julian Calendar

Table A1

DAY OF MONTH	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	001	032	060	091	121	152	182	213	244	274	305	335
2	002	033	061	092	122	153	183	214	245	275	306	336
3	003	034	062	093	123	154	184	215	246	276	307	337
4	004	035	063	094	124	155	185	216	247	277	308	338
5	005	036	064	095	125	156	186	217	248	278	309	339
6	006	037	065	096	126	157	187	218	249	279	310	340
7	007	038	066	097	127	158	188	219	250	280	311	341
8	008	039	067	098	128	159	189	220	251	281	312	342
9	009	040	068	099	129	160	190	221	252	282	313	343
10	010	041	069	100	130	161	191	222	253	283	314	344
11	011	042	070	101	131	162	192	223	254	284	315	345
12	012	043	071	102	132	163	193	224	255	285	316	346
13	013	044	072	103	133	164	194	225	256	286	317	347
14	014	045	073	104	134	165	195	226	257	287	318	348
15	015	046	074	105	135	166	196	227	258	288	319	349
16	016	047	075	106	136	167	197	228	259	289	320	350
17	017	048	076	107	137	168	198	229	260	290	321	351
18	018	049	077	108	138	169	199	230	261	291	322	352
19	019	050	078	109	139	170	200	231	262	292	323	353
20	020	051	079	110	140	171	201	232	263	293	324	354
21	021	052	080	111	141	172	202	233	264	294	325	355
22	022	053	081	112	142	173	203	234	265	295	326	356
23	023	054	082	113	143	174	204	235	266	296	327	357
24	024	055	083	114	144	175	205	236	267	297	328	358
25	025	056	084	115	145	176	206	237	268	298	329	359
26	026	057	085	116	146	177	207	238	269	299	330	360
27	027	058	086	117	147	178	208	239	270	300	331	361
28	028	059	087	118	148	179	209	240	271	301	332	362
29	029	*	088	119	149	180	210	241	272	302	333	363
30	030		089	120	150	181	211	242	273	303	334	364
31	031		090		151		212	243		304		365

The HIBC Supplier Labeling Standard Format for use of Julian dating includes the last two digits of the year followed by a three-digit day-of-the-year code. For example, November 7, 1994 is represented as “94311” (the 311th day of 1994).

*A leap year has 366 days with February having 29. Julian dating in leap years is the same through February 28 (059) with February 29 as 060. All dating from March 1 through December 31 is incremented by one during leap years.

Appendix B – Check Character Calculation

B.1.0 Check Character Calculation

Be sure to use the Modulo 43 calculation when using the HIBC LIC data structures regardless of the symbology used.

B.2.0 HIBC LIC Check Character Modulo 43 Generator

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Supplier Labeling Data Structure: + A 1 2 3 B J C 5 D 6 E 7 1
Sum of values: 41+10+1+2+3+11+19+12+5+13+6+14+7+1 = 145

Divide 145 by 43. The quotient is 3 with a remainder of 16. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 16, or "G". The complete Supplier Labeling Data Structure, including the Check Character, would therefore be:

+ A 1 2 3 B J C 5 D 6 E 7 1 G

Table of numerical value assignments for computing the HIBC LIC data format Check Character

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

B.2.1 Space Character Caution

The HIBC-LIC Check/Link character is **never** part of the **data message.** As such it should not normally be stored in a database or transmitted via EDI. It should be stripped away after the check and link functions have been executed. One of the possible values of the Check/Link Character is a space character (value 38). Although not recommended, if the link character must be stored or transmitted, the space character should be stored or transmitted explicitly as ASCII decimal 32 (ASCII Hex '20'). Note that some legacy systems and or software are unable to receive and or interpret trailing spaces as part of a data message.

Appendix C – Printing and Scanning Considerations

C.1 Printing Plates

Often, source printing requires the generation of a printing plate. Care should be given to produce the printing plate with smaller bars to compensate for ink spread. When “bar width reduction” or “X-dimension width reduction” is implemented, be sure that the spaces are enlarged by the same amount that the bars are reduced. The print quality requirement must be met on the final printed symbol. The printing plate can be fabricated using any method or accuracy as long as the final printed symbol meets the above specification.

C.2 Scanning Considerations

Scanners have different capabilities, be sure to match your scanner with your proposed symbol.

C.3 Example Symbols - Primary Data Structure

Example Data Structure:

+H123ABC01234567890D

Aztec Code

0.19" wide, 0.19" high
15 mil cell size, 19 x 19 matrix

Figure C1 Aztec Code

Data Matrix ECC200

0.18" wide, 0.18" high
15 mil cell size, 18 X 18 matrix

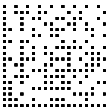


Figure C2 Data Matrix ECC200

QR Code

0.21" wide, 0.21" high
15 mil cell size, 21 X 21 matrix

Figure C5 QR Code

Appendix D – Reference Definitions

For the purposes of printing the HIBC Supplier Labeling Symbol, the following informative definitions are included for convenience.

D.1 Bars
The black or darker areas of the bar code symbol.

D.2 HIBC
Health Industry Bar Code.

D.3 HIBCC
HIBCC (Health Industry Business Communications Council) is the organization responsible for the development and maintenance of standards and services for use in the health care industry. HIBCC standards and information on its services, including the HIN System, Unique Device Identification (UDI) and other ecommerce applications are available from HIBCC at: 2525 E Arizona Biltmore Circle, Suite 127, Phoenix, Arizona. The telephone number for HIBCC is 602-381-1091. Fax: 602-381-1093. Email: info@hibcc.org Web site: http://www.hibcc.org.

D.4 Quiet Zone
An area free of printing, preceding and following all linear bar code symbols and surrounding 2D symbols, that is required for the decoding process. The quiet zones for Code 128 and Code 39 are at least ten times the X-dimension in size.

D.5 Scannability
A general term describing the property of a bar code symbol whereby an attempt to use bar code reading hardware is successful. Symbols that meet ISO/IEC 15415 and ISO/IEC 15416 with a print quality level of C/06/660 generally will be scannable with a broad range of hand held bar code reading hardware.

D.6 Spaces
The white or lighter areas of the bar code symbol including the quiet zones.

D.7 Symbology
A set of rules for encoding information in a bar code symbol.

D.8 Unit-of-Use
A packaging level containing the item (the each) that is to be individually administered in a health care provider facility.

D.9 X-Dimension
The intended width of the narrow bar and narrow space in a bar code symbol.

Appendix E – HIBC Secondary Data Fields

E1.0 HIBC LIC Secondary Data Field

Appendix E describes the Secondary Data Formats with some examples. See Appendix F for a complete listing of Secondary Data Format options.

E1.1 Date Fields

These examples are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is "G". Check characters have been calculated for these examples.

If the character following the leading "+" is a "$" but the next character is alphanumeric, then the Date Field is null, and the character following the "$" is the first character in the Lot/Batch Number.

For example:

+ $ A 1 2 3 4 G U *Lot # is A1234*

If there is a two character lot number flag "$$", or a three character serial number flag "$$+", following the leading "+", then the first digit following will specify the Date Field formats:

The digits 0 through 7 specify the Date Format:

0, 1 First digit of month in MMYY (month/year) Date format
2 MMDDYY (month/day/year) Date follows
3 YYMMDD (year/month/day) Date follows
4 YYMMDDHH (year/month/day/hour G.M.T.) Date follows
5 YYJJJ (year/Julian day) Date follows
6 YYJJJHH (year/Julian day/hour G.M.T.) Date follows
7 Date Field is null, Lot Field follows

E1.2 Lot/Batch and or Serial Number Field

The Lot/Batch or Serial Number field can be alphanumeric and vary in length up to a maximum of 18 characters. If the field is not required (because neither Lot/Batch nor Serial Number is desired), the field should be null. The string header +$$ is used for Lot/Batch cases, with +$$+ being used exclusively for Serial Number implementations.

E1.3 Link Character

The Link Character is intended to link the Primary and Secondary Code Data Structures when encoded in separate linear symbols. The Link Character for the Secondary Data Structure is the last character from the Primary Data String in the Primary Symbol (Check Character). The Link Character is not included in concatenated data structures.

Appendix F – Data Formats for HIBC Secondary Bar Codes

The following tables show the correct data formats for HIBC secondary bar codes. If a column is left blank, then that information is not used. The following field descriptions are used:

MM	2 digit expire date month indicator (fixed length of 2 numeric digits)
YY	2 digit expire date year indicator (fixed length of 2 numeric digits)
DD	2 digit expire date day indicator (fixed length of 2 numeric digits)
HH	2 digit expire date hour indicator (fixed length of 2, G.M.T. format)
JJJ	3 digit expire date Julian Day indicator (fixed length of 3 numeric digits)
LOT	up to 18-digit alpha/numeric lot/batch number
S/N	up to 18-digit alpha/numeric serial number
L	Link Character
C	Modulo 43 Check Character

The following example data is always used in table F1:

Lot Number	3C001
Serial Number	0001
Link Character	L (Check Character from Primary Symbol)
Check Character	C (1 character Modulo 43 Check Character)
Expire	Date September 28, 2005 at 10 PM

The following are the secondary data formats. As stated before, when encoding in separate linear symbols, the link character 'L' is the last character from the primary data string. If the primary message were +A123BJC5D6E71G as in example 4.3.1, the link character 'L' would have a value of 'G'. The Check Character 'C' has not been calculated in these examples.

Table F1

HIBCC Qty Flag	Exp Date Flag	Exp Date Format	Lot/Batch Field	Serial Number Field	Link Char	Mod 43 Ck Char	Example Data
+		YYJJJ	Note 1		L	C	+05271LC
+$			LOT		L	C	+$3C001LC
+$$		MMYY	LOT		L	C	+$$09053C001LC
+$$	2	MMDDYY	LOT		L	C	+$$20928053C001LC
+$$	3	YYMMDD	LOT		L	C	+$$30509283C001LC
+$$	4	YYMMDDHH	LOT		L	C	+$$4050928223C001LC
+$$	5	YYJJJ	LOT		L	C	+$$5052713C001LC
+$$	6	YYJJJHH	LOT		L	C	+$$605271223C001LC
+$$	7		LOT		L	C	+$$73C001LC
+$+				S/N	L	C	+$+0001LC
+$$+		MMYY		S/N	L	C	+$$+09050001LC
+$$+	2	MMDDYY		S/N	L	C	+$$+20928050001LC
+$$+	3	YYMMDD		S/N	L	C	+$$+30509280001LC
+$$+	4	YYMMDDHH		S/N	L	C	+$$+4050928200001LC
+$$+	5	YYJJJ		S/N	L	C	+$$+5052710001LC
+$$+	6	YYJJJHH		S/N	L	C	+$$+605271200001LC
+$$+	7			S/N	L	C	+$$+70001LC

Note 1: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5".

Note 2: Secondary Supplemental Data can be included in the data string by the following the rules defined in Section 2.3.

Appendix H – Backward Compatibility

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced. Among these is the use of quantity in the secondary data structure. From this point forward labelers that wish to include quantity will do so in the supplemental data field as indicated in section 2.3.2.4 of this document. Existing labels are still valid, but should not be used for Unique Device Identification (UDI).

References to ISO/IEC 15434 and ANS MH10.8.2 have been removed from this document. For more information refer to the previous standard or ISO/IEC 15434 and ANS MH10.8.2 directly.

Appendix I – Bibliography

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols

ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification

ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification

ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification

ISO/IEC 29158, Information technology – Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline

ANS MH10.8.2-2006 American National Standard – Data Identifier and Application Identifier Standard

The above International Standards can be obtained at either http://www.ansi.org or http://www.iso.org

CENTRUM VAN NORMALISATIE

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Health Industry Business Communications
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2525 E Arizona Biltmore Circle / Ste. 127
Phoenix AZ 85016
USA

NEN-Electro & ICT

ons kenmerk/ our reference:	doorkiesnr./ direct number:	direct faxnr./ direct fax number:	datum/ date:
Bwr/15459/08-041	+31 (0) 15 2 690 141	+31 (0) 15 2 690 242	2008-06-17

Subject: application for IAC

[redacted]

The Registration Authority of ISO/IEC 15459 has reviewed the application Health Industry Business Communications Council (HIBCC) d.d. June 12, 2008 for issuing agency under ISO/IEC 15459 - *Information Technology - Unique Identification of Transport Units* and subsequent information submitted by Health Industry Business Communications Council (HIBCC).

The Registration Authority has concluded that the application meets the approval criteria set out in ISO/IEC 15459-2, except for clause 4.2.2.e) (payment of fee) and has provisionally registered an Issuing Agency Code (IAC). The allocation and registration will be confirmed after receipt of the registration fee and applies for a period of 2 year.

You will receive an invoice for the registration fee of EUR 400,- (excl. VAT) separately.

The IAC value allocated Health Industry Business Communications Council (HIBCC) is indicated on the enclosed copy of the application form.

May I draw your special attention to the responsibilities allocated by ISO/IEC 15459 to Issuing Agencies and the adherence of your organisation, and of organisations authorised by Teikoku Databank Ltd., to these rules and to the rules of ISO/IEC 15418 when use is made of the IAC in an open environment. These are essential to safeguard the integrity of the methodology and the uniqueness of license plates.

If we do not receive the registration fee within a period of 4 months, we will assume that the registration is not longer of interest to your organisation and we will cancel the provisional registration.

[redacted]

[DATE]

Mr. [Contact Name at Company], [Title, if available]
[Company Name]
[Address Line 1]
[Address Line 2]

Re: HIBCC Labeler Identification Code (LIC)

Dear [Contact Name at Company]:

It has recently come to our attention that [Company Name] is using an altered or incorrect LIC. HIBCC-Registered Labelers are required to use the Labeler Identification Code (LIC) assigned by HIBCC only in barcodes that conform to the HIBC Supplier Labeling Standard (SLS). The LIC is not intended to be a stand-alone identifier, but is a component of the HIBC SLS and/or the FDA required UDI. Labelers are not permitted to alter their LIC in any way.

The LIC may only be used by the entity listed on the labeler's original application. In the event that the labeler must change the contact information and/or company name associated with the original application, the labeler must complete the LIC Change Form (located on HIBCC website) and return to HIBCC.

Your reply in this matter is expected within 30 days of the date of this letter. If action is not taken within 30 days of receiving this letter, HIBCC will remove [Company Name] from our list of labelers and the FDA will be notified. Should you have any questions please feel free to contact our office.

Sincerely,

President & CEO

RAH/cam

cc: Person's Name, Legal Department
HIBCC Legal Department

ANSI
American National
Standards Institute 11 WEST 42ND STREET, NEW YORK, NEW YORK 10036
TEL. 212.642.4900
FAX. 212.398.0023
Cable: Standards, New York
International Telex: 42 42 96 ANSI UI
D-U-N-S 07-329-4837

July 12, 1995

[redacted]
President
Health Industry Business Communications Council
5110 N. 40th Street, Suite 250
Phoenix, AZ 85018

[redacted]

On behalf of the Executive Standards Council, I am pleased to inform you that the accreditation of Health Industry Business Communications Council using the Organization method, has been approved effective July 11, 1995.

I wish to take this opportunity to call your attention to Clause 4 of the *ANSI Procedures for the Development and Coordination of American National Standards (ANSI Procedures)* which covers the designation, publication and maintenance of American National Standards. Should you have any questions concerning these requirements, please do not hesitate to contact me.

The staff person who will be responsible for this activity is Mr. Steven Cornish. Please do not hesitate to contact him at (212) 642-4969 if you have any questions.

Sincerely,

[redacted]

HIBC solution for
EU MDR/IVDR Basic UDI-DI

European Medical Device regulation (1) and In-Vitro Diagnostica regulation (2) defines the Basic UDI-DI for the Eudamed Data Base and for the Certificates issued by Notified Bodies.

The Basic UDI-DI is constructed by the device manufacturer following the rules of the accredited issuing agencies. This document is describing the construction rules for Basic UDI-DI of the issuing agency for HIBC.

1. Content

2. Abbreviated terms and mathematical/logical notations

This chapter lists the abbreviated terms and mathematical notations of this document.

2.1. Abbreviated terms

Basic UDI-DI Unique ID for a set of physical devices/packages (e.g. set of PCN numbers)

HIBC	Health industry business code (3).
IAC	Issuer Agency Code. A code prefix given to an issuing agency (synonym: issuing entity) to generate unique numbers (4).
LIC	Labeller issuer code. This code is a unique identifier for medical device labelers issued by the HIBC issuing entity.
PCN	Abbreviation for "Product or Catalog Number". This is the field in the UDI-DI describing the physical product/package. The PCN may be chosen to be identical to the REF (3).
BDN	Basic UDI-DI Device Number. The subfield of Basic UDI-DI chosen by the manufacturer.
REF	Abbreviation for "Reference number". The REF is an identifier for physical devices/packages of the same type.
UDI-DI	Unique identifier for physical devices/packages of the same type. This is often directly linked to the REF number.

2.2. Mathematical notations

mod	is the integer remainder after division. 13 mod 2 is 1: 13 divided by 2 gives 6 remainder 1.

3. What is a Basic UDI-DI?

The Basic UDI-DI is grouping a set of physical devices/packages and establishes a link to the relevant certificate issued by the notified body. Thus, It is defined for use in the Eudamed database and on device certificates issued by notified bodies.

The Basic UDI-DI is assigned by the device manufacturer following the rules of issuing entities.

The manufacturer creates one descriptive device record per Basic UDI-DI in the Eudamed Device UDI module.

Each physical device has a UDI on its label, which is referencing to a Basic UDI-DI within its record in the Eudamed UDI module. Each entry in the UDI module of Eudamed references one Basic UDI-DI.

The Basic UDI-DI is not printed on the device label.

4. HIBC rules for Basic UDI-DI

4.1. Structure

Basic UDI-DI values are created by the LIC-holder. The Basic UDI-DI consists of the following fields being concatenated:

Abbreviation	Name	Format	Example	Description
IAC	Issuing Agency Code	0..3 alphanumerics	RH	Issuing agency code for the issuer as defined by . ISO/IEC 15459 (4).
LIC	Labeler Issuer Code	1 alpha + 3 alphanumeric	E999	Labeler Issuer Code. This unique labeler identification code is assigned by the issuing agency.
BDN	Basic UDI-DI Device Number	1 to 20 alphanumerics plus special characters "-.,:;"§$%&()=?+#<>" The HIBC field separator "/" and space " " is explicitly omitted.	AQ7B5	Basic UDI-DI issued uniquely by the LIC-holder.[1]
Check	Modulo43 check digits	1 alphanumeric plus special characters "-.$/+%" and the space character " "	F	Check digits calculated from the concatenated fields IAC, LIC and BDN

4.2. Check Digits calculation following the modulo 43 algorithm

The last two digits of the Basic UDI-DI string are the Check digits calculated from all preceding characters following the modulo97 algorithm as described below:

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Char	R	H	E	9	9	9	A	Q	7	B	5
Numerical Assignments	27	17	14	9	9	9	10	26	7	11	5
Sum of Products	27 + 17 + 14 + 9 + 9 + 9 + 10 +26 + 7 + 11 + 5 = 144										
Modulo 43	144/43 = 3 with a remainder of 15. The remainder is the Mod 43 check sum. 15 = F										

Divide 145 by 43. The quotient is 3 with a remainder of 15. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 15, or "F". The complete Basic UDI-DI, including the Check Character, would therefore be:

RHE999AQ7B5F

[1] Within a draft MDCG document, the Basic-UDI DI length is limited to 25 characters. In consequence, the field BDN is limited to 17 characters.

Table of numerical value assignments for computing the HIBC LIC data format Check Character

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

4.3. Uniqueness to Basic UDI-DI issued by other issuing entities

The Issuing agency code is used as a prefix to get world unique codes issued by different issuing agencies.

The definition of the GS1 Global Model Number GMN (6) is following this rule, as the GS1 issuing agency code is 0 to 9.

4.4. Uniqueness of Basic UDI-DI and UDI-DI

Basic UDI-DI and UDI-DI should not overlap.

This condition is fulfilled if no LIC code starts with "RH". This is the case as those codes are not issued.

4.5. Basic UDI-DI Device Number

Each manufacturer may use the BDN field to create a Basic UDI-DI according his numbering scheme.

There are no rules implied of the construction of this field other than the character set of the BDN.

Nevertheless, the following strategies may be considered on a company level:

- Choose the Basic UDI-DI Device Number field as the certificate number plus a number to identify the device covered by the certificate.
- Choose the Basic UDI-DI equal to the UDI-DI PCN field, if there is a 1:1 relationship (3).
- Choose a device document number from the life-cycle management system of the manufacturer, which is unique within the companies domain.

The upper possibilities may be used as a mixed setup as long as uniqueness is maintained.

4.6. Example

The example values given in the upper table result in the final Basic UDI-DI value:

RHE999AQ7B5F

This number is constructed by the concatenation of the fields IAC, LIC and BDN and by the addition of the check digits calculated from the preceding fields.

5. Literature

1. **European_Union.** EU Medical Device Regulation 2017/745. [Online] 2017. http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC.

2. —. EU In-Vitro Diagnostica Regulation 2017/846. [Online] 2017. http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC.

3. **HIBCC.** ANSI HIBC 2.6 Supplier Labeling Standard. [Online] 2016. http://www.hibcc.org/udi-labeling-standards/barcode-standards/.

4. **ISO/IEC.** *ISO/IEC 15459-2:2015 Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 2: Registration procedures.* 2015.

5. —. *ISO/IEC 646:1991, Information technology — ISO 7-bit coded character set for information exchange.* 1919.

6. **GS1.** GS1 General Specifications. [Online] January 2018. https://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications.

Health Industry Business
Communications Council

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602-381-1091
www.hibcc.org

Policy for Use of the HIBCC Standard

HIBCC-Registered Labelers are required to use the Labeler Identification Code (LIC) assigned by HIBCC only in barcodes that conform to the HIBC Supplier Labeling Standard(SLS). The LIC is not intended to be a stand-alone identifier, but is a conponent of the HIBC SLS and/or the FDA and European Union required UDI. Labelers are not permitted to alter their LIC in any way.

The LIC may only be used by the entity listed on the labeler's original application. In the event that the labeler must change the contact information and/or company name associated with the original application, the labeler must complete the LIC Change Form (located on HIBCC website) and return to HIBCC.

If a HIBCC registered Labeler is found to be using an altered or incorrect LIC HIBCC will notify the labeler in writing. There after, the labelers will be removed from HIBCC's list of labelers and the FDA will be notified, unless the correction is made within 30 days.

For additional questions contact HIBCC at (602) 381-1091 or by email at info@hibcc.org

Health Industry Business Communications Council

MEETING GUIDELINES FOR ANTITRUST POLICY

The HIBCC policy for Technical/Advisory Committee meetings prohibits any discussions, which constitute or imply an agreement or understanding concerning:

- Prices, discounts, or terms or conditions of sale
- Profits, or profit margins or cost data
- Market shares, sales territories or markets
- Allocation of customers or territories
- Selection, rejection or termination of customers or suppliers
- Restricting the territory or markets in which a company may resell products
- Restricting the customers to whom a company may sell

or any matter which is inconsistent with the proposition that each member company of the HIBCC Technical/Advisory Committees must exercise its independent business judgement in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HIBCC Technical/Advisory Committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items; there shall be no substantive discussions of HIBCC Technical/Advisory Committee matters other than at official meetings; and minutes shall be distributed to attendees promptly following adjournment of each meeting.

HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL (HIBCC)

CONFLICT OF INTEREST POLICY AND STATEMENT OF ACCEPTANCE

A. All officials (board members, officers, committee members) of the Health Industry Business Communications Council (HIBCC) shall scrupulously avoid conflicts – potential or real – between their own personal interests and those of HIBCC.

B. All officials of HIBCC have a fiduciary relationship with and owe a duty of loyalty to HIBCC. The fiduciary and loyalty obligations of officials require them to act on behalf of and for the benefit of HIBCC in all matters connected with or involving the interests of HIBCC. Therefore, it will be a conflict of interest and breach of the fiduciary and loyalty obligations for an official to:

- Actively solicit for or encourage a competitive venture;
- Fail or refuse to maintain and protect HIBCC's confidential, proprietary and/or trade secret information;
- Fail or refuse to assist, promote, encourage and, through the cooperative efforts of the officials, develop and advance the business and economic welfare of HIBCC.

C. Officials of HIBCC should not be financially interested or involved in any contract made by them in their official capacity or by the Board of Directors. Nor should said officials make sales to or purchases from this corporation or receive any compensation or fees for services to this corporation without the prior approval of the Board of Directors. Officials must disclose any direct financial interest or involvement in or with any matter coming before the board or committee.

D. Any official having a duality of interest or conflict of interest on any matter, (1) should make a full disclosure to the board, (2) should not vote or use personal influence on the matter, and (3) should be absent during the review and vote on the decisions in question. The minutes of the meeting should reflect that a disclosure was made, the abstention from voting, the absence

from the room during the review and vote. The foregoing requirements should not be construed as preventing the official from providing the board or committee with any and all relevant information known by the person having a conflict. When there is a doubt as to whether a conflict of interest exists, the matter shall be resolved by a vote of the Board of Directors or a committee, as the case may be, and the board member shall recuse him/herself from participating in the voting process.

E. Each official of HIBCC shall be given a copy of this conflict of interest policy and shall be required to disclose in writing any direct or indirect benefits each year, by no later than the close of HIBCC's fiscal year. This conflict of interest policy shall be reviewed periodically for the information and guidance, directors, officers and staff, and any new directors, officers, or staff shall be advised of the provisions of this policy upon undertaking the duties of such office.

I acknowledge receipt and have read the above Conflict of Interest Policy and I agree to abide by its provisions during my tenure as an official of HIBCC.

Signature: _____

Printed Name: _____

Date: _____

Health Industry Business Communications Council
STANDARD OPERATIONAL PROCEDURES
2016

1.0 TITLE

The name of the organization is the Health Industry Business Communications Council (HIBCC).

1.1 SCOPE

The primary function of HIBCC is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners.

1.2 RESPONSIBILITIES

HIBCC shall be responsible for developing proposed American National Standards (ANS) through the work of broad-based technical committees. The Auto-ID Technical Committee (AITC), and any subgroups created in accordance with these standard operating procedures, shall be responsible for developing, revising, re-affirming ANS and withdrawing ANS. Any substantive changes to ANS shall be referred to the AITC (the designated consensus body) for final approval (as indicated on the BSR-9). The HIBCC Board will provide oversight as designated herein, and will authorize by majority vote the submission to ANSI of the ANS. The HIBCC Board Chair shall serve as a voting member of the Committee. The HIBCC Board shall also have the right to approve the formation of additional technical committees as it deems necessary. HIBCC will maintain the standards in accordance with ANSI requirements and ensure that all requests for interpretation of the standard(s) are addressed according to the Interpretation Policy. In addition, all ANSI requirements for due process, criteria for accreditation and consensus will be met. HIBCC will ensure that the Standard(s) are periodically reviewed and continuously maintained. HIBCC will complete action (or request an extension of time) to revise, reaffirm or withdraw an ANS by the fifth year after the initial approval of the document as an ANS.

The HIBCC administrative office/secretariat shall organize technical committees, apply for committee accreditation by ANSI and maintain accreditation in accordance with ANSI requirements, including submission of the committee roster. In addition, HIBCC shall maintain a roster of the Committee and a list of the standards for which it is responsible. HIBCC shall provide a secretary to provide administrative work including secretarial services; meeting notices and arrangements; preparation and distribution of meeting agendas, minutes, ballots and draft standards; and maintenance of adequate records for each technical committee.

HIBCC shall submit candidate standards approved by the Committees and the HIBCC Board, with supporting documentation for ANSI review and approval as American National Standards and publish or arrange with ANSI for publication of its standards, revisions and addenda.

Any additional administrative functions as required by these procedures will be the responsibility of the HIBCC administrative office. These Standard Operating Procedures will be maintained by the HIBCC office and are subject to approval by a majority vote of the HIBCC Board. They will apply to the AITC, subgroups created by the AITC, as well as any other committees designated by the HIBCC Board.

2.0 OFFICERS

The HIBCC Chairman upon the approval of the HIBCC Board will appoint a chair and have the option of also appointing a co-chair for each Committee from the individual members of the Committee. Each will serve for one year and until a successor is selected and ready to serve. The co-chair shall carry out the chair's duties if the chair is temporarily unable to do so. Alternatively, a Committee secretary appointed by the HIBCC administrative office shall carry out the duties of the chair in the event of the absence of both the chair and a co-chair.

2.1 COMMITTEE PARTICIPATION

A request for representation on a Technical Committee shall be addressed to HIBCC and shall indicate the applicant's direct and material interest in the Committee's work, qualifications and willingness to participate actively, and, if the applicant is an organization, company or government agency, shall identify a principal (and an alternate, if desired) representative. All requests for Committee representation are subject to approval by the HIBCC Board and the Committee itself. Interested parties must attend two consecutive meetings as guests, in order to be considered for membership.

A modest annual registration fee is charged for each representative who attends Technical Committee meetings. Registration fees will be determined by the HIBCC Board and administered by the HIBCC Executive Office. It is not intended that the fees create undue financial barriers to participation. A request for a fee waiver may be made in writing to the HIBCC Executive office and will be considered based on individual circumstances.

2.2 RECOMMENDATION

In recommending appropriate action on applications for Committee representations, the HIBCC Board and Committee shall consider the following:

- Need for active participation by each interest;
- Potential for dominance by a single interest category;
- Extent of interest expressed by the applicant and the applicant's willingness to participate actively;
- The representative identified by the applicant organization, company or government agency.

The secretariat and/or HIBCC Board may consider reasonable limits on committee size.

2.3 DIVERSE INTERESTS

If distinct divisions of an organization can demonstrate independent interests and authority to make independent decisions with regard to the activity of the Committee, each may apply for Committee representation. If an interest is already represented on a Technical Committee, the secretariat may recommend that an applicant seek representation through the existing representative.

2.4 REVIEW OF COMMITTEE MEMBERSHIP

HIBCC shall review committee membership lists annually. Committee members are expected to fulfill obligations of active participation. When members are found in habitual default of these obligations, HIBCC shall direct the matter to the Committee chair and co-chair and/or the HIBCC Board for appropriate action, which may include termination of membership on the Committee.

2.5 OBSERVERS AND INDIVIDUAL EXPERTS

Individuals and organizations, having an interest in committee work may request listing as committee observers and will be subject to approval by the HIBCC Board. The Committee may also select individual experts to assist with Committee activities and deliberations. Individual experts shall serve for a renewable term of one year and shall be subject to approval by vote of the HIBCC Board. Observers and individual experts shall be advised of the Committee activities, may attend meetings, and may submit comments for consideration, but shall have *no* vote.

2.6 INTEREST CATEGORIES

All appropriate interests that might be directly and materially affected by the standards activity of HIBCC shall have the opportunity for fair and equitable committee participation without dominance by any single interest.

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

The standards development process should also have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

Each principal/alternate representative shall propose its own interest category as appropriate and in accordance with the Committee's established categories. Interest categories may include - user, producer and general interest as follows:

> **Healthcare Provider/User**: Individual/Representative of healthcare facility or Organization using Auto-ID Technology.
>
> **Producer**: Individual/Representative of Company or Organization manufacturing, distributing, producing or selling Auto-ID Technology.
>
> **General Interest**: Individual/Representative of Company or Organization with a general interest in Auto-ID Technology and/or the Committee's work.

Interest categories shall be established or revised by a vote of the Committee upon recommendation by the HIBCC Board. The rationale for the selection of categories shall be included in the committee ballot and submitted to ANSI as part of the accreditation requirements.

2.7 MEMBERSHIP ROSTER

HIBCC shall maintain current Committee rosters and shall distribute them to the Committee representatives at least annually and otherwise on request. If changes are made to the roster, HIBCC shall redistribute it to all members.

The roster shall include the following:

- Title of the Committee and its designation;
- Scope of the Committee;
- Name of organization, secretary and addresses;
- Chair and co-chair of the Committee;
- Name, address and business affiliation of individual Committee member(s);
- Classification of each member;
- Tally of classifications: total of voting members and subtotals for each interest category;
- Title, name of chair and names and addresses of all members (including chair) of sub-groups if applicable.

2.8 TERMINATION OF MEMBERSHIP

Voting representation on the Committee shall be terminated upon failure to:

1) attend two out of three successive meetings, in which case the representation shall be terminated if not represented at the next meeting; or
2) respond to 80% of the total letter ballots (non-accelerated) closing during the current calendar quarter, in which case the representation shall be terminated if the member fails to respond to at least to the subsequent letter ballot; or
3) fulfill obligations of active participation per section 2.4 (i.e. habitual non-responsiveness to secretariat or Committee Chair, failure to complete assigned committee tasks in a timely manner, etc); or
4) pay all applicable committee representation registration, unless a fee waiver has been requested and granted.

The principal and all alternate representative(s) shall be notified in writing upon failure of the organization to meet any of the above conditions.

An organization and/or individual that has had their representation terminated may re-establish representation in accordance with 2.1 and 2.2. Under extenuating circumstance, the Committee or the HIBCC Board may vote to continue the representation despite failure of the member to comply with the representation criteria above.

2.9 RESIGNATION OF MEMBERSHIP

Resignation of membership in the Committee or any of its subgroups should be made in writing to HIBCC who will forward a copy to the appropriate Chair.

3.0 SUBGROUPS CREATED BY THE COMMITTEE

When one or more subgroups of a Technical Committee are formed, their formation (and later disbandment) requires approval by a majority vote of the Committee and the secretariat. The scope and duties delegated to the subgroup shall be outlined and approved at the time it is formed. Subsequent changes in scope or duties shall require additional approval. The charge to the subgroup shall clearly state in what way the subgroup is responsible for assisting the Committee (e.g. drafting all or a portion of a standard, drafting responses to comments, drafting positions on international standards, voting on approval of ANS revisions or re-affirmations, or other purely advisory functions.)

3.1 CHAIRPERSON AND MEMBERS OF SUBGROUPS

The chair and members of a subgroup shall be appointed by the chair of the Committee and confirmed by the Committee. The scope, duties, and membership of all subgroups shall be reviewed by the Committee annually. The chairs and members of a subgroup need not be members of the Committee.

4.0 APPROVAL OF STANDARDS

Draft standards and any substantive change in the content of a standard or withdrawal of a standard proposed by a subgroup shall be referred to the Committee for approval.

4.1 MEETINGS

Technical committee meetings shall be held, as decided upon by the Committee, the chair, the secretariat or by petition of five or more members, to conduct business, such as making assignments, receiving reports of work, considering draft standards, resolving differences among subgroups, and considering views and objections from any source. Meetings of subgroups may be held as decided upon by the members or chair of the subgroup.

4.2 OPEN MEETINGS

Technical Committee meetings shall be open to all parties having a direct and material interest. At least four weeks' notice of regularly scheduled meetings shall be given by the secretariat in ANSI's *Standards Action*; or in other media designed to reach directly and materially affected interests; or in both. The notice shall describe the purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest. The secretariat may optionally maintain a permanent mailing list of other interests.

5.0 QUORUM

The presence of 51% of members of the Committee shall constitute a quorum for conducting business at a meeting. If a quorum is not present, actions may be taken subject to confirmation by letter ballot.

6.0 VOTE

Each Committee member shall vote one of the following positions:

- Affirmative;
- Affirmative, with comment;
- Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objections);
- Abstain, with reasons.

6.1 VOTE OF ALTERNATE

An alternate's vote is counted only if the principal representative fails to vote.

6.2 SINGLE VOTE

Generally no Committee representative shall have more than one vote. However, if two or more organizations appoint the same individual to represent them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing to the secretariat that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the Committee, excluding the vote of that individual.

6.3 VOTING PERIOD

The voting period for letter ballots shall end two weeks from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the chair's option, when warranted. A follow-up letter requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members whose votes have not been received within five calendar days of the ballot close.

6.4 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF COMMITTEE REPRESENTATIVES

The following actions require approval by a majority of the Committee representatives at a meeting or by letter ballot, excluding abstentions:

- Formation of a Committee subgroup, including its procedures, scope and duties;
- Disbandment of subgroups;
- Addition of new Committee members and designation of their interest categories.

The following actions, by Committee vote at a meeting, require approval by a majority of the members present:

- Approval of minutes;
- Authorization of a letter ballot (unless initiated per Section 6.7).

6.5 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF THE HIBCC BOARD

The following actions require a letter ballot or an equivalent formal recorded vote with approval by at least a majority of the HIBCC Board, excluding abstentions:

- Adoption of Committee procedures, interest categories, or revisions thereto;
- Approval annually of Committee roster;

- Approval of change of Committee scope;
- Approval of termination of the Committee.

6.6 ACTIONS REQUIRING OPPORTUNITY FOR CONSIDERATION BY ENTIRETY

The following actions require the opportunity to cast a letter ballot or an equivalent formal recorded vote by all voting committee members and Board of Directors. Consensus within the Committee is required for all such actions:

- Approval of a new standard or reaffirmation and/or withdrawal of an existing one;
- Approval of revision or addendum to part or all of a standard.

All members of the Committee will be given the opportunity to vote on ANS related actions, even if they cannot attend a meeting (e.g. via follow-up confirmation ballot or the equivalent). Consensus will be determined by the majority voting rule (see Clause 6.8).

6.7 AUTHORIZATION OF LETTER BALLOTS

A letter ballot may be authorized by any of the following:

- Majority vote of those present at a meeting;
- The Chair;
- The HIBCC Executive Committee;
- The secretariat;
- Petition of five or more members of the Committee.

6.8 DEFINITION OF CRITERIA FOR APPROVAL

- **Majority**
  For on-site, hand meeting votes, a majority is defined as approval by more than half of the members voting, excluding abstentions and provided that a quorum is present. For letter ballot votes, a majority is defined as approval by more than half of the qualified voting membership, excluding abstentions.

7.0 OTHER REVIEW[1]

Proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form, or its equivalent, for listing in Standards Action in order to provide an opportunity for public comment. If it is the case, then a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard shall be included as part of the description of the scope summary that is published in Standards Action. The comment period shall be one of the following:

- A minimum of thirty days if the full text of the revision(s) can be published in Standards Action;
- A minimum of forty-five days if the document is available in an electronic format, deliverable within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in Standards Action; or
- A minimum of sixty days, if neither of the aforementioned options is applicable.

The secretariat shall determine whether listing of proposed standards actions shall be concurrent with the final committee letter ballot and whether announcement in other suitable media is appropriate.

Views and objections resulting from the above shall be handled in accordance with section 8.0. Any substantive change made in the ANS shall be re-listed in accordance with the following.

8.0 DISPOSITION OF VIEWS AND OBJECTIONS

When the balloting on ANS has been closed, the ballot tally will be forwarded to the chair of the Committee or, if appropriate, of the subgroup; the chair shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting.

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in Standards Action.

Any comments received in response to the filing of PINS (Project Initiation Notification System) with ANSI for new and revised standards shall be addressed in accordance with clause 2.5 of the most current edition of the ANSI Essential Requirements.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each such objector shall be advised in writing (including

[1] Although a 60-day public comment period is not required in all instances, a number of provisions in the ANSI Essential Requirements, when read in combination, satisfy the WTO's 60-day rule. Before adopting a standard, ANSI-Accredited Standards Developers shall allow a period of at least 60 days in total for submission of comments on the draft standard if requested by an interested party within the territory of a Member of the WTO. Exceptions outlined in the rule are permitted due to issues of safety, health or environment. (See WTO Agreement on Technical Barriers to Trade (TBT), Annex 3 Code of Good Practice for the Preparation, Adoption and Application of Standards (CGP) Substantive Provision L.)

electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists. In addition, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved will be reported to the ANSI BSR. All substantive changes made to an ANS resulting from public comment or in an attempt to resolve a consensus body vote will be re-listed for public review.

HIBCC may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Each unresolved objection and attempt at resolution, and any substantive change made in a proposed ANS shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm, or change their vote within two weeks.

8.1 REPORT OF FINAL RESULT

The final results of the voting shall be reported, by interest categories, to the Committee.

9.0 SUBMITTAL OF STANDARD

Upon completion of the procedures for voting, disposition of views and objections, and appeals, the proposed standard shall be approved by the HIBCC Board and submitted to ANSI by the secretariat. The proposed ANS will be submitted to ANSI within one year of the close of the public review period, or two years, if an extension is requested in accordance with clause 4.2 of the ANSI Essential Requirements. If the secretariat does not submit the proposal to ANSI within a reasonable period of time, any member(s) of the Committee may make the submittal.

9.1 INFORMATION SUBMITTED

With respect to submitting American National Standards to ANSI without BSR approval, HIBCC shall agree to provide ANSI the following:

1. title and designation of the proposed American National Standard;
2. indication of the type of action requested (that is, approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard);
3. a declaration that applicable procedures were followed;
4. a declaration that the proposed standard is within the scope of the previously registered standards activity;
5. a declaration that conflicts with another American National Standard have been addressed in accordance with these procedures;

6. a roster of the consensus body that indicates: the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
7. a declaration that all appeal actions related to the approval of the proposed standard have been completed;
8. a declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
9. identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

9.2 DISCONTINUANCE OF A STANDARDS PROJECT

An accredited standards developer may abandon the processing of a proposed new or revised American National Standard or portion thereof if it has followed its accredited procedures. A written justification for such an action shall be made available upon receipt of any written request received by the accredited standards developer within 60 days of the date of the final action.

Appeals of such actions shall be made to the HIBCC Board based on procedural noncompliance.

10.0 TERMINATION OF COMMITTEE

A proposal to terminate a Technical Committee may be made by a directly and materially affected interest to the HIBCC Board. Proposals to disband sub-committees should be directed to the primary Committee under which they are governed. The proposal shall be submitted in writing and shall include at least the following:

- Reasons why the Committee (or sub-committee) shall be terminated;
- The name(s) of the organization(s) or committee(s) that will assume responsibility for maintenance of any existing ANS that are the responsibility of the Committee.

In the instance that a sub-committee has governance of an existing ANS, the ANS will revert back to the primary committee under which they were governed.

11.0 COMMUNICATIONS

Copies of correspondence involving issues or decisions (i.e. not routine matters) affecting other sub-committees shall be sent to all affected Committee chairs and the secretariat.

Inquiries relating to Committees should be directed to the secretariat. All replies to inquiries shall be made through the secretariat.

All inquiries requesting interpretation of approved ANS shall be responded to in accordance with HIBCC's interpretation policy. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.

12.0 APPEALS

Persons who have direct and materially affected interests and/or who have been or will be adversely affected by a standard within the Committee's jurisdiction shall have the right to appeal procedural actions or inactions of the Committee or the secretariat.

12.1 COMPLAINT

The appellant shall file a written complaint with the secretariat within thirty days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objections(s) including any adverse effects, the clause(s) of these procedures or the standard that are at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

12.2 RESPONSE

Within thirty days after receipt of the complaint, the Committee chair or secretariat shall respond in writing to the appellant, specifically addressing each allegation or fact in the complaint to the extent of the respondent's knowledge.

12.3 HEARING

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the secretariat shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten working days notice.

12.4 APPEALS PANEL

The appeals panel shall consist of three individuals plus one alternate who have been elected by the HIBCC Board. In the case that one of the individuals can not take part in the appeals process due to either the inability to attend or if one of the parties in question requests the person be replaced, the alternate shall be used. Panel members shall serve a term of one year. The panel shall consist of a balanced representation from the represented interest groups, and will exclude any persons currently serving within the consensus body.

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the committee and the secretariat took all actions in compliance with these procedures. Each party may introduce other pertinent arguments, and members of the appeals panel may address questions to individuals. *Robert's Rules of Order* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

12.5 DECISION

The appeals panel shall render its decision in writing within thirty days, stating findings of fact and conclusions, with reasons therefore, based on preponderance of the evidence. Consideration may be given to the following positions, among others, in formulating the decision:

- Finding for the appellant, remanding the action to the committee or the secretariat with a specific statement of the issues and facts in regard to which fair and equitable action was not taken;

- Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections;

- Finding that new, substantive evidence has been introduced, and remanding the entire action to the Committee or the secretariat for appropriate reconsideration.

13.0 PARLIAMENTARY PROCEDURES

On questions of parliamentary procedure not covered in these procedures, *Robert's Rules of Order* (latest edition) may be used to expedite due process.

ANNEX A: POLICIES

Interpretation Policy
Due to potential liability issues, HIBCC will not provide interpretations of its standards.
All written and oral requests for interpretation of approved HIBCC standards will be received by the HIBCC administrative office. These requests for interpretations will be processed as follows: A form letter shall be sent to the requester, informing the requester that no interpretations are provided and suggests that the requestor participate in HIBCC to revise the standard so it is clearer.

Note: " interpretations of its standards" means the clarification of any portion of the standard(s) that contains ambiguous wording. Explanations of technical specifications are <u>not</u> "interpretations of its standards".

Metric Policy
In general, HIBCC standards will adopt style rules that utilize units of measurement according to the International System of Units (SI), the modernized metric system.

When referencing technical specifications of system components that would potentially use HIBCC standards, the HIBCC standard(s) may adopt the same units of measurement that are used in those technical specifications.

Record Retention Policy

Records relating to any standards activity shall be retained to demonstrate compliance with all aspects of ANSI Essential Requirements and HIBCC's Standard Operating Procedures.

Records concerning new, revised, or reaffirmed American National Standards shall be retained by HIBCC for one complete standards cycle, or until the standard is revised.

Records concerning withdrawn standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

Patent Policy

The Health Industry Business Communications Council (HIBCC), does not hold and does not currently intend holding any essential patent claim(s). HIBCC will comply with the current ANSI Patent Policy.

Commercial Terms & Conditions Policy

The Health Industry Business Communications Council (HIBCC) does not have its own Commercial Terms and Conditions Policy. HIBCC will comply with the ANSI Commercial Terms and Conditions Policy.

Health Industry Business
Communications Council

HIBCC Labeler Identification Code (LIC) Fee Schedule

Required to meet the FDA's UDI Requirements

The first step to meeting the FDA's UDI requirements is to obtain a company prefix from HIBCC. A HIBCC company prefix is called a Labeler Identification Code (LIC), a unique four character alphanumeric code assigned to your organization.

The HIBCC LIC application fee is the only financial transaction you will make with HIBCC in the UDI process. It is a one-time fee, based on you organization's international gross annual sales as reported on your last audited fiscal year. There are no renewal fees or additional fees whatsoever.

The LIC fee schedule is below, as well as on our HIBCC LIC application form. The application form can be completed online or downloaded as a PDF.

SALES	ONE-TIME FEE	SALES	ONE-TIME FEE
❒ to $2 million	$1,000	❒ to $100 million	$7,500
❒ to $5 million	$1,500	❒ to $150 million	$9,000
❒ to $10 million	$2,500	❒ to $500 million	$12,000
❒ to $30 million	$4,000	❒ above $500 million	$20,000
❒ to $60 million	$5,000		

For any additional questions please contact us at info@hibbc.org or by phone at (602) 381-1091.

Health Industry Business
Communications Council

2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
www.hibcc.org

What is the HIBC Device Identifier?

The HIBC Device Identifier (DI) is the portion of the Unique Device Identifier (UDI) that you are required to submit to the FDA's GUDID. The Production Identifier (PI) is the other portion of the UDI that is not submitted to the GUDID.

The HIBC DI has the following components: the Labeler Identification Code (LIC), the Product/Catalog Code, and the Unit of Measure (also referred to as Package Level Indicator). For more information on Unit of Measure see HIBCC's Guide to Understanding Unit of Measure.

Example:

HIBCC Flag = +
LIC = A999
Product Code = ABC123
Unit of Measure = 0 (single unit)
Check Character = V

DI that is entered in to the GUDID = A999ABC1230

DI that appears on the device label =

+A999ABC1230V

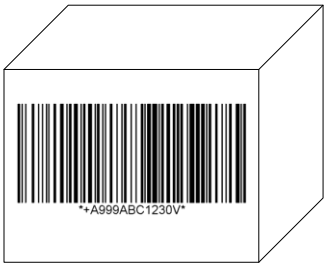
Note: The UDI on the device label includes additional characters (Stop/Start Characters "*", HIBC Flag "+", Check Character, and all other Data Identifiers/Delimiters). Refer to the HIBC Supplier Labeling Standard for more information.

What do I include in the GUDID?

Primary DI:

The Primary DI is the DI located on the lowest package level that contains a UDI.

Example 1: The package below contains a single device that is exempt from the Direct Marking UDI requirement.

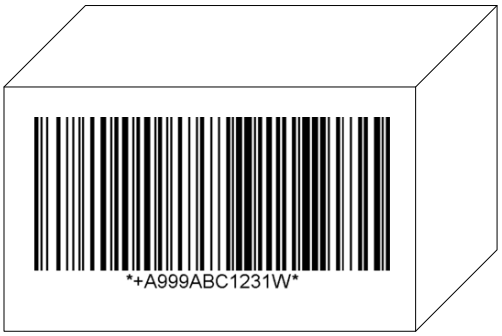


Primary DI = A999ABC1230

Example 2: The device below does not have a package and is Directly Marked with a UDI.

Primary DI = A999ABC1230

Example 3: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).



Primary DI = A999ABC1231

Direct Marking DI:

Devices intended to be used more than once and intended to be reprocessed before each use are required to be directly marked with a UDI.*

The Direct Marking DI component of the UDI can be the same as that which appears on your device label. However, you may choose to use a different DI for direct marking in order to distinguish the unpackaged device from the device packaging. If so, then you must enter ***both*** the Primary and Direct Marking DIs in the GUDID.

Example: The device below has a Direct Marking DI that is different from the DI on the device packaging. The red arrow points to the DI that is directly marked on the device.

Direct Marking DI: A999DEF4560

Note: The Direct Marking DI must include the LIC, Product/Catalog Code, and Unit of Measure.

*Please review FDA's UDI: Direct Marking of Devices Draft Guidance for more information.

Unit of Use DI:

A Unit of Use DI is required to be entered in the GUDID when the Primary DI contains more than one device of the same version/model and those devices are not individually labeled with a UDI (see Example 3 under Primary DI).

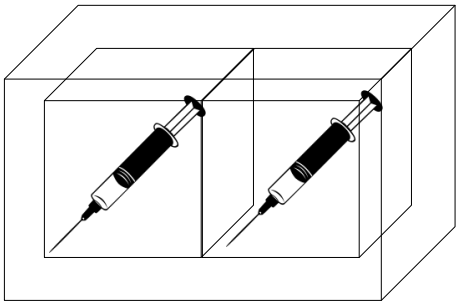
Example: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).

Primary DI = A999ABC1231
Unit of Use DI= A999ABC1230
Note: The Unit of Use DI does not appear on any of the device labeling.

Package DI:

A Package DI is an identifier for the package configuration that contains multiple units of the base package.

Example: The device below is available in sets of two. The packaging containing both devices is labeled with the Package DI barcode below.



+A999ABC1231W

Primary DI = A999ABC1230
Package DI= A999ABC1231
Note: See HIBCC's Guide to Understanding Unit of Measure for more information on package level indicators.

For an explanation of all GUDID fields refer to the FDA's GUDID Data Elements Reference Table.

For additional questions contact HIBCC by email at info@hibcc.org

Health Industry Business Communications Council (HIBCC)
2525 E. Arizona Biltmore Circle #127
Phoenix, AZ 85016

(602) 381-1091 . info@hibcc.org

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What is Unit of Measure(Package Level Indicator)?

All HIBC UDIs & Auto-ID symbols contain a Unit of Measure field in the Device Identifier (primary data structure). The Unit of Measure is a number (0-9) assigned by the labeler to indicate package level. The Unit of Measure is always located directly after the Product Code. In the image below, the Unit of Measure is the "0" above the red arrow.

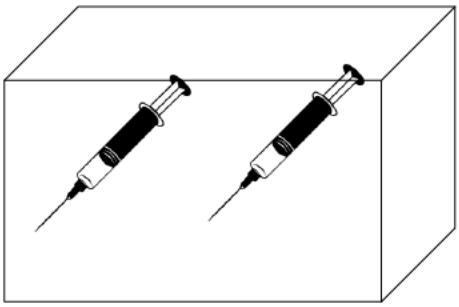
How Do I Assign a Unit of Measure?

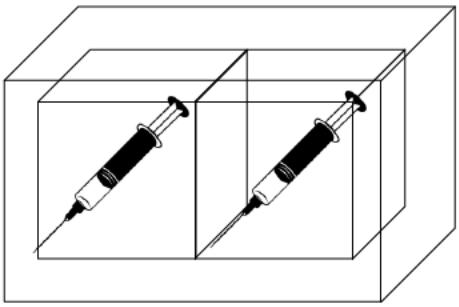
A single unit (i.e. an "each")is always represented by a Unit of Measure of "0". The Unit of Measure "9" is reserved for packages containing variable quantities (i.e. the package quantities are customized). Units of Measure 1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest. The example below shows how to assign the Unit of Measure to different package levels for a device.

Example:

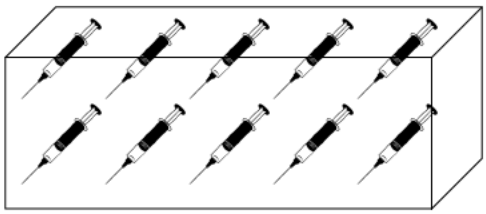
The syringe below is packaged as a single unit, so the Unit of Measure would be "0".

The syringe is also available in sets of two. The images below show two different packaging scenarios for the set of two devices. The Unit of Measure is the same whether the box contains two unpackaged syringes or two individually packaged syringes. The Unit of Measure would be "1" for both scenarios.





Finally, the syringe is available in a case of 10. The Unit of Measure for the case of 10 syringes would be "2". It is also fine to skip numbers and assign a higher Unit of Measure if there is a chance that the device will be available in smaller quanties later on.



Note that the HIBC standard allows labelers to use the same Product/Catalog Number for all package levels of a device (as shown in the example above). The Device Identifier is still unique for each packaging level because the each level is assigned a different Unit of Measure, as required for the FDA's UDI rule.

Note: The term "Package Level Indicator" can be used interchangeably with "Unit of Measure".

For additional questions contact HIBCC by email at info@hibcc.org

Health Industry Business Communications Council (HIBCC)
2525 E. Arizona Biltmore Circle #127
Phoenix, AZ 85016

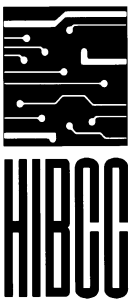
(602) 381-1091 . info@hibcc.org

LABELER IDENTIFICATION CODE INFORMATION CHANGE FORM

To make changes to your existing LIC(s) complete this form & return it to our office.

Health Industry Business Communications Council

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
Tel: 602.381.1091
Email: info@hibcc.org
Web site: www.hibcc.org



■ LIC Change Form

PURPOSE OF FORM: LABELER IDENTIFICATION CODE (LIC) CHANGES

CURRENT (OLD) INFORMATION:

LIC Number _____

_____
Organization Name

_____
Division / Subsidiary

_____
Name of Official Representative

_____
Title

_____
Phone # Fax #

_____
Number and Street

_____
City/State/Zip Code/Country

_____
E-Mail Address

By signing below I agree to this change and certify that the above information is correct and true to the best of my knowledge.

_____
Signature of Official Representative Date

■ LIC Change Form

NEW INFORMATION:
(Please provide official documentation of any organization name changes)

LIC Number _____

_____
Organization Name

_____
Division / Subsidiary

_____
Name of Official Representative

_____
Title

_____
Phone # Fax #

_____
Number and Street

_____
City/State/Zip Code/Country

_____
E-Mail Address

By signing below I agree to this change and certify that the above information is correct and true to the best of my knowledge.

_____
Signature of Official Representative Date

■ LIC Change Form

LIC Number _____

LIC CHANGE FEE (in US Dollars): $50.00

METHOD OF PAYMENT

❒ Please charge to my credit card account. ❒ Visa ❒ MasterCard ❒ AmEx

_____

CREDIT CARD # EXPIRATION DATE CSV/CID CODE

_____

CARDHOLDER'S NAME (as it appears on the card) SIGNATURE

_____

CARDHOLDER'S ADDRESS

_____

CARDHOLDER'S CITY STATE ZIP/POSTAL CODE

❒ A check made payable to HIBCC is enclosed.

❒ Please Invoice Me – Purchase Order # _____

_____

Signature of Official Representative Title

_____

Date

Legal Notice: All fees are non-refundable.

FOR OFFICE USE ONLY:

_____

Date Received Form Date Received Payment Date Changes Entered

LABELER IDENTIFICATION APPLICATION

Required for the FDA's Unique Device Identification (UDI) Rule

Included here:

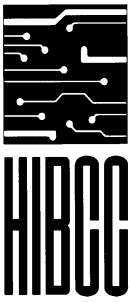
- **Instructions**
- **Form A** ***LIC Assignment***
- **Form B** ***Labeler Fee***
- **Form C** ***Certification Report***

Any organization interested in adopting and using the HIBCC uniform bar coding system must apply for assignment of a Labeler Identification Code (LIC).

To apply for assignment of an LIC follow the steps outlined in the instructions which follow.

Health Industry Business Communications Council

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
Tel: 602.381.1091
Email: info@hibcc.org
Web site: www.hibcc.org



Rev. 11/2016

■ INSTRUCTIONS: FOR COMPLETING FORM A

(To be completed by all applicants)

Purpose of Application LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

1. Contact Information

Enter your organization's name, address and the name, title and telephone number of your organization's official representative to HIBCC. The official representative will represent your organization in all affairs dealing with your code assignment and HIBCC.

Also enter the name, address, title and telephone number of your organization's chief executive officer (CEO). If your organization is a subsidiary or division of a parent organization, you should enter your subsidiary's or division's CEO, not the parent's.

2. Transfer of Assignments

LIC assignments are non-transferable.

■ INSTRUCTIONS: FOR COMPLETING FORM B

(*To be completed by all applicants)*

Labeler Fee

You must certify your most recent calendar or fiscal year sales level by completing the CERTIFICATION REPORT.

■ INSTRUCTIONS: FOR COMPLETING FORM C

(*To be completed by all applicants*)

Specify your annual sales and the calendar or fiscal year of those sales. Next, check the appropriate sales category which determines your fee for the LIC assigned. Sign and date and return with your application.

LIC: Enter the fee for the LIC in Section A, Form B (determined in the CERTIFICATION REPORT). Sign, date and send forms A, B, and C to: **HIBCC, 2525 E. Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016.** Make all checks payable to HIBCC. If paying by credit card send via email to info@HIBCC.org.

■ FORM A:
LIC ASSIGNMENT

PURPOSE OF APPLICATION: LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

PRIMARY ORGANIZATION:

_____
Primary Organization Name

_____
Division / Subsidiary

_____
Name of Official Representative | Title | Phone

_____
Number and Street | PO Box

_____
City/State/Zip Code/Country

_____
E-Mail Address

_____
Name of Chief Executive Officer | Title | Phone

_____
Address, if different from above

_____
CEO's E-Mail Address, if different from above

		MEDICAL	DENTAL	ANIMAL HEALTH
TYPE OF ORGANIZATION (*check applicable box for primary market)*	❒ MANUFACTURER OF GOODS OR SERVICES	_____	_____	_____
	❒ DISTRIBUTOR/WHOLESALER	_____	_____	_____

FOR OFFICE USE ONLY:

_____
Date Received Application | Fee | Date Received Payment

_____
LIC # | Date Assigned | Initials

■ FORM B:

LABELER FEE (*complete appropriate section*)

SECTION A:
Labeler Identification Code (LIC) Assignment

Our organization hereby applies for assignment/registration of a Labeler Identification Code (LIC) from the Health Industry Business Communications Council.

In making such application, we agree to be bound by all rules and regulations of the Council including, but not limited to the Articles of Incorporation, the Bylaws, the Health Industry Bar Code Standard, and any and all other rules and regulations which the Council has now or may hereafter adopt concerning the use of the Health Industry Bar Code Standard and the Labeler Identification Code assigned. The Council will notify us of our assigned Labeler Identification Code upon receipt of our application fee and Council approval of our completed application.

Our organization hereby agrees to indemnify, and hold harmless, the Health Industry Business Communications Council and their officers, directors, employees, agents, successors and assigns from any and all claims, losses, damages, and liabilities whatsoever resulting from the use or misuse of the Health Industry Bar Code Standard and our assigned Labeler Identification Code.

We understand and acknowledge that the Council has taken all reasonable precautions to prevent the assignment of duplicate Labeler Identification Codes. If duplicate codes are assigned, the liability of the Council shall be limited to a refund of the application's Labeler Identification Code fee or the actual damages, if any, whichever is less.

METHOD OF PAYMENT

❒ Please charge $_____ (amount from above) to my credit card account. ❒ Visa ❒ MasterCard ❒ AmEx

_____

CREDIT CARD NUMBER EXPIRATION DATE CSV/CID CODE

_____

CARDHOLDER'S NAME (as it appears on the card) CARDHOLDER'S SIGNATURE

_____

CARDHOLDER'S ADDRESS

_____

CARDHOLDER'S CITY STATE ZIP/POSTAL CODE

❒ A check in the amount of $_____ (from above) made payable to HIBCC is enclosed.

❒ Please invoice me directly. Purchase Order Number _____

_____

Signature of Official Representative Title

_____

Date

■ FORM C:
CERTIFICATION REPORT

Please certify your most recent fiscal year sales level. Applicants are required to submit one of the following from the last fiscal/calendar year: Dun & Bradstreet Report, Profit & Loss Statement, or page 1 of your company's Corporate Tax Return (and any related documents). This information will be kept confidential and will only be used to determine the LIC fee.

Gross global sales of all products/devices labeled with your organization's name or brand.

THIS INFORMATION WILL BE TREATED ON A CONFIDENTIAL BASIS

Specify annual sales $_____ for the most recent calendar or fiscal year: _____.

Check the appropriate box and enter the ONE-TIME FEE amount in Section A - LABELER FEE on FORM B.

SALES	ONE-TIME FEE	SALES	ONE-TIME FEE
❒ up to $2 million	$1,000	❒ up to $100 million	$7,500
❒ up to $5 million	$1,500	❒ up to $150 million	$9,000
❒ up to $10 million	$2,500	❒ up to $500 million	$12,000
❒ up to $30 million	$4,000	❒ above $500 million	$20,000
❒ up to $60 million	$5,000		

Legal Notice:
By signing this application you are certifying that all financial information provided is correct and in accordance with the guidelines stated above. If HIBCC determines that the financial information provided is incorrect, you will be invoiced for the balance due prior to issuing your LIC. HIBCC reserves the right to deactivate any LIC that was obtained under false financial pretenses and notify all invested parties. All fees are non-refundable.

Signature of Official Representative Title

_____
Date

Health Industry Business
Communications Council

2525 E. Arizona Biltmore Cir.
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602-381-1091
FAX 602-381-1093
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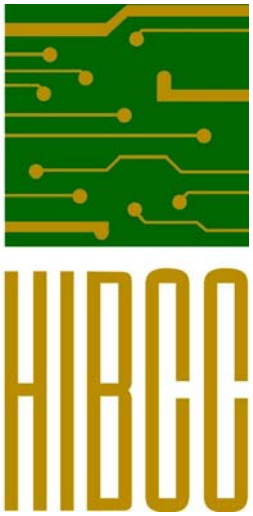

June __, 2017

Mr.
[Company Name]
[Address Line 1]
[Address Line 2]

Dear Mr. _____:

We are pleased to welcome your company as a participant in the automatic identification/bar code labeler program. As such your HIBC-compliant labeling will be in compliance with Unique Device Identifier (UDI) requirements, and your participation in standardized product labeling supports the healthcare industry's efforts to improve patient safety and promote effective cost containment practices.

Based on the information provided on your recent application, HIBCC has assigned a Labeler Identification Code (LIC) for your use. The LIC is matched with a permanent record which is maintained in HIBCC's LIC database.

This letter is our official notification of your assignment and should be preserved as your permanent record. Your assigned LIC is as follows:

BD### [COMPANY NAME]

You will use your LIC, in combination with your existing product codes and production information, to create UDIs and bar codes for all your devices.

The integrity of the LIC database depends on your cooperation. Please keep us fully informed of current and accurate information on your LIC by notifying us of any change in your company name or address, as well as any change in your business alignment or ownership, such as a merger, acquisition, dissolution, or creation, elimination or divestiture of divisions/subsidiaries.

The *HIBC Supplier Labeling Standard* is available on our website, www.hibcc.org (copy also enclosed), to assist you in developing your product identifiers. Your close attention to the specifications will enhance the value of standardized automatic identification to the entire industry and assure compliance with UDI and other regulatory initiatives.

I also urge you to consider membership and participation in our organization by becoming an HIBCC Corresponding or Corporate Member (see enclosure). Membership is intended to keep you informed of developments in the use of automatic identification technologies in healthcare.

If we can be of any assistance, please do not hesitate to contact us.

Yours Truly,

President

RAH/cam

Enclosures

Health Industry Business
Communications Council

Agreement of Non-Disclosure of Confidential Information

This LETTER OF AGREEMENT will serve to confirm and set forth the terms of agreement between the Health Industry Business Communications Council (HIBCC) and **NAME** (herein referred to as "Primary Consultant"). In consideration of the mutual undertakings of HIBCC and the Primary Consultant, the parties agree as follows:

In the course of this Agreement, Primary Consultant acknowledges that he may have access to information that HIBCC considers confidential, proprietary and/or sensitive, the disclosure of which could result in substantial and irreparable damage to HIBCC.

Definition of Confidential Information:
Confidential information shall mean business or technical information including, but not limited to, product data, sales data, financial data, customer data, formula processes, techniques and methods or ideas that are not generally known or available. Confidential Information shall also include information of HIBCC Affiliates that HIBCC is under an obligation to maintain in confidence.

No Disclosure of Confidential Information:
Primary Consultant agrees that he will regard and preserve as confidential all Confidential Information of HIBCC and its Affiliates received by Primary Consultant in connection with this agreement. To preserve the confidentiality of such Confidential Information Primary Consultant will not, without first obtaining the written consent of HIBCC, disclose to any person, firm or enterprise, or use for his own benefit, any such Confidential Information.

Limits on Confidential Information:
Confidential Information shall not be considered confidential, proprietary or sensitive only to the extent that such information: (a) is already known to Primary Consultant at the time it is obtained from HIBCC; (b) is or becomes publicly known through no wrongful act of Primary Consultant; or (c) is rightfully received by Primary Consultant from a third party without an accompanying restriction of use or disclosure.

Confidentiality of Work Products:
All work products developed by Primary Consultant for HIBCC and its Affiliates, including but not limited to computer programs and applications and associated documentation, shall be the sole property of HIBCC and are subject to the terms of this Agreement as deemed appropriate by HIBCC.

Terms & Termination:
This Agreement shall remain in effect after termination of the work contract/employment.

This Non-Disclosure Agreement shall be interpreted in accordance with and governed by the laws of the State of Arizona.

In the event of breach or a threatened breach of terms and conditions of this Agreement, HIBCC shall be entitled to immediate injunctive relief to prevent the use or disclosure of Confidential Information, in addition to all other remedies available to it at law or equity.

Any suit or action arising out of a dispute under this Agreement shall be brought only in a court of competent jurisdiction, state or federal, sitting in Phoenix, Arizona. Both parties agree to accept venue in such county.

Accepted this 8th day of October, 2013.

HIBCC

By_____

[redacted]

Title: President & CEO

Primary Consultant

By_____

Name:

Title: Consultant

Health Industry Business Communications Council

Registered Labelers:
Accredited Auto-ID Labeling Standards

The following companies (and/or their subsidiaries/ divisions) have applied for a Labeler Identification Code (LIC) assignment with HIBCC or one of our international affiliates. By doing so, they have demonstrated their commitment to patient safety and logistical efficiency for their customers, the industry and the public at large.

Any organization that is interested in using the HIBC uniform labeling system may apply for the assignment of one or more LICs.

Last updated 1-03-2019

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Suite 127
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www.hibcc.org

Austria

AMI GmbH
Bender Medsystems GmbH
PAA Laboratories GmbH
W & H Dentalwerk Burmoos GmbH

Australia

Adv. Surgical Design & Manufacture, Ltd.
Apollo Medical Imaging Technology Pty Ltd
Benra Pty Ltd dba Gelflex Laboratories
Bioclone Australia Pty. Ltd.
Candelis, Inc.
DePuy Australia Pty. Ltd.
EC Certification Service GmbH
Fink Engineering Pty Ltd
H Trak Pty Ltd
Kesem Health
Kico Knee Innovation Company Pty Ltd.
Med.& Surg. Requisites Pty. Ltd.
Medigroup Australia Pty. Ltd
Norseld Pty Ltd.
Novadien Healthcare Pty Ltd
Opto Global Pty. Ltd.
Orthocell Limited
Red Milawa Pty Ltd dba Magic Mobility
SDI Limited
Signostics Ltd.
Sirtex Medical, Ltd.
Smith & Nephew Surgical Pty. Ltd.
Staminalift International Limited
The Pipette Company Pty. Ltd.
Thermo Electron Corporation
William A Cook Australia Pty. Ltd.

Belgium

3M Europe
Advanced Medical Diagnostics SA/NV
Analis SA/NV
Baxter World Trade
Bio-Rad RSL
Bio-Rad Lab Inc Clinical Diag. Group
Biosource Europe SA
Cilag NV
Coris Bioconcept
Fuji Hunt Photographic Chemicals NV
GC Europe N.V.
icometrix NV
Int'l Pharmaceutical Services BVBA
Johnson & Johnson International
Medical Products
Materalise NV
Mayne Pharma
Medical Electronic Construction R&D Sprl
Molnlycke Europe SA
Orange Scientific SA
Pierre Fabre Benelux
Scimed Europe S.P.R.I.
Théa Pharma SA

Brazil

Angelus Indústria de Produtos Odontológicos S/A
Biolab Diagnostica SA
Dentsply International Inc.
Dentsply Ind E Com Ltda Brazil
Johnson & Johnson Prod. Prof. LTDA
Labcor Laboratorios Ltda.

British Virgin Islands

Registered Labelers

Philips Medical Systems Nederland BV

Canada

Baylis Medical Company, Inc.

Beavers Dental
  Sybron Dental Specialties

Bio-Dent

Biomatcan Ltd.

BLS Systems Limited

Braebon Medical Corporation

Calgary Scientific, Inc.

CardioMed Supplies

CD Newco LLC

Clearwater Clinical Limited

C.M.P. Canadian Medical Products Ltd.

Controle General Informatique B.F. Inc.

Datrend Systems Inc.

Delfi Medical Innovations

DenPlus Inc.

Dental Savings Club

Dental Wings Inc.

Diagnos Inc.

Diagnostics Biochem Canada Inc.

Dymedso Inc.

ECI Medical Technologies, Inc.

Etymonic Design Incorporated

Fio Corporation

Garaventa Canada Ltd.

Glustitch, Inc.

GS Medical Packaging Inc.

Hedy Canada Inc

HR Dental Products Inc

ID Labs, Inc.

IMI Healing Technologies Inc.

In. Genu Design Group Inc

Intelerad Medical Systems Incorporated

International Point of Care

Jac-Cell Medic Inc.

Johnson & Johnson, Inc.
  Iolab Canada, Inc.
  Janssen Pharmaceutica, Inc.
  Johnson & Johnson Med. Prod.
  Ortho Diagnostic Systems, Inc.
  Ortho Pharmaceutical Corp.

Kent Imaging Inc.

Maxill Inc

Meditech International Inc.

Mespere LifeSciences Inc.

Mitroflow, Inc.

Navigate Surgical Technologies Inc

Numed Canada, Inc.

Object Research Systems (ORS) Inc.

Octostop

Oculo-Plastik, Inc.

O-Two-Systems International

Pinel Medical, Inc.

Primed Instruments, Inc.

Primeline Medical Products, Inc.

ProBed Medical Technologies Inc.

Prodrive Systems, Inc.

Qvella Corporation

QXMedical, LLC

Rainbow Specialty + Health Products Inc

RamSoft Inc.

Simpler Implant Solutions Inc.

Solarc Systems Inc.

Span Medical Products Canada Inc.
  MC Healthcare Products

Spectral Medical Inc.

Stryker Corporation
  Stryker Bertec

Synergy Disc Replacement, Inc.

The Canadian Red Cross Society

The Westaim Corporation
  Nucryst Pharmaceuticals

Universal Pain Technology Canada Inc.

Usine Rotec Inc.

Vivosonic, Inc.

Wisent, Inc.

Younes Medical Technologies

Zephyr Sleep Technologies

Zimmer, Inc.
  Zimmer CAS
  Zimmer Manufacturing BV
  Zimmer Orthopedics Mfg. Ltd.

China (includes Hong Kong)

Changzhou Eighteeth Medical Tech Co Ltd

Firstar Healthcare Co. Ltd. (Guangzhou)

Gentec (Shanghai) Corporation

HOB Biotech Group Suzhou, Co. Ltd.

Huge Dental
  Huge Dental Material Co., Ltd.

Isen Tech & Trading Co., Ltd.

Maanshan Bond Medical Instruments Co. Ltd.

Ming Industries Limited

Nantong Poly Technology Co., Ltd.

Ningbo Five Continents Medical Instrument Co. Ltd.

Precision One Lifecare Limited

Premium Plus International Limited

Shenzhen Kingyield Technology Co., Ltd.

Stryker Corporation
  Stryker Suzhou

Wujiang City Shenling Medical Device Co., Ltd.

Columbia

Masterdent LTDA

Czech Republic

Spofadental SA

Denmark

ARO Medical ApS

BGI Europe A/S

Coloplast A/S

Contura International A/S

Radiometer Medical A/S

Virogates A/S

William Cook Europe A/S

Finland

Abacus Diagnostica Oy

Bioretec, Ltd.

Helsinki University Central Hospital

Inion Oy

Kolmi-Set OY

Linvatec Biomaterials, Ltd.

LM - Instruments OY

Mediala OY

Orgenium Laboratories

Oy Fluorplast AB

Sataside OY

Stick Tech Ltd

Tyke OY

France

Amplitude

ARTHRO-DIF

ATF-Vitatech

Becton Dickinson France SA

Biomatlante

BioMérieux BV

Registered Labelers

BioMérieux SA
C2F-Implants
Cardiologs Technologies
CFPM
Dedienne Sante
Denstply France SAS
DePuy Bioland
DePuy France
DOSIsoft
Endo Control
Ethicon Ethnor SAS
Eurospine Sarl
Evolutis SAS
FFDM Pneumat
Fluoptics
Graftys - Sarl
Groupe Lepine
Helioscopie-Ceerdil
Hesperis
Hexacath Sarl
IMACTIS SAS
Implants Serv. Orthopediques (Iso-Ortho)
Intervascular Sas
Ioltech Laboratoires
Itena-Clinical
Johnson & Johnson Medical Sarl
Kasios
LDR Medical
Lisi Medical Orthopaedics
LPG Systems
Medicoscop
Medicrea
Med-Imaps
Memometal Technologies
Micro-Mega SA
Neosteo
Newdeal
Obvieline
Phakos
Pierre Rolland
Protheos Industrie
Quetin SA
Sarl Biomatlante
Satelec (Acteon Group)
Sedat
Serf
SGM
Sofradim Production
Sopro
Surfix
Teknimed Sas
Theraclion SA
Thiebaud Biomedical Devices
Tornier SA
Vexim
Visible Patient Sas
Vitalitec International

Germany (Deutschland)

3M ESPE AG
A. Schweikhardt GmbH & Co. KG
AAP Biomaterials GmbH
AAP Implantate AG
Abbott Vascular Instruments De. GmbH
Acandis GmbH & Co KG
AD GmbH
Adamus GmbH
Adentatec GmbH
Adeor Medical Technologies GmbH
Aesculap AG
Aesculap AG & Co. KG
AJ Roboscreen GmbH
Alpro Dental Produkte GmbH
Altatec GmbH
Amann Girrbach GmbH
ANM Adaptive Neuromodulation GmbH
Applichem GmbH
AristoTech Implant Technologies GmbH
Artoss GmbH
Asanus Medizintechnik GmbH
Auritec Medizindiagnotische Syst. GmbH
B Braun Melsungen AG
Bandelin Electronic GmbH & Co KG
BEGO GmbH & Co
  BEGO Implant Systems GmbH & Co. KG
  BEGO Medical AG
  BEGO Semados GmbH
Beiersdorf AG Inc.
Berchtold Holding GmbH
Bernhard Förster GmbH
Bess Pro GmbH
Biocam GmbH
Biocer Entwicklungs GmbH
Biocheck GmbH
Bio-Rad Laboratories GmbH
  Bio-Rad Lab Inc Clinical Diag. Group
  Bio-Rad Medical Dianostics GmbH
Biotest AG
Bluepoint Medical GmbH & Co. KG
BLV Licht und Vakuumtechnik GmbH
Bosch + Sohn GmbH U. Co KG
Bredent Medical GmbH & Co. KG
Busch & Co. GmbH & Co. KG
Carl Teufel GmbH & Co. KG
Carl Zeiss Surgical GmbH
Coltène/Whaledent GmbH & Co. KG
Croma GmbH
Cumdente GmbH
DeguDent GmbH
Degussa AG
Dental Wings GmbH
Dentaurum GmbH & Co. KG
Dentaurum J P Winkelstroeter KG
Dentrade E.K.
Dentsply GmbH
Dentsply Implant Manufacturing GmbH
DePuy Orthopadie Gmbh
Detax GmbH & Co. KG
Devemed GmbH
Devon Medical GmbH
Diasorin Deutschland GmbH
DMG
Dr. Fenning - BioMed GmbH
Dr. Hopf GmbH & Co. KG
Dr. Hopf, Ringleb & Co. GmbH
Dr. Ihde Dental AG
Dr. Jean Bausch KG
Dr. Schmidt Intraocularlinsen GmbH
Dreve
DRS International GmbH
Dufner Instrumente GmbH
Durr Dental AG
E. Hahnenkratt GmbH
ED GmbH
Eemagine Medical Imaging Solutions GmbH
Einfeldt
Eisenbacher Dentalwaren ED GmbH
Elmicron
Emil Lange Zähnbohrerfabrik E.K.
Espident GmbH
Ethicon GmbH

Registered Labelers

Eucatech AG
Eukamed E.K.
Eve Ernst Vetter GmbH
Favodent Karl Huber GmbH
Fischer Analysen Instrumente GmbH
Fotochemische Werke GmbH
G. Heinemann Medizintechnik GmbH
GEBDI Dental-Products GmbH
Gebr. Brasseler GmbH & Co. KG
Gebruder Martin GmbH & Co. KG
Geister Medizintechnik.De
Genzyme Virotech GmbH
GKE GmbH
Greiner Bio-One GmbH
Greiner Bio-One GmbH (Austria
Greiner Bio-One GmbH (Hungary)
GME German Medical Engineering GmbH
Hager & Meisinger
Hager & Werken GmbH & Co.KG
Harvard Dental International GmbH
HEBU Medical GmbH
Hedent GmbH Dentalgeräte U. Materialien
Heimerle+Meule GmbH
Heine Optotechnik GmbH & Co KG
Heinz Kurz GmbH Medizintechniek
Helmut Zepf Medizintechnik GmbH
Heraeus Kulzer GmbH
Heraeus Medical GmbH
Hermann Medizintechnik GmbH
Hicat GmbH
Hint-Els GmbH
Horcher GmbH
IBA Dosimetry GmbH
IMAGE Information Systems Europe GmbH
Implantcast GmbH
Inomed Medizintechnik GmbH
IT Concepts GmbH
iRT Systems GmbH
Jakoubek Medizintechnik GmbH
Johnson & Johnson Medical GmbH
Kallmeyer Medizintechnik GmbH
Kaltenbach & Voigt
Kaniedenta
Karl Berg GmbH
Karl Storz - Endoskope
KaWeCo Gmbh - Kimetec GmbH
Kentzler-Kaschner Dental GmbH
Kettenbach GmbH & Co. KG
Kimetec Medizintechnik GmbH
Kohler Medizintechnik GmbH
Lawton GmbH & Co. KG
Leoni Fiber Optic GmbH
Lohmann Gmbh & Co. KG
M&W Dental
Medentika GmbH
Medicoplast International GmbH
Medi-Globe
Medisys GmbH
Mediwiss Analytic GmbH
Mednet GmbH
QCORE
Megadenta Dentalproduckte GmbH
Merz & Co. GmbH
Merz Dental GmbH
Metrax GmbH
Meyer-Haake GmbH Medical Innovations
MGB Endoskopische Gerate GmbH Berlin
MIPM Mammendorfer Institut GmbH
Mitsubishi Pharma Deutschland GmbH
Moller-Wedel GmbH
Müller-Omicron GmbH & Co. KG
Noba-Verbandmittel
Normed Medizin-Technik GmbH
Novatec Immundiagnostika GmbH
NTI-Kahla GmbH
OHST Medizintechnik.De
Okodent Preusser OHG
Omnident GmbH
OptoMedical Technologies GmbH
Orbis Dental
Orochemie Durr & Pflug GmbH & Co. KG
Osmed GmbH
OT Medical GmbH
Pioneer Medical Devices AG
PLUM Medical Solutions GmbH
Polytech Ophtalmologie GmbH
PRO-MED Instrumente GmbH
Protec GmbH & Co. KG
Prowital Dental Implants GmbH
PTW-Freiburg
PVB Medizintechnik GmbH
QIAGEN GmbH
Reitel Feinwerktechnik GmbH
Renfert GmbH
Resorba
Richard Wolf GmbH
RoweMed AG
Sartorius Stedim Plastics GmbH
Scheu-Dental
Schutz Dental GmbH
Scopis GmbH
Serag-Wiessner KG
SiCAT GmbH & Co. KG
Signus Medizintechnik GmbH
Sirona Dental Systems GmbH
Sopro-Comeg GmbH
Speiko - R. Speier GmbH
Spiggle & Theis Medizintechnik GmbH
Stericop GmbH & Co.KG
Steristics AG
Storz Am Mark GmbH
Stryker Leibinger GmbH & Co. KG
Stryker Trauma GmbH
Sutter Medizintechnik GmbH
Sybron Implant Solutions GmbH
Transatl. Handels-Ges. Stolpe &Co. GmbH
Trumpf Medizin Systeme GmbH
Tut-Instruments GmbH
Ulrich Storz GmbH & Co. KG
Universitatsklinikum Bonn
Urotech Medizinische Technologie Gmb
Valmex Photographische Produkte GmbH
Vanguard A.G.
VDW GmbH
Vims Sas
Viramed Biotech AG
Vita Zahnfabrik
Voco GmbH
Völker AG
Wagner GmbH
Wassermann Dental-Maschinen
Wavelight GmbH
Weber Medical GmbH
Welch Allyn GmbH & Co. KG
WhiteSmile GmbH
Willmann & Pein GmbH
Xion GmbH
Yeti Dentalprodukte GmbH
Zhermack GmbH Deutschland
Zimmer Medizin Systeme GmbH

Registered Labelers

ZL-Microdent Attachment GmbH & Co.KG

Hungary

Medimetal, Ltd.

Sanatmetal

India

Aaropna Protesi Private Limited

Ethicon Div. of Johnson & Johnson, Ltd.

SoftLink International Private Limited

Ireland

Abbott Ireland, Ltd.

Abbott Vascular Devices

Allergan, Inc.

Astellas Ireland Co., Ltd

Creagh Medical Ltd.

Howmedica Int'l., Inc.

Johnson & Johnson Professional, Ltd.

Mednova

Proxy Biomedical, Ltd.

Stryker Ireland (Cork)

Stryker Orthopaedics

Takumi Medical

X-Bolt Orthopaedics

Israel

Cortex Dental Implants Industries Ltd.

Etview

MDT Micro Diamond Technologies Ltd.

Medinol, Ltd.

MIS Implants Technologies, Ltd.

OHK Medical Devices, Ltd.

PeriGen Solutions Ltd.

Q Core Medical

Strauss & Co. Industrial Diamonds Ltd.

T.A.G. Medical Products Corporation, Ltd.

Virtual Ports, Ltd.

VisionCare Ophthalmic Technologies

Italy

AB Medica SPA

Adaltis SRL

Adler Ortho S.p.A.

ASA Dental SPA

B & B Dental Srl

Bioengineering Laboratories SPA

Biotec S.R.L.

Biotek SRL

Biotekne SRL

Blue X Imaging SRL

BMI Biomedical International SRL

BTS S.p.A.

Comecer SPA

Cominox SRL

Copan Flock Technologies SRL

Copan Italia SPA

Critikon-Johnson & Johnson Prof. Prod.

C-Tech Implant S.R.L.

De Götzen S.rl.

Dia. Pro Diagnostic Bioprobes SRL

Diasorin SPA

Dideco SPA

ELTECH K-LASER S.R.L.

Ethicon SPA Italy

Euronda SPA

Fidia Farmaceutici S.p.A.

Gallini Srl

Gambro SPA

Hofmann SRL

IGEA SRL

Intrauma SRL

Johnson & Johnson Medical Holding SPA

Kerr Italia SPA

Lima Corporate SPA

M.O. Com SRL

Mauritius SRL

MD & I SRL

Mectron SPA

Medical Plastic SRL

Meta Ergonomica

MIR Medical International Research

NeoLogica S.R.L.

Next Sight SRL

NGC Medical SPA

Nidek Technologies Srl

Novater SRL Unipersonale

O.M.S. SPA

Optikon 2000 SPA

Paramed S.R.L.

Q.R Srl

Rand SRL

Rhein '83 Srl

RS Medica SRL

Sclavo Diagnostics International SRL

Sentinel CH. SPA

Sintea Biotech SPA

Sire Analytical Systems
Alifax SPA

Sorin Biomedica Cardio SPA

Sweden & Martina S.p.A.

Tecno-Gaz SPA

W&H Sterilization SRL

Zirkonzahn Srl

Japan

Asicon Tokyo, Ltd.

Fuji Photo Film Co., Ltd.

GC Corporation

Konica Corporation

Kuraray Medical, Inc.

Mitaka Kohki Co., Ltd.

Sakura Finetek Japan Co., Ltd.

Seikagaku Corporation

Tomey Corporation

Liechtenstein

Inovis Vivadent AG

Ivoclar Vivadent AG

Kenda AG

SDS Swiss Dental Solutions

Malaysia

Careplus (M) SDN. BHD.

Mexico

Mallinckrodt Medical, Inc,

Mallinckrodt Medical TPI, Inc.

Ortosim, S.A. De C.V.

Radiotecnologia Industrial S.A. de C.V.

The Netherlands

Abbott BV

Abott Products BV/Solvay Pharma BV

Academisch ZKH. Maastricht

Actavis BV

Actelion Benelux

Added Pharma

AHP Pharma BV

Albic BV

Alcon Pharmaceutical, Ltd.

Allgen Pharmaceuticals & Generics

Registered Labelers

Alliance Health Care
Amgen Europe BV
Astellas Farma Europe BV
Astra Pharmaceutical Products, Inc.
Astra Zeneca BV
B V Euromedica
Basic Pharma Mfg. BV
Basiq Dental BV
Bayer BV
Biomet Nederland BV
Bipharma BV
Blue Medical Devices BV
Boehringer Ingelheim BV
Boots Pharma./Healthcare BV
Bournonville-Pharma BV
Brocacef BV
Brocacef Intramuraal BV
Bufa - Chemie BV
Byk Nederland BV
Catharina Ziekenhuis
Cavex Holland BV
Centrafarm BV
Central Lab VD Bloedtransfusiedienst
Chiron BV
Christelijke Vereniging Het Diaconessenhuis Leiden
Christiaens BV
Clinimed Holding BV
Confedera BV
CSL Behring BV
De Koningh Coding & Packaging
Delphi Pharmaceuticals BV
DG Lederle Nederland BV
Disphar International BV
Dowelhurst Netherlands BV
Dr. Coenraad Consortium CV
Dumex BV
Duphar Nederland BV
E Merck Nederland BV
Elana
Elephant Dental BV
Eli Lilly Nederland BV
Enraf-Nonius B.V.
EU-Pharma BV
Eureco-Pharma BV
Eurobase BV
Eurocept Pharmaceuticals
Extrapharm
E-Z-EM Nederland BV
Fagron Farmaceauticals BV
Fagron Services BV
Farmaceutische Ond. Lansberg-Rotterdam
Ferring B.V.
Fisher Farma
Fisons Pharmaceuticals
Fresenius BV
FRG Farma BV
Fysicon B.V.
Galderma SA
Genfarma
GenRx
Genthon BV
Getronics
Gist Brocades
GlaxoSmithKline BV
Grapharma BV
Grünenthal BV
Guerbet Nederland BV
Handelsonderneming Tempus BV
Hexal BV
Hoechst-Holland NV
Holland Pharmaceutical Supply BV
Homeoropa BV
ICI-Farma
Inpharzam/Zambon Nederland BV
Interpharm BV
Ipsen Farmaceutica BV
Jansen TMI BV
Janssen-Cilag BV
Janssen Pharamceutica BV
Johnson & Johnson Medical BV
Kabi Pharmacia BV
Karib Limited
Katwijk Farma BV
KNMP
Knoll BV
Koninklijke Utermohlen NV
Kring-Apotheek BV
Laboratorium Almirall Prodesfarma
LAGAP BNL BV
Leids Universitair Medisch Centrum
Leo Pharma BV
Leyden Delta BV
Lilly Nederland BV
Lorex Synthelabo BV
Lundbeck BV
Maastricht
Machnet B.V.
Magnafarma BV
McNeil BV
Mecomfa BV
Meda Pharma BV
Medcor Pharmaceuticals BV
MEDECO BV
Medical NV
Medicopharma NV
Medis Medical Imaging Systems BV
Medport BV
Menarini Benelux NV
Mentor Medical Systems BV
Merck BV
Merck Generics BV
Merck Sharp & Dohme BV
Merops Pharma BV
MSD
Multipharma
N.V.I
Nedcox Pharma BV
Neopharm BV
New Neopharm BV
Nikinc Dental B.V.
Nordic Pharma BV
Norgine BV
Novartis Consumer Health
Novartis Pharma BV
Novo Nordisk Farma BV
NPBI International BV
Nycomed BV
Occam International BV
Onderlinge Pharm Groothandel UA
OPG Groep NV
Ophtec BV
Ortomed BV
Parke-Davis BV Warner Lambert
PCH Pharmachemie BV
Pfizer BV
Pharbil
Pharbita BV
Phardis BV
Phareur BV

Registered Labelers

Pharmachemie BV
Pharmacia Upjohn BV
Pharmacin International BV
Pharmagent
Polyfarma BV
Prosan International BV
Ratiopharm BV
Reckitt Benckiser Healthcare
Rhone-Poulenc Rorer/Pharbil
Roche Nederland BV
Rooster & ZN. BV
Samenwerkende Apothekers Ned. BV
Sandoz BV
Sankyo Pharma Nederland BV
Sanofi Aventis
  Sanofi Aventis Nederland BV
  Sanofi Winthrop,
  Bristol Myers Squibb VOF
Sanquin
Schering-Plough Nederland BV
Searle Nederland BV
Sigma Tau Ethifarma BV
Sigma Tau Healthscience Int'l. BV
SmithKline Beecham Farma
Spruyt Hillen BV
St. Volksgez en Milieuhygiene
Stephar BV
Stephim BV
Stichting Registratie Beheer (SANDOZ)
Stichting Ziekenhuis Leyenburg
Syntex BV
Synthon BV
Taxandria Pharmaceitica BV
Technomed Europe BV
Tempus BV
Terapharm BV
The Surgical Company International B.V.
Tio Farma
Tramedico BV
Trendpharma BV
UCB Pharma B V
United Pharma Group BV
Ursapharm Benelux BV
Valeant Pharmaceuticals International
Van Den Berg Nederland BV
Van Heek Meander BV
Viatris Manufacturing BV
ViiV Health Care
Wellcome Pharmaceuticals BV
Wyeth Laboratoria BV
Wyeth Pharmaceuticals BV
Yew Tree Pharmaceuticals
Zambon Nederland BV
Zyma-Nederland BV

Norway

Nycomed Imaging AS
Saga Dental Supply AS

New Zealand

Enztec Limited

Philippines

Lifetrack Medical Systems Inc

Portugal

Johnson & Johnson Produtos Profissionals

Singapore

Medlinx Acacia Pte Ltd
Pasture Pharma PTE LTD

Slovakia

Apothecon BV (0183)
Bristol-Myers Squibb BV

South Africa

Diasorin South Africa Pty. Ltd.
Johnson & Johnson Medical Prof. Prod.
Ortho Sol Pty. Ltd.

South Korea

Migun Medical Instruments Co. Ltd.
Neobiotech Co., Ltd.
U&I Corporation

Spain

Howmedica Faimon SA
Howmedica-Iberica SA
Johnson & Johnson Prod. Prof.
Metalor Iberica
Transcendencias Comerciales SL.

Sweden

AB Ardent
All Of It Skandinavia AB
BrainCool AB
Carmel Pharma AB
Hospal - Gambro Renal Products
LIC Hygien AB
Medscand Medical AB
Molnlycke Health Care AB
Nobelpharma AB
Nordiska Dental AB
S2Medical AB
ScandiCare Products AB
Swemac Innovation AB

Switzerland

Assut Medical Sarl
Bien-Air SA
Biotronik AG
Candulor AG
Cendres & Métaux SA
Central Labs Blood Transfusion SVCS
Coltène AG
Degradable Solutions AG
Dentsply, Ltd.
Edenta AG
EMS-Electro Medical System SA
Endosense SA
Hamilton Medical AG
Hospal, Ltd.
Institut Straumann AG
JOTA AG
Kerrhawe SA
Maillefer Instruments SA
Medacta International SA
Medaxis AG
Metalor Technologies SA
  Division UGDO
Neo Medical S.A.
Nouvag AG
Oro Clean Chemie AG
Polydentia SA
Precimed SA
Primequal SA
PRISMAN Pharma International AG
Prodonta SA
Produits Dentaires SA

Regedent Ag
Regen Lab SA
Rodent AG
Schiller AG
Schneider (Europe) AG
SIC invent AG
Stryker Trauma SA (Jaquet)
Tip Top Tips Sarl
Unor AG
Valtronic SA
Zimmer, Inc.
  Zimmer GmbH

Turkey

Altera Tibbi Malzeme San. Ve Tic. A.S.
Disera Tibbi Malzeme Lojistik Sanayi Ve Ticaret A.S.

United Kingdom

ABenge Advanced Biotechnologies, Ltd.
Activinsights Limited
B Braun Meslungen AG
Biocomposites, Ltd.
Bio-Rad Laboratories Deeside, Ltd.
Bio-Rad Lab Inc. Clinical Diag. Group
Body Clock Health Care Limited
Brainomix Limited
Bridgemaster Medical, Ltd.
BTL Industries Limited
CamNtech Ltd.
City Technology Limited
Corin, Ltd.
Critikon - Johnson & Johnson Prof. Prod.
Davis Schottlander & Davis, Ltd.
Den of Goods Ltd.
  Tempir
Dentsply International, Inc.
  Ash Instruments Dentsply
  C M W Laboratories
  Detrey Dentsply, Ltd.
  Medical & Industrial Equipment
DePuy International, Ltd.
  DePuy CMW
De-Soutter Medical, Ltd.
Ethicon Ltd. United Kingdom
E-Z-EM Limited
Finsbury Orthopaedics Limited
Future Spine Technologies Ltd.
Goldshield Group plc
Grant Instruments (Cambridge), Ltd.
HeartSine Technologies Ltd.
Howmedica (Uk) Limited
Hyaltech, Ltd.
Iolab Intraocular
IVAX Pharmaceuticals UK
J & J Medical Ltd. UK
J & J Ortho Clinical Diag - Wales
Johnson & Johnson Orthopaedics Ltd
Johnson & Johnson Prod.Prof. Ltda.
Lidco, Ltd.
Lloyds TSB Registrars / BOC Health Care
Medtrade Products Limited
Metalor Dental Products, Ltd.
Mirada Medical Ltd.
Mitsubishi Pharma Europe, Ltd.
Myconostica, Ltd.
Neoligaments, Ltd.
Orthodynamics
Ortho-Trauma International LLP
Paxman Coolers Ltd.
Perspectum Diagnostics Ltd.
Planar PLC
Plasma Surgical Investments
  Plasma Surgical, Ltd.
Portex, Ltd.
Poulten & Graf, Ltd.
Ranbaxy UK, Ltd.
Ranier Technology Ltd.
Real Doctors
Regent Hospital Products, Ltd.
  LRC Products, Ltd.
ScanTrack Healthcare Systems, Ltd.
Sherwood Medical Int.
Smith & Nephew Healthcare, Ltd.
Smiths Industries
Stanmore Implants Worldwide, Ltd.
  SIW Holdings, Ltd.
Stryker Howmedica Osteonics
Sulzer Vascutek, Ltd.
Summit Medical, Ltd.
Surgicraft (Mandaco 569) Ltd.
Synthes
Technical & General Ltd.
Tensonix Limited
The Dental Directory,
  Billericay Dental Sup. Co.
Thermo Fisher Scientific
Tissue Science Laboratories PLC
Vadin Implants, Ltd.
Vicon Motion Systems Ltd. (A Wholly Owned Subsidiary of OMG PLC)
Vision RT

United States

3M
  3M Imaging
  3M Med\Surg
  3M Orthopedic
  3M Pharm
  3M Vision Care
4M Screening Solutions, Inc.
410 Medical Innovation LLC
A & A Medical Supplies, Inc.
AADCO Medical Inc.
A Plus International
A.R. Hinkel Co., Inc.
Aalto Scientific, Ltd.
  Audit Microcontrols, Inc.
Aaron Medical Industries, Inc.
  Bovie Medical
  Omniflex
Aastrom Biosciences
Abbott Laboratories
  Abbott Critical Care
  Abbott Diagnostic
  Abbott Hospital Production
  Abbott Pharma. Production
  Perclose, Inc.
Abco Dealers, Inc.
Ability One Corporation
Absorbent Products Company, Inc.
Access Closure, Inc.
Acclarent, Inc.
Accuray Inc.
Accuvein, LLC
ACell, Inc.
Acme United Corporation
ACMI
Acorn Engineering Company
  Whitehall Manufacturing
Acumed, Inc.
Acutus Medical
AdDent, Inc.
Addition Technology, Inc.
A-Dec, Inc.
Adenna Inc.
Adhezion Biomedical, LLC

Registered Labelers

Adler Instrument Company

Adroit Medical Systems

Ad-Tech Medical Instrument Corporation

Advan Dx, Inc.

Advance Medical Designs, Inc.

Advanced Back Technologies, Inc.

Advanced Biomaterial Systems

Advanced Bionics LLC

Advanced Breath Diagnostics, LLC
dba Cairn Diagnostics

Advanced Circulatory Systems, Inc.

Advanced Instrumentation for Medicine, Inc.

Clear Flush

Advanced Instrumentations, Inc.

Advanced Maternity Innovations

Advanced Medical Optics

Advanced Meditech International, Inc.

Advanced Orthopaedic Solutions, Inc.

Advanced Vertebral Solutions, LLC

Advanced Vision Science

Advantec Vascular Corporation

Advin Biotech

Aesculap Instruments Corp.

Aesthetic & Reconstructive Technologies

AFP Imaging Corporation
Dent-X Corporation

AFP Manufacturing, Inc.

AGA Medical Corporation

Agent Medical, LLC

AGFA Corporation
Matrix Division
AGFA Healthcare

AIDI Biomedical

AirStrip Operations, LLC

Air Techniques, Inc.
All Pro Imaging

Airsep Corporation

Aktina Medical Corp.

Alafair Biosciences

Alba -Waldensian, Inc.
Alba-Waldensian Health Prod. Div.

ALC Enterprises Inc

Aura Medical LLC

Alcide Corporation

Alcon Laboratories
Pharmaceuticals

Alycone Lifesciences Inc.

Alere San Diego Inc dba Biosite, Inc.

Alevio, LLC

AliveCor

All American Dental Supply LLC

All Dental Prodx, LLC

Allergan, Inc.

Alliance Spine, LLC

Alliant Enterprises, LLC
Alliant Healthcare Products

Allo Source

Almore International, Inc.

ALPCO

Alpha Medical Instruments, LLC

Alpha-Tec Systems, Inc.

Alto Development Corporation
A & E Medical Corporation

Altracore Biomedical

AltroCare Inc.

Altus Spine

AMCOL International
Chemdal Corporation

Amedica/US Spine

American Australian Medical

American Cyanamid
Davis & Geck

American Dental Cooperative

American Dental Implant Corp

American Dental Supply, Inc.

American Diamond Instruments

American Health Products Corp.
Quinton Instrument Company

American Health Service Sales Corp

American Home Products Corp.
Argyle Division of Sherwood
Dover Urologicals Div.
Monoject Div. of Sherwood Medical
Oxford Chemistries Div.
Oxford Lab Supplies Div.
Oxford Liquid Handling Div.
Sherwood, Davis & Geck
US Clinical Products
Veterinary Div. of Sherwood
Wyeth-Ayerst Laboratories

American I.V. Products

American Sterilizer Company

American Tooth Industries

Amerisource Bergen

Amersham Health/GE

Amerx Health Care Corp.

Amici, Inc.

Amsino International, Inc.

Anatomical Concepts, Inc.

Anchor Innovation Medical, Inc.

Anesthesia Associates, Inc.

Anesthesia Medical Specialties, Inc.

Angeion Corporation

Angiodynamics
E-Z-EM, Inc.

Angioguard, Inc.

Angioscore Inc.

Angiotech
Angiotech Biocoatings Corp.
Angiotech Pharmaceuticals, Inc.

Anika Therapeutics, Inc.

Anmuth Medical International

Ansell Healthcare Products LLC

APC Workforce Solutions, LLC dba Zero-Chaos

APDM

Apdyne Medical Company, Inc

Apex Biologix

Apogent Technologies
Erie Scientific Co.
Nalge Nunc Co.
Nerl Diagnostics Corp.
Richard Allan Scientific

Apotheus Laboratories, Ltd.
Scott Laboratories, Ltd.

Applied Medical Resources

Applied Spine Technologies

Aptis Medical, LLC

Aqueduct Critical Care, Inc.

Arch Therapeutics

Arcos, Inc.

ArcScan Inc.

Ardent, Inc.

Argon Medical Devices, Inc.

Armour Pharmaceutical Company
USV Lab. Div. Pharma Corp.

ARP Manufacturing, LLC

Arquilla, Inc. dba X-Cel X-Ray Corporation

Arrhythmia Solutions Inc

Arrow International, Inc.
Precision Products

Arstasis, Inc.

Arteriocyte, Inc.

Arteriocyte Medical Systems, Inc.

Arterys Inc

Arthrex, Inc.

Arthrosurface, Inc.

Arthrotek

Registered Labelers

ArtVentive Medical Group
ArtVentive
Aseptica, Inc.
Aspen Surgical Products, Inc.
Aspyra, LLC
Astra USA
Astron Dental Corporation
Astute Medical, Inc.
Asuragen, Inc.
Athena Champion
Athena GTX
AtheroMed, Inc.
Ati Orion
Atlas Spine, Inc.
ATOMO Dental, Inc.
Atricure, Inc.
Atritech, Inc.
Atrium Medical Corp.
ATS Medical, Inc.
Auric Enterprises, Inc.
Diack
Aurora Manufacturing LLC
Auris Health Inc
Aurora Spine, Inc.
Aus Systems Pty Ltd
Austenal Dental, Inc.
Authentic Options, LLC
Automated Medical Products Corp.
Autonomic Technologies
Avantis Medical Systems, Inc.
Avanti Systems, Inc.
Aveco Health LLC
Aventusoft, LLC
Avenu Medical Inc.
Avid Medical, Inc.
Avinger, Inc.
Awareness Technology Inc.
Axiobionics
Axiom Medical, Inc.
Axis Dental Corporation
Axis Orthopaedics Corp
Axo Gen, Inc.
Axonics Modulation Technologies, Inc.
B& B Dental Ceramic Art, Inc. dba 3D BioCAD
B Braun Medical, Inc.
B Braun Interventional Systems
Burron Mfg. Division
B G Industries, Inc.
Bacchus Vascular
Bacharach, Inc.
Bacterin International, Inc.
Bahadir USA LLC
Banta Healthcare
Bard Peripheral Vascular
Barnstead International
Baron Medical Corp.
Barriermed, Inc.
Barriermed Glove Co.
Barrx Medical, Inc.
Basic Dental Implant Systems, Inc.
Bausch & Lomb, Inc.
Baxa Corporation
Baxter Healthcare Corp.
Baxter Compass
Bay Corporation
Bayer Corporation
AGFA Division
Bayer Healthcare
Diagnostics
Beacon Endoscopic
Bear Down Consulting dba Pure Enrichment
Beaverstate Dental Inc
Beckman Coulter, Inc.
Australia
Kentucky
Primary Care Diagnostics
Becton, Dickinson & Company
Acutecare
Becton Dickinson Division
Diagnostic Instrument Systems
Immunocytometry Systems
Infusion Systems
Labware
Medical Glove Division
Medical Technique Products
Microbiology Systems
Phase Medical, Inc.
Pharmaceutical Systems
Vacutainer Systems
Vascular Access
Beiersdorf, Inc.
Beiersdorf Medical
Jobst Institute, Inc.
Beitler McKee Optical Company
Bel-Art Products
Maddak, Inc.
Belle de St. Claire
Bellegrove Medical Supply, Inc.
Belport Company
Gingi-Pak
Bemis Health Care, Inc.
Bemis Mfg. Co.
Benco Dental Supply Co.
Benson Medical Instruments Co.
Bergan Mercy, Inc.
Berkley Medical Resources, Inc.
Berns Medical LLC
Best Vascular Inc.
BETA Biomed Services, Inc.
Better Water LLC
Biddle & Crowther Company
Bihani Corporation dba American Medicals
BiO2 Medical, Inc.
Bio2 Technologies, Inc.
Bio Compression Systems
Bio Derm, Inc.
Bio Medical Enterprises, Inc.
Bio Merieux, Inc.
Bio Plas, Inc.
Bio Sb Inc
Bioaccess, Inc.
Biocompatibles, Inc.
Biocompatibles International PLC
Biocompatibles Cardiovascular, Inc.
Bioflo LLC
BioLife Solutions, Inc.
Biological & Environmental Control Labs
Biomed Diagnostics, Inc.
Biomed Packaging Systems, Inc.
Bio-Medical Devices, Inc.
Biomerieux, Inc.
Biomerix Corporation
Bion Enterprises Ltd. dba MBL Bion
Bioness, Inc.
Bionica Inc.
BionX Medical Technologies
Bioplate, Inc.
Biopro
Bio-Rad Laboratories, Inc.
Bio-Rad Lab Inc Clinical Diag. Group
Redmond Operations
Biosculpture Technology, Inc.
Bioseal Medical Packaging Concepts
Biosearch Medical Products, Inc.
Biosensics LLC
Biosphere Medical, Inc.
Biosynergy, Inc.
Biotech, Inc.

Registered Labelers

Biotek Instruments, Inc.

BioTex, Inc.

BioTime, Inc.

Biotricity

Biotrol International
Pro-Dex, Inc.

Bioventus LLC

BioVue, LLC

Birchwood Laboratories, Inc.

Bisco, Inc.

Black & Black Surgical, Inc.

Blackstone Medical, Inc.

Block Medical, Inc.

Blue Endo

BodyTrace, Inc.

Boehringer Laboratories, Inc.

Boekel Industries, Inc.

Bone Foam Inc

Bone Solutions LLC

Boots-Celltech Diagnostics Ltd.

Boston Endo-Surgical Technologies, Inc.

Boston Scientific Corporation
Advanced Bionics
Cardiac Assist
EPT
Interventional Technologies, Inc.
Meadox Medicals, Inc.
Medi-Tech
Microvasive Endoscopy
Microvasive Urology
Scimed
Target Therapeutics

Bound Tree Medical

Braemar Manufacturing LLC

Brain Sentinel, Inc.

Branchpoint Technologies, Inc.

Brennen Medical, Inc.

Breveon, Inc.

Bridger Biomed, Inc.

Briggs Medical Service Corp.

Brinkmann Instruments Co., Inc.

Bryan Medical Inc

BSD Medical Corporation

Buckeye Medical Technologies Ltd.

Bulbtronics Inc.

Burke/Leisure Lift Inc.

Burke L Mays and Associates, Inc.

Burton Medical

Busse Hospital Disposables

CCRI, Inc.

C R Bard, Inc.
Bard Access Systems
Bard Canada, Inc.
Bard Cardiopulmonary
Bard Critical Care Div.
Bard Electrophysiology
Bard Interventional Products
Bard Medical
Bard Medsystems Division
Bard Radiology Division
Bard Reproductive Systems
Bard Urological Division
Bard Vascular Systems Division
Birtcher Medical
Davol Inc/Bard Access
Medchem Products, Inc.
USCI Division

Cabot Medical Corp.

Cactus LLC

Caire, Inc.

Calhoun Vision, Inc.

Calvary Spine, LLC

Camber Medical Technologies

Camber Spine Technologies, LLC

Cambridge Heart, Inc.

Cameron Miller Inc.

Candelis, Inc.

Captiva Spine

Capture Vascular, Inc.

Carbon Medical Technologies

Cardiac Designs, Inc.

Cardiac Science Corporation

CardiacAssist, Inc.

Cardica, Inc.

Cardinal Health
Alaris Medical Systems

Cardinal Scale Mfg. Co.
Detecto Scale

Cardiogenesis Corp.

Cardiomems, Inc.

Cardionics

Cardiovascular Dynamics, Inc.
Interpoint Medical Systems

Cardiovascular Innovations, LLC

Cardiva Medical, Inc.

Carelife USA

Careside Medical

Carestream Health, Inc.

Cargus International

Carl Parker Associates, Inc.
Dental Materials Group
Mydent Corporation

Castle Professional Services, Inc.
Cardio Medical Solutions, Inc.

Catheter Connections, Inc.

Cayenne Medical, Inc.

CC Wellness LLC

Cederroth, Inc.

Celera Corporation

Celerus Diagnostics

Cellay, LLC

Cellera, LLC

Cenogenics Corporation

Centrix, Inc.

Century Plastics
Mac-Lee Medical Products

Cerapedics, Inc.

Certol International, LLC

Cervilenz Inc.

Cetylite Industries, Inc.

CFS Dental Inc.

Chameleon Dental Products Inc.

Channel Investments, LLC dba Tria Beauty

Chart Inc.

Chatsworth Latex, Inc.

Checkpoint Surgical, Inc.

Chesebrough-Ponds, Inc.
Home Services Division

Chester Labs, Inc.

Chestnut Medical

Children's Hospital Medical Center

Christie Medical Holdings, Inc.

Churchill Medical System, Inc.

Cianna Medical Inc.

Cida

Cincinnati Surgical Company

CIRCA Scientific, LLC

Circadiance, LLC

Circon Corporation
Cabot Medical Corporation

Citra Anticoagulants, Inc.

Civco Medical Solutions

Clarus Medical, LLC

ClarVista Medical

ClearCorrect, Operating
ClearCorrect, LLC

ClearFlow, Inc.

Clear Guide Medical LLC

Clearmedical

ClearPath Surgical, Inc.

Registered Labelers

ClearSpec LLC
Clearwater Colon Hydrotherapy, Inc.
Cleveland Medical Devices, Inc.
Clinical Innovations, Inc.
Clinical Instruments International, Inc.
CliniComp International Inc.
Clinimed, Inc.
Clinipad Corp.
CME America, LLC
CMP Industries LLC
Coalescent Surgical, Inc.
Coapt, LLC
Coaxia, Inc.
Codonics, Inc.
Coeur, Inc.
  Coeur Medical
Cohera Medical, Inc.
Coherex Medical
Collagen Matrix, Inc.
Coloplast, Inc.
  Coloplast AS
Coltene/Whaledent, Inc.
Columbia Diagnostics, Inc.
Combat Medical Systems, LLC
Comfortex, Inc.
  Avatar Enterprises
Compass International Innovation, Inc.
Compression Therapy Concepts
Computer Sports Medicine, Inc.
Con Med
Conceptus, Inc.
Conforma Laboratories, Inc.
Conformis, Inc.
Conmed Corp.
  Andover Medical
  Aspen Laboratories, Inc.
  Linvatec
Conor Medsystems
Consolidated Polymer Tech., Inc.
Consolidated Research of Richmond, Inc.
Constant Care Technology, LLC
Contec, Inc.
Control Company
Control Medical Technology
ControlRad, Inc
Cook Group, Inc.
  Cook Biotech, Inc.
  Cook Urological
  Wilson-Cook Medical, Inc.
Cooley & Cooley, Ltd.
Cooper Biomedical, Inc.
Coors Ceramics Company
CoorsTek Medical
Corbin Clinical Resources, LLC
CoreLink
Corning, Inc.
Corpak MedsySystems, Inc.
Correx, Inc.
Cosmedent, Inc.
Cottrell, Ltd.
  Advance Suture, Inc.
  Alliance Western Mfg.
  Prochem Company
CP Medical, Inc.
  Theragenics
CPAC
  Allied Diagnostic Imaging Resources
Cranial Technologies
Crest Electronics
  DBA Crest Healthcare Supply
Cretex
  RMS Company
Critical Diagnostics
Critacare, Inc.
  Infusion Devices
Criticare Technologies Inc.
CrossBay Medical, Inc.
Crosstex International
Crosstrees Medical, Inc.
Cryovascular Systems, Inc.
CSC Scientific Co., Inc.
CS Medical LLC
Cuattro Medical, LLC
Cura Medica LLC
Curaseal
Cure Medical LLC
Curiteva LLC
Currie Medical Specialties
Curtin Matheson Scientific, Inc.
Custom Spine, Inc.
Custom Ultrasonics, Inc
Customer Service Associates, LLC
  CSA Service
Cuyahoga Falls General Hospital
CVR Global, Inc.
Cx Orthodontic Supply, LLC
Cyber Medical Imaging dba XDR Radiology
Cygnus, Inc.
Cypress Medical Products, LP
Cytogen Corporation
CytoSorbents, Inc.
D&S Dental
Daavlin Distributing Company
Dade International
  Dade Chemistry Systems, Inc.
Dale Medical Products, Inc.
Dallen Medical, Inc.
Darby Dental Supply, LLC
DARCO International Corporation
Data Innovations LLC
Data Medical
Datascope Corporation
David Scott Company
Davryan Laboratories, Inc.
Daxor Corp
D.B.I. America Corporation
DCI International
Decon Laboratories
Delcath Systems, Inc.
Delta Gloves
Delta Hi-Tech Inc.
Delta Surgical Instruments, Inc.
Deltec
  Graseby Medical, Inc.
Denali Corporation
Den-Mat Holdings, LLC
DeNovo Products, LLC
Dentalree.com International Inc
Dental Health Products, Inc.
Dental Technologies, Inc.
Den-Tal-Ez, Inc.
  Custom Vacuum
  Den-Tal-Ez Equipment
  Star Dental
Denticator International, Inc.
Dentium USA
Dentsply International, Inc.
  Ash USA
  Ceramco, Inc.
  Dentsply Caulk De Mexico SA
  Dentsply GAC International
  Dentsply GmbH
  Dentsply Industria E Comeri
  Dentsply, Ltd.
  Dentsply Raintree Essix
  Dentsply Tulsa Dental Specialties
  Professional
  Prosthetics Division
  Ransom & Randolph Co.

Registered Labelers

Sultan Healthcare
The L D Caulk Co.
Dent Zar Inc.
DEP Shape Memory Therapeutics, Inc.
DePuy, Inc.
DePuy Ace Medical
Derby Dental Laboratories
Deroyal Industries, Inc.
Deroyal Technologies, Inc.
Devax, Inc.
Devicor Medical Products, Inc.
Dexide, Inc.
Iotec Industries
Nurse Assist
Trotec Medical Corporation
Dey Laboratories LP
DGIMED Ortho, Inc.
DHD Healthcare
Diacor Inc.
Diagnostics for the Real World Ltd
Diamatrix, Ltd.
Int'l. Science & Technology, LP
Diamond Orthopedic LLC
DIamoDent
Diasol, Inc.
Diasorin, Inc.
Diasorin SPA
Dicom Grid dba Ambra Health
Di-Chem Inc
Difco Laboratories, Inc.
Digital Cognition Technologies
Digital Heat Corporation
Dipro Diagnostic Products
Dirac Formulation Medical Science Co., Ltd.
DirectCrown Products
Disc Motion Technologies
Disorb Systems, Inc
DistribuDent LLC
Dittmar, Inc.
Diversatek Healthcare
Dixtal Medical, Inc.
Dixtal Biomedica Indus. e Comercio, Ltd.
DJ Orthopedics, LLC
DMG America LLC
Goldsmith & Revere
DMX-Works Imaging, Inc.
DNTLworks Equipment Corporation
DOC Development, Inc.
Doctor Down, Inc.
Doctors Regional Medical System
Doctors Research Group, Inc.
Domino Pads LLC
MeLuna USA
Dow Corning Corp.
Dragon Heart Medical, Inc.
Drummond Scientific Company
DT MedTech, LLC
Duchesnay USA, Inc.
Dukal Corporation
Duplex Products, Inc.
Dura Tap LLC
DUSA Pharmaceuticals, Inc.
Dux Dental
DxNA LLC
Dymicron
Dynarex Corporation
Dynatech Laboratories, Inc.
E Dental Products
E I Dupont de Nemours
Dupont Critical Care-Med Prod. Dept.
Medical Products Department
Eastern Systems Research, Inc.
ESR Medical Products Group
Eastman Kodak Company
Eclipse Medical, Inc.
Eco Lab
Edge Biologicals Inc
Edge Endo, LLC
EEG Software LLC
EFOS, Inc.
Eisertech
Ekso Bionics, Inc.
Ekos Corporation
EKR Therapeutics, Inc.
Electromed, Inc.
Electromedical Technologies, LLC
Electromedics, Inc.
Electronic Development Labs, Inc.
Eli Lilly & Company
Dista Products
E.M. Adams Company, Inc.
Embla Systems
Embolx, Inc.
EMD Chemicals, Inc.
Emerald Supply
Emerge Diagnostics Inc.
Emergency Medical Education Tech Sys.
Eminent Extremities LLC
Eminent Spine, LLC.
Encore Medical LP
Encore Soft Goods
Endius, Inc.
Endocardial Solutions, Inc.
EndOclear, LLC
Endoco, Inc. dba Ultimate Dental
Endodent, Inc.
Endologix, Inc.
Endoscopic Technologies, Inc. dba Estech
Endothelix
EndoVantage LLC
Endure Industries
Engage UNI, LLC
Engineered Medical Systems
Engineered Tissue Solutions (ETS)
Enhancement Medical, LLC
Enlightenvue, Inc.
Enochs Manufacturing, Inc.
Enpath Medical, Inc.
Lead Technologies Div.
ENT Innovations
Cytophil, Inc.
Entellus Medical
Enterprise Systems, Inc.
Entopsis LLC
Entrotech Life Sciences Inc.
Enzyme Industries, Inc.
EpiEP, Inc.
Epimed International, Inc.
EPIX Orthopaedics Inc.
Epsimed LLC
Equipmed USA LLC
Erie Scientific International
Barnstead International
ESI, Inc.
Essential Dental Systems, Inc.
Essential Medical, Inc.
Ethicon Inc. and Ethicon Endo
Ethox Corporation
EUSA Global LLC
ev3 Inc.
E-Vac, Inc.
eVent Medical Ltd.
Evergreen Orthopedic Research Lab LLC
dba Operativ
Evergreen Scientific, Inc.

Registered Labelers

Evolution Spine, LLC

Evoqua Water Technologies, LLC

Exactech Inc.

Exami-Gowns, Inc.

ExoToe LLC

Express Diagnostics International, Inc.

Exsomed Corporation

Extremity Medical LLC

Eyekon Medical, Inc.

Eyenez LLC

E-Z-EM, Inc.

EZ Medical Supply LLP

FareTec, Inc.

Fenem, Inc.

FFM Med Reps, LLC
Excel Medical Products, LLC

FiberOptic Bulbs, Inc.

Fiberoptic Components, LLC

Fibralign Corp.

Fidia Pharma USA Inc.

Fine Surgical Instruments, Inc.

Fisher Healthcare/Curtin Matheson Scient.
Pacific Hemostasis

Fisher Scientific
Chemical Mfg. Division
Diagnostics Division
Instrument Mfg. Division

Five Star Orthodontic Lab & Supply

Fixes 4 Kids, Inc.

FKS Health and Life Medical Care Inc

Flashback Technologies Inc

Florida Medical Industries, Inc.

FloSpine, LLC.

Flow-FX, LLC

Flowmedica, Inc.

Forbes Rehab Services, Inc.

Forestadent USA, INC

Forest Medical, LLC

Foxhollow Technologies, Inc.

FreeHold Surgical, Inc.

Fresca Medical, Inc.

Fresenius Kabi
Fenwal, Inc.

Fresenius Pharma
Fresenius AG

Fricke International Inc

Frontier Medical Devices, Inc.

Frye Electronics, Inc.

FTT Medical, Inc.

Fujifilm
Fujifilm Electronic Materials USA, Inc.

Fujisawa USA, Inc.

Fuller Laboratories

Fusion Dental Implants LLC

Fusion Medical Technologies, Inc.

Fusion Orthopedics, LLC

Future Health Concepts, Inc.

Galileo Corporation
Leisegang Medical, Inc.

Galt Medical Corp.
Theragenics

Gambro Co.

Gamma Biologicals, Inc.
Division of Imucore

Gammex Inc.

Garreco, LLC

Gateway Medical, Inc.

Gaymar Industries, Inc.
Medisearch PR, Inc.

Gaymar Industries, Inc.

GC Corporation
GC America, Inc.

GC Orthodontics America

GE Healthcare

Geisinger Foundation
Geisinger System Services

Gelman Sciences, Inc.

Gendex Corporation
Gendex Dental X-Ray
Gendex Europe
Midwest Dental Products
Universal X-Ray

General Glassblowing Co., Inc.

Generic Medical Devices

Genesee BioMedical, Inc.

Genesys Spine

Genetic Laboratories Wound Care, Inc.
Derma Services

Genetics Systems Corp.

Genii, Inc.

Gentex Pharma

Genus Medical Technologies, LLC

Genzyme Corporation

George Medical, LLC

George Taub Products

George Tiemann & Company

Gergens Orthodontic Lab

Gergens Sleep Lab

Gesiva Medical, LLC

G-F Health Products, Inc.

GFC Bridgeview, Inc.
Derma Care Div.

Ghost Mfg. LLC

GI Dynamics Inc.

Gibbons Surgical Corporation

Gillette
Oral-B Laboratories

Gimbel Glove Company, LLC
Gimbel Medical Glove Company, LLC

Glasir Medical, LP

GlasSpan

Glaukos Corporation

Global Biomedical Technologies, LLC

Global Dental Science LLC

Global Diabetic Distributors Inc.

Global Health Solutions

Global Manufacturing Industries, LLC

GlobalMedia Group, LLC dba GlobalMed

Global Medical Products, Inc.
dba Tava Surgical Instruments

GlobalMed Technologies

Globe Enterprises, Inc.

Gobiquity, Inc.

Golden Brothers, Inc.

Gold Standard Diagnostics

Gold Standard Orthopaedics, LLC

Good-Lite Co.

Good Samaritan Hospital
Legacy Health System

Goosen Enterprises, Inc.

GRA Medica

Graham-Field
Everest and Jennings

Gramercy Extremity Orthopedics

Grande Ronde Hospital

Graphic Controls Corporation

Great Basin Scientific

Great Lakes Orthodontics, Ltd.

Greenville Hospital System

Grieshaber Mfg. Co., Inc.

gSource, LLC

G Surgical LLC

GTI Diagnostics

G.T. Laboratories, Inc

Guardian Angel Products, Inc.

Guidant Corporation
Cardiac Rhythm Management
Guidant CVS

Registered Labelers

Vascular Intervention
Guided Therapeutics Inc.
Gulden Opthalmics Inc.
GWR Medical, Inc.
Gynecare, Inc.
Gynex Corporation
Gyrus Ent
Gyrus Medical
Gyrx, LLC
Endox LLC
H & O Inc.
H W Andersen Products, Inc.
Hager & Werken
Hager Worldwide
Hamamatsu Corp.
Photonics Management Corp.
Hankook Latex Gongup Co. Ltd.
Calatex Inc.
Hantel Technologies, Inc.
Hanson Medical, Inc.
Harbor Medical Devices, Inc.
Harbor Safety Products Group LLC.
Hard Mfg. Co.
Hardwood Products Co.
Harry J. Bosworth Co.
Harvest Dental Products LLC
Harvest Technologies
Havel's, Inc.
Hawaii Medical, LLC
Hayes Handpiece Co.
Health Care Logistics, Inc.
Health Dent'l, LLC
Health Services Corp. of America
Healthcare Materials Network
Healthcare Products Plus
Healthlink, Inc.
Healthmark Industries Co.
Health-Mor Industries, Inc.
Health-Mor Personal Care Corp.
HealthMyne, Inc.
HealthyWiser LLC
Heart Imaging Technologies, LLC
Heart Technology, Inc.
Heart Ware, Inc.
Hearten Medical, Inc.
Heartport
HeartVista, Inc.
Hedwin Corp.
Helena Laboratories, Inc.
Hemedex, Inc.
Hemostasis LLC
Henry Schein, Inc.
Henry Troemner, Inc.
Heraeus Kulzer, Inc.
Dental Products Group
Heuer Time & Electronics Corp.
Hexim Pharmaceuticals Inc.
Higi Sh LLC
Hill-Rom, Inc.
Medic PRN
HK Surgical, Inc.
Hobbs Medical, Inc.
Home Access Health Corporation
Hospira, Inc.
Hospital Mktg. Services Co., Inc.
Hotspur Technologies, Inc.
Howard Medical Company
Howard Young Medical Center
Hudson Respiratory Care, Inc.
Hu-Friedy Mfg. Company
Hu-Friedy Mader Medical
Human Motion and Control
Huntleigh Technology, Inc.
Huntleigh Healthcare, Inc.
Huot Instruments, LLC
HWI
Hycor Biomedical Inc
Hydrocision Inc
Hydrotech Enterprises
Hy-Tape International
Iconacy Orthopedic Implants, LLC
Iconlab, Inc.
ICP, Inc. dba Dental City
ICP Medical
ICU Medical, Inc.
Ideal Implant Incorporated
IDEV Technologies, Inc.
IEC - Innovative Endoscopy Components, LLC
IlluminOss Medical Inc.
Imaging Biometrics, LLC
Imagyn Medical Tech
Imbed BioScience, Inc.
Immuno Concepts
Immuno-Biological Laboratories Inc
Impact Products
ImpediMed Limited
ImpediMed Inc.
Imperative Care Inc
Imperial Medical Technologies, Inc.
Impeto Medical, Inc.
Implant Innovations, Inc.
Implant Logistics, Inc.
Implantech Associates, Inc.
InBios International Inc.
Incisive Surgical, Inc.
Incite Innovation, LLC
Independent Medical Co-op (IMCO)
Ind. for the Blind and Visually Impaired
Indian Wells Medical, Inc.
InfoBionic Inc
Infraredx, Inc.
InFront Medical LLC
Infusive Technologies, LLC
Ingen Orthopedics, LLC
Innara Health (formerly KC BioMedix)
Inneroptic Technology, Inc.
Innerspace Corp.
InNeuroCo, Inc.
InnoMed Technologies
Innovasis, Inc.
Innovasive Devices, Inc.
Innovasive Inc.
Innovative Healthcare Corporation
Innovative Neurotronics, Inc.
Hanger Orthopedic Group, Inc.
Innovative Surgical Designs
Innovative Therapies, Inc.
Inova Diagnostics, Inc.
Inova Labs
Inovise Medical, Inc.
INRAD, Inc.
Insert Molding Solutions Inc.
Inspirstar Inc.
Instrumentation Industries Inc.
Integra Lifesciences Corporation
Integra Luxtec, Inc.
Integra Life Sciences
Integra Pain Management
Integra Radionics
Integrated Biomedical Technology
Integrated Dental Systems
Integrated Medical Technologies, Inc.

Registered Labelers

CPAC Equipment, Inc.
Integrity Life Sciences, LLC
Interflo Medical
International Biophysics Corp.
International Business Solutions Alliance
International Equipment Company
International Hospital Products, Inc.
International Medical Development
International Medical Devices, Inc.
International Medical Distributors, Inc.
International Medical Industries, Inc.
International Medical Research & Design
International Win, Ltd.
Interpore Cross International
Interpore Orthopaedics, Inc.
Intersect ENT
Intersect Partners LLC
Intra-Lock International, Inc.
Intraluminal Therapeutics
Intra-Sonix, Inc.
Intrinsic Interventions Inc.
Intrinsic Therapeutics, Inc.
Intuitive Imaging Informatics, LLC
Intuitive Surgical, Inc.
Invitro Systems, Inc.
Invotec International, Inc.
Invuity, Inc.
I Play., Inc.
IQ Implants Ltd.
IT3 Medical, LLC
Irrimax Corporation
Irvine Biomedical, Inc.
IsoAid, LLC
Isolyser Company, Inc.
IsoRay Medical, Inc.
Ivera Medical
Ivoclar Vivadent, Inc.
Ivy Sports Medicine, LLC
J & R Enterprises, Inc.
Jac-Cell USA Inc.
Jaece Industries, Inc.
James River, Inc.
Health Care Division
James W Daly, Inc.
Japan Medical Dynamic Marketing, Inc.
Ortho Development Corp.
Jason Marketing Company
JBC & Company (Elite Syndication Incorporated)
JBC Corp.
Jedmed Instrument Company
Jensen Tools, Inc.
Jeremiah Sales Professional Inc.
Jewel Preceision Sheet Metal & Machining, Inc.
Johnson & Johnson
Advanced Sterilization Products
Codman & Shurtleff, Inc.
Cordis Biot Div.
Cordis Miami Div.
Cordis Roden Div.
DePuy Acromed
DePuy Mitek
Independence Technology
J&J Dental Care
J&J Hospital Services
J&J Consumer Products Co.
J&J Medical, Inc.
J&J Medical (China) Ltd
J&J Professional, Inc.
Janssen Pharmaceutical, Inc.
Lifescan, Inc.
McNeil Pharmaceutical Canada
OMJ Pharmaceuticals, Inc.
Ortho Clinical Diagnostics
Ortho-McNeil Pharma. Corp.
Sarl
Therakos
Jordco, Inc.
JS Dental Manufacturing, Inc.
Justrite Manufacturing Company
K2M, Inc.
K5 Brands, LLC
Kaia Health Inc
Kalitec Direct, LLC
Kapp Surgical Instrument, Inc.
Kareco International, Inc.
Katena Products, Inc.
Kator LLC
KC Biomedix
K-C Medical, Inc.
KCI New Technologies, Inc.
Kinetic Concepts, Inc.
Keller Medical Specialties, Inc.
Kenad SG Medical, Inc.
Kendro Laboratory Products
Kennedy Memorial Hospitals
Kensey Nash Corporation
(dba - DSM BioMedical)
Kent Laboratories Inc.
Keos
Kerberos Proximal Solutions, Inc.
Kerr Corporation
Alden
Key Electronics
Keystone Industries
Mizzy, Inc.
Keystone Manufacturing
Kids Med Inc.
Kimberly Clark Corp.
Health Care Products Group
Kinamed, Inc.
Kinetic Concepts, Inc.
King Pharmaceuticals, Inc.
Kips Bay Medical, Inc.
Kirschner Medical Corp.
K-Laser USA LLC
Kleen Test Products
KMedic
Knoll Pharmaceutical Co.
Koehler Instrument Co., Inc.
Korr Medical Technologies Inc
Kronus, Inc.
KUB Technologies Inc.
Kyowa Kirin Inc
Kyphon, Inc.
L&R Mfg. Company
Lab Depot, LLC
Labconco Corporation
Lab-Line Instruments, Inc.
Laborie Medical Technologies
Lacrimedics, Inc.
Lafayette Pharma., Inc.
Lake Hospital Systems, Inc.
Lake Region Mfg., Inc.
Lakeside Mfg., Inc.
Lamico, Inc.
Lang Dental Mfg. Co., Inc.
Lares Research
Laschal Surgical
Latexx Partners Berhad
Medtexx Partners, Inc.
Lazarus Medical, LLC
LC Medical Concepts, Inc.
LD Technology LLC
LED Intellectual Properties LLC
LED Technologies, Inc.
Lee Memorial Hospital
Leeder Group, Inc.

Registered Labelers

Legend Spine LLC

Leggero LLC

Leica
Optical Products Division

Leomed, LLC

LGM International, Inc.

Liberty Medical, Inc.

Lifecell Corporation

Life Corporation

Life Instrument Corp.

Life Science Outsourcing, Inc.

Lifesignals, Inc

LifeSouth Community Blood Centers, Inc.

Lifestream International, Inc.

Lifestream Purification Systems

Life-Tech, Inc.

LifeVac LLC

Liger Medical LLC

Light Age, Inc.

Lighthouse for the Blind

Lilli Pads Inc

Linvatec
Hall Surgical

Lin-Zhi International, Inc.

Laboratory Corporation of America

Little Rapids Corporation

Lohmann GmbH & Co.
Carapace, Inc.

Loma Vista Medical

Lone Star Medical Products, Inc.

Lone Star Technologies

Loon Medical, Inc.

Lorrex Health Products

Louisville APL Diagnostics, Inc.

Louisville Pharmacy

LSI Solutions Inc.

Lucas Medical Inc.

Luitpold Pharmaceuticals, Inc.

Lumend, Inc.

Lumiquick Diagnostics, Inc.

Lumitex Medical Devices, Inc.
Surgical Division

Lutech Industries, Inc.

Luwi, LLC

LYMOL Medical Corp.

LZR7 Inc

M2S, Inc.

Maclin Power Inc.

MAC Medical Inc.

Maersk Medical, Inc.

Magellan Biosciences
Dynex Technologies
ESA Biosciences

Magnatone Hearing Aid Corp.

Mako Surgical Corp.

Mallinckrodt Baker, Inc.
Mallinckrodt Chemical
Mallinckrodt Anesthesia Products
Mallinckrodt Anesthesiology
Mallinckrodt Diag. Products Div.
Mallinckrodt Medical, Inc.

ManaMed

Mann Chemical Corp.

Maramed Orthopedic Systems

Marie Reiko Inc.

Mark Clark

Maryland Plastics, Inc.

Masimo Corporation

Mason Tayler Med. Products Corp.

Masterlink

Math Resolutions

Matrx Medical, Inc.

Matrix Surgical Holdings, LLC

MaxiFlex LLC

Max Mobility, LLC

Maxtown Medical Corp. LLC

Maxxim Medical
Containment Products
Medical Diagnostics
Medical Nonwovens & Gloves
Sterile Trays/ Non-sterile Kit

Maveron Health

Maytex Corporation

MC10, Inc.

McGinley Orthopaedic Innovations LLC

MCM Environmental Technologies Ltd
GMS Marketing

MD Industries, Inc.

MD Technologies Inc.

Measurement Specialties, Inc.

Medcanica, Inc.

Medegen, Inc.

Medegen Medical Products

Medela Healthcare

Medennium, Inc.
Eyepx LLC

Medental International Inc

Mederi Therapeutics Inc.

Medex, Inc.
Medex Medical Mktg.

Med-Fit Systems, Inc.

Medge Platforms, Inc.

Mediaid Inc.

Medgyn Products, Inc.

Mediblu Medical LLC

Medica Holdings, LLC

Medical Action Industries, Inc.

Medical Chemical Corporation

Medical Concepts Dev., Inc.

Medical Designs LLC

Medical Device Technologies, Inc.
Angiotech Pharmaceuticals, Inc.

Medical Devices International
MDI Plasco, Inc.

Medical Facets NC, LLC

Medical Graphics Corporation

Medical Illumination Int'l., Inc.

Medical Imaging Applications, LLC

Medical Informatics Corp

Medical Infusion Technology

Medical Instrument Dev. Labs, Inc.

Medical Inventors Corporation. Inc.

Medical Laboratory Automation, Inc.

Medical Latex Corp.

Medical Products Laboratories, Inc.

Medical Resources Int'l.
BNT Co., Inc.

Medical Solutions International, Inc.

Medical Technology Products Inc.

Medication Delivery Devices

Medichoice (Owens & Minor)

Mediflex, Division of Flexbar Machine Corp.

Medifocus, Inc.

Medigroup Inc. / Janin Group

Medipoint, Inc.

Medisono LLC

Meditech International Corp.

Meditech Spine, LLC

Medivance, Inc.

Medivest, Inc.

Medline Industries, Inc.

Medlogic

Mednium Corporation

Medovex Corporation

Medrad, Inc.

Registered Labelers

Medscience Research Group, Inc

MedShape, Inc.

Medstreaming

Medtek Devices, Inc.
- Buffalo Filter

MedTek Skin Care Inc

MedTrak VNG, Inc.

Medtrex Incorporated

Medtronic, Inc.
- Biotek International SPA
- Blood Systems
- Cardiopulmonary
- Cardiorhythm
- CAS Venture
- DLP
- Drug Administration Systems
- Interstim Venture
- Interventional Vascular Inc
- Medtronic Bio Medicus
- Medtronic, Inc (CPRA)
- Merocel Scientific Division
- Neurological Division
- Pacing Business Unit
- Physio-Control Corp.
- Vascular Division
- Vitatron, Inc.
- Xomed

Mentor Corp.

Mercator MedSystems, Inc.

Merck-Medco Managed Care, Inc.
- SysteMed

Mercy Healthcare System

Merge Healthcare

Meridian Health Systems P.C.
- InterCare DX, Inc.

Meridian Medical Systems

Meridian Technique Ltd.

Merit Medical Systems

Merz Aesthetics, Inc.

Mesa Biotech, Inc.

Mesa Laboratories, Inc.

Methodist Hospital of Indiana, Inc.

Methodist Hospitals of Memphis

Metrex Research Corporation

Metric Medical Devices, Inc.

Mettler Toledo

MHC Medical Products, LLC

Micro Motors, Inc.

Microaire Surgical Instruments

Micromed Technology, Inc.

Micromedical Technologies, Inc.

Micromedics

MicroPhage, Inc.

MicroPort Orthopedics, Inc.

Micro-Scientific Industries, Inc.

Microtherapeutics, Inc.

Microvention, Inc.

Microvision, Inc.

Micrus Corporation

Midwest Textiles, Inc.

Migun Life, Inc.

Millennium Biomedical, Inc.

Millennium Dental Technologies, Inc.

Millennium Surgical

Miltex, Inc.

Milton Roy Company
- Analytical Product Division

Mimedx Group, Inc.

Mindframe, Inc.

Mindways Software, Inc.

Minnesota Resuscitation Solutions LLC
dba Advanced CPR Solutions

Minnow Medical, Inc.

Minrad, Inc.

Mirecal, LLC
- Remicalm, LLC

Misonix, Inc.

Mitre Medical Cop Corp

MIVI Nueroscience, Inc.

Mizuho OSI, Inc.

MM Herman & Associates, LLC
- Flu Armour
- Herman Products

MMS, LLC

Moberg Research, Inc.

Mobius Therapeutics, LLC

Modal Manufacturing, LLC

Modec, Inc.

Molded Products

Molded Products, Inc.

MolecularMD Corp

Molecular Biometrics, Inc.

Momelan Technologies, Inc.

Monarch Labs

Moore Business Forms, Inc.

Mortan, Inc.

Mortara Instrument, Inc.

Motloid/Yates & Bird
- Bird-X, Inc.

Moximed, Inc.

M-Pact Worldwide, LLC

MPL Technologies

MPS Acacia

MPS Medical, Inc.

MRIaudio Inc

MRLB International, Inc.

MTI Precision Products

Musculoskeletal Transplant Foundation

My-Cardia (USA) Inc

MyCardio LLC

Myco Medical

Myelotec, Inc.

Mynosys Cellular Devices

Myotronics Noromed Inc.

Myocardial Solutions

MytaMed, Inc.

Nanogen, Inc.

Nanoscale Materials, Inc.

Nanosphere, Inc.

Nashville Surgical Instruments

Nasiff Associates, Inc.

National Distribution and Contracting

National Medical Products, Inc.

National Standard Company
- Medical Products Division

Natus Medical, Inc.

Nellix, Inc.

Neocare

NeoChord Inc.

Neodevices, Inc.

Neo Medical Inc.

Neotract, Inc.

Nephros Inc.

Neptune Products, Inc.

Netech Corporation

Neucoll

Neuhaus Laboratories, Inc.

NeuroChaos Solutions, Inc.

Neuro-Fitness LLC

Neuro Kinetics Inc.

Neurolumen LLC

Neuronetrix Solutions, LLC

NeurOptics, Inc.

Neurorecovery, Inc.

Neurotron Medical Inc.

Neurovasx, Inc.

Neurovision Medical Products, Inc.

Registered Labelers

Nevro
New Wave Surgical Corp.
Newby/Coombs, LLC
Newell Rubbermaid, Inc.
Rubbermaid Commercial Products, LLC
Newman Medical
Newtex Industries, Inc.
Nexcore Technology
Nextremity Solutions, LLC
Next Science, LLC
Nexus CMF, LLC
Nexus Medical, LLC
Nexus Spine
Niche Medical
Ni-Med, Inc.
Nivo Industries Inc.
Nmt Medical, Inc.
Nobles Medical Technology II
Nordent Manufacturing Inc.
Norfolk Medical Products, Inc.
Norma Tec, Inc.
North Coast Medi-Tek ,Inc.
Northeast Monitoring, Inc.
Northeast Scientific, Inc.
Norvell, LLC
Body Invest, LLC
Novarad Corporation
Novomedics, LLC
NovoSci
Novoste Corporation
Nucryo, Inc.
Numed, Inc.
Numia Medical Technology, LLC
Nu Radiance, Inc.
Nurse Assist, Inc.
Nutek Orthopaedics, Inc.
Nutriseal
Nxstage Medical, Inc.
Oasis Medical
OBP Corporation
OCO Biomedical, Inc.
OcuJect, LLC
Oculus Surgical, Inc.
Ohaus Scale Corporation
Olson Medical Sales, Inc.
Olympus Biotech Corporation
Omega Medical Products Corp.
Omega Surgical Instruments, Inc.
OMNA
Omni International, LLC
Omni-Flow, Inc.
Omnisonics Medical Technologies
Omni-Tract Surgical
Integra Life Sciences
OMT LLC
One Cell Systems, Inc.
Ongoing Care Solutions
Onkos Surgical
Opa Dental, LLC
Open Implants, LLC
OphthalMed LLC
Ophthalmic Innovations International, Inc.
Opthalmic Solution Inc.
Optical Integrity Inc.
Optical Radiation Corp.
Opticon Medical
Optimedica Corporation
Optimotion Implants, LLC
Opus Medical, Inc.
Ora Innovations, Inc.
Orbus Medical Technologies, Inc.
Origen Biomedical
Ortho Solutions, LC - Dynaflex
Ortho-Tain, Inc.
Ortho Technology
OrthoCircle
Orthofix Inc.
OrthoMedFlex LLC
Orthomerica Products, Inc.
Orthopaedic Implant Company
OrthoPediatrics Corp.
Orthopedic Designs North America, Inc.
OrthoScan, Inc.
Oscor Inc.
Osprey Medical Inc.
Osseolink USA LLC
Osseon LLC
Osseon Therapeautics Inc.
Osseus Fusion Systems, LLC
Osteogenics Biomedical, Inc.
OsteoReady LLC
Ostex International, Inc.
Ostial Corporation
Ostial Solutions, LLC
OT Medical, LLC
Otoharmonics Corporation
Ototronix, LLC
Owens-Illinois, Inc.
Owens Brigam
Owens-Illinois Health Care Group
Pacira Pharmaceuticals, Inc.
Packaging Services Corp. of Kentucky
Olsen Medical
Pall Corp
Pall Biomedical Products Co.
Palmero Health Care
Palm Springs Partners, LLC dba Maxim Surgical
Palo Alto Health Sciences
Pantheon Spinal LLC
Panther Orthopedics Inc
Paragon Vision Sciences, Inc.
Parascript, LLC
Parcus Medical, LLC
Pare Surgical, Inc.
Park Dental Research Corp.
Parkell, Inc.
Parker Hannifin Corp.
Parker Medical Associates
Parts Warehouse
ParvoMedics Inc
Pascal Company, Inc.
Patient Pocket LLC
Patterson Dental Company
Patton Surgical Corporation
PAVmed Inc.
PDI/Professional Disposables Int'l.
Pearson Dental Supply Co.
Peerbridge Health, Inc
Peerless International, Inc.
Pelikan Technologies, Inc.
Pemco Inc.
Pennsylvania Engineering Company
Pentair Filtration Solutions LLC
Engineered Filtration
Penumbra, Inc.
Percutaneous Systems, Inc.
Perfecseal
Medi-Plus
Perigon Medical Distribution Group
PerioEndoscopy LLC dba OraVu
Peripheral Visions, Inc.

Registered Labelers

PerMedics, Inc.

Pfizer Hospital Products Group, Inc.
American Medical Systems, Inc.
Schneider (USA)
Shiley, Inc.
Valleylab, Inc.

Pfizer Warner Lambert Co.
Parke-Davis Division

Phalanx Innovations LLC

Pharmacia, Inc.

Pharmacia Ophthalmics

Pharma-Plast, Inc.
Pharma-Plast Denmark
Pharma-Plast USA

Phase One Medical

Philips Medical Systems

Phoenix Dental, Inc.

Pilling Weck
Weck Closure Systems

Pinnacle Products, Inc.

Pintler Medical, LLC

Pioneer Surgical Technology

Plasdent Corporation

Plastek Industries, Inc.

Plasti-Products, Inc.

Pluromed, Inc.

Poly Vac

Polytechnic Resources, Inc.

Pope Scientific, Inc.

Porex Technologies Corp. of Georgia
Porex Surgical, Inc.

Porton Diagnostics, Inc.
Porton International PLC

Posey Company

Post Medical, Inc.

Pouch Support Systems, Inc.

Power Medical Interventions, Inc.

pNeo LLC

Practicewares Dental Supply

Precision Dynamics Corp.

Precision Laboratory Plastics, Inc.

Precision Scientific, Inc.

Precision Systems, Inc.

Precision Vascular Systems

Premier Biotech Inc.

Premier Dental Products Company

Premier Heart, LLC

Premium Plastics, Inc.

Presby Corporation

Prescient Logistics, LLC

Preventive Technologies

Prevent-Plus LLC

Primotec LLC

Principle Business Enterprises

Priority Environmental Solutions Inc. dba PRO1TEK

Prismatik Dentalcraft, Inc.

Prism Clinical Imaging, Inc.

Procedure Products, Inc.

Procept Biorobotics Corporation

Professional Hospital Supply, Inc.

Professional Medical Products

Professional Products, Inc.
Government Sales Division

Prograft Medical, Inc.

Progressive Dynamics, Inc.

Proma, Inc.

Promex Technologies, LLC

Propper Manufacturing Co., Inc.

ProTech Professional Products, Inc.

Protect U Guard, LLC

Protekmed, LLC

Providence Medical Technology, Inc.

PSC of Kentucky
Olsen Medical

PSS World Medical
Gulf South Medical Supply

PT Eka Wira Asia

Puerto Rico Hospital Supply, Inc.

Pulmonetic Systems, Inc.
Viasys Healthcare, Inc.

Pulmonx, Inc.

Pulpdent Corporation

Pulse Biosciences

Pure Life Solutions

PureLife LLC

PureWay Compliance, Inc.

Puritan-Bennett Corporation
Bennett Group
Boston Division
Cyrogenic Equipment Division
Ireland, Ltd.
Medicomp, Inc.
Oxygen Concentrator Division
Portable Ventilator Division
Puritan Group

Pursuit Vascular, Inc.

Pymah Corp.
ATI Division

QBC Diagnostics

QI Imaging, LLC

Qorpak

QRS Diagnostic, LLC

Quality Assembly & Logistics LLC

Quantimetrix Corporation

Quantum BioEngineering, Ltd.

Quintus, Inc.

QView Medical, Inc.

R Medical Supply Inc.

R-Med, Inc.

R2 Dermatology

R4 Vascular, Inc.

Radius, LLC

Radius Medical Technologies, Inc.

Radtech, Inc.

RAMM Technologies LLC

RAMVAC Dental Products, Inc.

Ramsey Diagnostics Corp

Ranfac Corporation

Rapid Reboot Recovery Products

RD Medical Manufacturing, Inc.

Reckitt & Colman, Inc.
R & C Probrands

Recovery Force

Relda LLC dba Dermatec Direct

Red Bird Service
Ricca Chemical Company, LLC

Redicare LLC

Reed Technology & Information Svcs, Inc.

Reflow Medical Inc.

ReGear Life Sciences, LLC

Regenerative Processing Plant, LLC

Regent Hospital Products, Ltd.
London International Group PLC

Reliance Mobility LLC

Reliance Orthodontic Products, Inc.

Remicalm, LLC

Renovis Surgical Technologies, Inc.

ReNovo, Inc.

Renovo Life LLC

Reproductive Solutions, Inc

Republic Spine, LLC

Reshape Lifesciences

ReShape Medical Incorporated

Respironics, Inc.

Restorative Therapies, Inc.

Restore Medical, Inc.

Registered Labelers

Rex Implants LLC
Rex Medical LP
Rhausler, Inc.
Rhythmlink International, LLC
Ribbond, Inc.
Ricca Chemical Company, LLC
Richard-Allan Medical Industries
Image & Medical Technologies
Rinn Corp.
Rivanna Medical
Riverain Technologies
Riverside Community Hospital
RJL Systems
Roche Diagnostic Systems
Rox Medical, Inc.
Roxane Laboratories, Inc.
Roxwood Medical, Inc.
Royal Biologics
Royce Medical
Roydent
Rumex International Co.
S.A. Instrumentation Difra
SAC LLC
Orange Surgical Instruments
Sacred Heart Medical, Inc.
Sadra Medical Corporation
Safco Dental Supply Co.
Safety Medical International, Inc.
Saf-T-Med
Sage Products, Inc.
Saint Gobian Performance Plastics
Sakura Finetek USA, Inc.
Salient Imaging, Inc.
Samco Scientific, Inc.
Sandhill Scientific
Sanovas, Inc.
Santa Barbara Imaging Systems
Saphena Medical
Savannah River Mills, Inc.
SBW Medical Products, Inc.
Scandius Biomedical, Inc.
Schleicher & Schuell, Inc.
Schwarz Pharma
Kremers Urban Co
Science, Inc.
Scientia LLC
Scientific Equipment Products Co.
Scientific Pharmaceuticals
Scientific Safety Solvents
Scieran Technologies, Inc.
Scigen Scientific
Scion Cardio-Vascular, Inc.
Scitech Dental, Inc.
Scivolutions, Inc.
Scott's Dental Supply
SDI Diagnostics, Inc.
Seamless Hospital Products Co.
Sea Spine, Inc.
SeaSpine Orthopedics Corporation
IsoTis Orthobiologics, Inc.
Second Sight Medical Products, Inc.
Secqure Surical Corporation
Securisyn Medical, LLC
Semler Technologies, Inc.
Sempermed USA, Inc.
Senorx, Inc.
Sentreheart, Inc.
Septodont, Inc.
Seradyn, Inc.
Fisher Scientific International
Serene Medical Inc
Serim Research Corporation
Shamrock Scientific Specialty Systems
Shape Medical System
Sharklids Eye Gear
Sharn Anesthesia
Sharon Metal Stamping Corp.
Walk on Air
Sharp Fluidics, LLC
Sharps Terminator, LLC
Sheldon Manufacturing, Inc.
Shepard Medical Products
Sherwood Pharmaceutical Co.
Shockwave Medical Inc.
Shoulder Innovations
Si Bone, Inc.
Sicage, LLC
Sicor, Inc.
Gensia Pharmaceuticals, Inc.
Sienco, Inc.
Sigma Rx LP
Sigma Supply & Distribution, Inc.
Signal Medical Corporation
Silicon Valley Medical Instruments, Inc.
Silex Medical, LLC
Simpact, LLC
Simpex Medical
SinuSys Corporation
SiO2 Nanotech, LLC
Siris Medical, Inc.
Sirona Dental, Inc.
Skedco, Inc.
SkinStitch Corp.
Sklar Corporation
Slater Endoscopy, LLC
Smart Medical Technology, Inc.
SmartPractice, Inc.
Smartcare
Smartpill Corporation
Smith & Nephew
Endoscopy Division
Orthopaedic Division
Orthopaedics AG (Switzerland)
Orthopaedics Co., Ltd (Beijing)
Orthopaedics GmbH (Germany)
Orthopaedics, Ltd.
United Wound Management Division
SMK Imaging LLC dba ImageWorks
SML - Space Maintainers Laboratories
SNAP Diagnostics LLC
Soberlink Healthcare LLC
Sodium Systems LLC
Sofregen Medical Inc
Solina Medical, Inc.
Solo-Dex LLC
Solutions Inc.
Somahlution LLC
Somatics, LLC
Somnetics International
Somnus Medical Technologies
Sonavex, Inc.
Sonic Innovations, Inc.
SonoCine Inc.
Sonotech, Inc.
Sontec Instruments, Inc.
Sony Corporation
Sorb Technology, Inc.
Sorin Biomedica
Cobe Cardiovascular UK
Sota Medical Products
Sorin Group,USA, Inc.
Sourceone Healthcare Technologies
South East Instruments Corporation

Registered Labelers

Southeast Signal, Inc

Southland Medican LLC

Spacelabs Medical, Inc.

Span-America Medical Systems, Inc.

Sparta Surgical Corporation
Sparta Maxillofacial Products, Inc.

Spartan Micro, Inc.

Spatz FGIA Inc

Spaulding Clinical Research
Spaulding Medical

Specialized Health Products

Specialty Appliance Works, Inc.

Specialty Health Products, Inc.

Specialty Surgical Instrumentation, Inc.

Specialty Surgical Products, Inc.

Specialty Water Technologies, Inc.

Spectra Medical Devices, Inc.

Sprectramed

Spectramed, Inc.

Spectranetics Corporation

Spectrum Designs Medical

Spectrum Designs Inc.

Spectrum International, Inc.

Spectrum Medical Industries, Inc.

Spinal Kinetics

SpinalMotion, Inc.

Spinal Resources Inc.

Spinal Simplicity, LLC

SpineCraft

SpineNet, LLC

Spineology Inc.

SpiralTech Superior Dental Implants

Spire Corporation
Spire Biomedical

Spyder Medical

SPR Therapeutics, LLC

SRI/Surgical Express, Inc.

Sroufe Healthcare Products
Remington Products

SRS Medical Systems, Inc.

SSCOR Inc.

SS White Burs, Inc.

St. Francis Regional Medical Center

St. Francis-St. George Hospital

St. George Technology, Inc.

St. Gobain Performance Plastic

St. Johns Mercy Medical Center

St. Jude Medical
Diagnostic Division, Inc.

St. Jude Medical CRMD

St. Peter Hospital

St. Vincent Hosp. & Hlth. Care Ctr.

Stabiliz Orthopaedics LLC

Staco Energy Products Company

Standard Register
Advanced Medical Systems

Starchem, Inc.

Starion Instruments

Starline Dealers Association

Statcorp, Inc.

Stellar Lasers, LLC

Stellen Medical, LLC

Step Forward Co.

Stereotaxis, Inc.

Steris Corporation
Amsco Canada - Ingram & Bell
Amsco Service Co. - Ingram & Bell

Stern Metals, Inc.
Sterngold

Stiehl Tech LLC

Stingray Surgical Products, LLC

Stinson Orthopedics Inc.

Storz-GmbH
American Cyanamid

Streck Laboratories, Inc.

Stradis Medical DBA Stradis Healthcare

Strata Skin Sciences, Inc.

Structure Probe, Inc.
SPI Supplies Division

Stryker Corporation
Dimso Division
Stryker Ascent
Stryker Endoscopy Division
Stryker Dental
Stryker Global Quality & Operations
Stryker Howmedica Osteonics
Stryker Instruments
Stryker Medical
Stryker Orthopaedics (Otis Med)
Stryker Osteo AG

SuitX

Sulzer Carbomedics

Sulzer Medica
Sulzer Intermedics USA

Summit Industries LLC

Summit Medical Center

Summit Spine LLC

Sun Capsule Inc.

Sun Medical Inc.

Sun Nuclear Corporation

Sun Scientific, Inc.

Sun-Med

Sunoptic Technologies

Sunquest Information Systems

Superdimension, Inc.

Superior Health Care Group, Inc.

Superior Surgical Products

SureTek Medical

Surgical Direct

Surgical Site Solutions, Inc.

Surgical Specialties Corporation

Surgical Warehouse, Inc.

Surgicot, Inc.
Value Medical Products, Inc.

Surgikor

Surgimedics, Inc.
Denver Biomedical, Inc.

Surgi-Pak, Inc. dba National Hospital Packaging

SurgiQuest, Inc.

Surx, Inc.

Sutura Inc.

Suture Concepts, Inc.

Svelte Medical Systems

Sweet Spot Diabetes Care

Sybron Chemicals
Clinical Technology Div.

Sybron Corp.
Analytical Products Div.
Barnstead Co.
Mediatech Div.
Panorama Plastics
Sybron Endo
Thermolyne Corp.

Sybron Corpnalge Nunc Int'l.
Apogent

Sybron Dental Specialties
Ormco

Symmetry Medical USA, Inc.

Synergetics USA, Inc.

SynergEyes, Inc.

Synergy Biomedical, LLC

SynGen, Inc.

Syntermed, Inc.

Synthasome, Inc.

Synthemed, Inc.

Syntheon, LLC
ID LLC

Synthes

Registered Labelers

Synthes Spine Company LP

Synthes USA
Maxillofacial Division

SZY Holdings, LLC
Ever Ready First Aid

T2 Biosystems, Inc.

T.C. Dental Products, Inc.

Talladium Inc.

Tandem Medical, Inc.

Tangible Science LLC

Tapmedic LLC

Taut, Inc.

Taylor Bio-Medical, Inc.

Tecator, Inc.

Techdevice Corporation

Technical Products, Inc.

TeDan Surgical Innovations, LLC

Tekia, Inc.

Teledyne Technologies, Inc.

Teleflex CT Devices, Inc.

Tele-made Disposables Inc

Tempur-Pedic North America, LLC

Tendyne Holdings Inc.

Tenet Health

TENSproducts, Inc

TeraRecon, Inc.

Terumo Medical Corp.
Terumo Europe N.V.

Tessek

TestSmarter

Thayer Intellectual Property, Inc.

The Alger Company, Inc.

The Anspach Effort, Inc.

The Argen Corporation

The Burrows Company

The Cheshire Medical Center

The Coopers Companies, Inc.
Cooper Surgical, Inc.

The Gerresheimer Group
Kimble Glass
Kontes Glass, Inc.

The GID Group, Inc.

The Hygenic Corp.

The Morel Company

The Procter & Gamble Company
Norwich Eaton Pharmaceuticals

The Standing Company

The Texwipe Company

The Torrent Corp.

The Upjohn Company
Upjohn Pharmaceuticals

Theradome Inc.

Theravant Corporation

Thermo Cardiosystems, Inc.

Thermo Fisher Scientific
Trek Diagnostics

Thermopeutix, Inc.

Thermoplastic Comfort Systems Inc.

ThermoTek, Inc.

Think Surgical, Inc.

Thomas Jefferson University

Thomas Scientific

Thompson Surg. Instruments, Inc.

Three Palm Software

Tian Medical LLC

TIDI Products

Tiger Supply Inc.

Timemed Labeling Systems

Timrex Corporation

Tissue Link Medical, Inc.

Titan Spine, LLC

Titus Medical, LLC.

Tivic Health Systems Inc

TMJ Solutions, Inc. dba TMJ Concepts

TOMY International, Inc.

Top Quality Manufacturing, Inc.

Top Spins, Inc.

Topcon Medical Laser Systems, Inc.

TPC Advanced Technology, Inc.

Trademark Medical LLC

Transamerica Delaval Med. Prod.

TransAmerican Medical Imaging dba of Canyon Ridge Resources, LLC

Transamerican Technologies International

Transdermal Cap Inc.

TransEnterix

Transgenomic, Inc.

Transmedics

Transtracheal Systems, Inc.

Transvascular Inc.

Transverse Medical Inc.

Tredegar, Inc.
Therics, Inc.

TreyMed, Inc.

Tri State Distribution, Inc.

Tri-Anim
eValueMed
Magnus

Tri-Anim Surgical Solutions

Tri-Ject International Corp.

Trimed, Inc.

Trimedyne, Inc.

Trimira LLC
Remicalm LLC

Trinity Medical Implants, Inc.

Trinity Sterile, Inc.

Trireme Medical, Inc.

Tri-Star Medical

TriVascular, Inc. (A Wholly Owned Subsidiary of Endologix, Inc.)

Trudell Marketing International
Northgate Technologies, Inc.

Truemed Group LLC

Turenne Pharmed Co.
Turenne & Associates LLC

Tyber Medical LLC

Tyco Healthcare
Tyco Healthcare Ludlow

Typenex Medical, LLC

UARCO, Inc.

UCLA Medical Center

Uhler Dental Supply, Inc.

Ultradent Products, Inc.

Ultralite Enterprises Inc.

Ultrasound Medical Devices, Inc. dba Epsilon Imaging, Inc.

Unetix Vascular Inc.

Unicare Biomedical, Inc.

Uniforms Manufacturing, Inc.

Unimed Surgical Products, Inc.

UniPak Medical Corporation

Unique Technologies, Inc.

United States Surgical Corp.
HTR Sciences
Surgical Dynamics
Tyco Healthcare

Universal Medical Inc.

Universal Meditech Inc.
University of California Med. Ctr.

University of Michigan Hospitals

UreSil LLC

Urologix, Inc.

USA Think Inc.

USGI Medical

US Endoscopy, Inc.

Registered Labelers

US Medical Innovations, LLC
US Medical Instruments, Inc.
US Spinal Technologies, LLC
Utah Medical Products, Inc.
V2K Medical, LLC
Vacalon Company, Inc.
Vadus, Inc.
Valeris Medical, LLC
Vahalla Scientific, Inc.
Vapotherm, Inc.
Vascular Designs, Inc.
Vascular Solutions
Vascular Technology
Vastek
Vastrac, LLC
Vector, Inc.
Velocity Medical Solutions
Venetec International
Ventec Life Systems
Ventrex, Inc.
Veratex
Veritas Medical Innovations
Versah LLC
Vertex Industries, Inc.
  Torbal Division
Vertis Neuroscience
Vertos Medical, Inc.
Vesocclude Medical, LLC
Vestibular Research & Development dba Balanceback
Vestibular Technologies, LLC
Vestil Manufacturing
  Innovation in Motion
Vevazz, LLC
VGI Medical LLC
VH Technologies Ltd.
Viasys Healthcare, Inc.
  Bird Products
  Medical Data Electronics
  Nicolet Biomedical
  Sensormedics Corp.
Vidamed, Inc.
Viewlight, LLC
Viking Systems, Inc.
ViOptix Inc.
Vios Medical, Inc
Viral Control Technology, Inc.
Vision Sciences, Inc.
Visionary Medical Supplies, Inc.
Visioneering Technologies, Inc.
Visitec Company
Vistalab Technologies
Vital Signs, Inc.
Vitronix, Inc.
VLV Associates, Inc.
Voland Corporation
Volcano Therapeutics, Inc.
Vomaris Innovations, Inc.
Vortex Surgical, LLC
Vorum Research Corporation
VQ Company, LLC
VuCOMP, Inc.
VWR International Co.
W A Baum Co., Inc.
W L Gore & Assoc., Inc.
Walk Vascular, LLC
Wallach Surgical Devices, Inc.
Water Pik, Inc.
Waters Medical Systems, LLC
WaveSense, Inc.
WAVi Co
Wayne Metal Products Inc.
Weck Surgical Systems
Welch Allyn
  Tycos Instruments, Inc.
Welch Allyn, Inc.
Welch Allyn Monitoring
Welcon, Inc.
Weldenz America Inc.
WellDoc, Inc.
Wells Johnson Company
Wellsky Corporation
West Pharmaceutical Services
Western systems Research Inc.
Wexler Surgical, Inc.
Whatman, Inc.
  Balston, Inc.
  Balston, Ltd.
  PCI Scientic Supply
  Whatman Far East PTE Ltd.
  Whatman Int'l. Ltd.
  Whatman K K
  Whatman Lab Sales
  Whatman Scientific, Ltd.
Wheaton Industries
Whip Mix Corporation
White Mountain Imaging
White Square Chemical, Inc.
Whitney Products, Inc.
  Ascent Medical Corp.
WilMarc Medical, LLC
Windstone Medical Packaging
Winprobe Corporation
WishBone Medical Inc.
Wolf X-Ray Corp.
  Flow Dental
  Flow X-Ray Corp.
Wolfe Tory Medical, Inc.
World Class Technology Corporation
Wright Medical Technology, Inc.
Wyant Healthcare
Wy'east Medical Corp.
Xanacare Technologies, LLC
XCR Diagnostics
Xemax Surgical Products, Inc.
Xenco Medical, LLC
Xhale Assurance, Inc.
X-Spine Systems, Inc.
YMed, Inc.
Young Dental Mfg. Company
Zassi Medical Evolutions
  Bowel Management System LLC
Zefon International
  Zefon Medical Products
Zeto Inc
Zevex International
ZIEN Medical Technologies
Zimmer, Inc.
  Zimmer Biologics
  Zimmer Dental
  Zimmer Orthopaedic Implant Div.
  Zimmer Orthopaedic Surgical Products
  Zimmer Spine
  Zimmer Tmt, Inc.
Zirc Dental Products, Inc.
ZYTO Technologies

HIBCC Clarification on LIC Fees

This statement is being released to respond to several inquires concerning the cost to acquire Labeler Identification Code (LIC) assignments for labeling and UDI Implementation.

HIBCC is the accredited Secretariat and ANSI-Standards Development Organization for the HIBC Supplier Labeling Standard. We are also the designated FDA Issuing Agency for LIC assignments for HIBC-based Unique Device Identifiers (UDIs). It is our responsibility to assure the integrity of assigned LICs and establish equity in the cost to acquire LIC assignments.

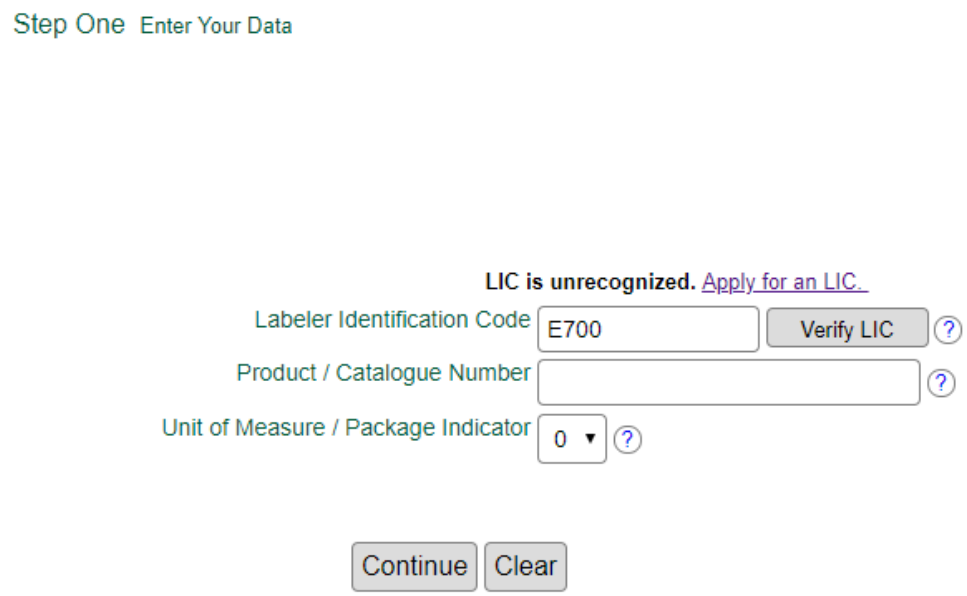
HIBCC reaffirms its long-standing position that labelers are not required to pay continuing fees to acquire and maintain their LIC assignments. When HIBCC developed our Supplier Labeling Standard (SLS) in 1984 we established a one-time fee basis for assignment of the required Labeler Identification Code (LIC), i.e., the company prefix in the HIBC primary data structure (and more recently in the FDA required UDI). We have never waivered from this position, which has been in place for over thirty years. Assigned LICs are permanent, never rescinded or reassigned, and globally deployable. Other than the initial one-time fee, LIC holders thereafter have no financial obligation to HIBCC.

Some HIBCC Labelers have previously registered for an LIC through HIBCC-affiliated organizations, and as a consequence may be paying recurring charges (or "dues"). This has led to some confusion. In order to assist those labelers, we are confirming that if they so choose they may elect to cease these payments and notify HIBCC so that we can update their contact information on our Global Labeler Database and continue to maintain their LIC on our registry. There is no charge associated with this update.

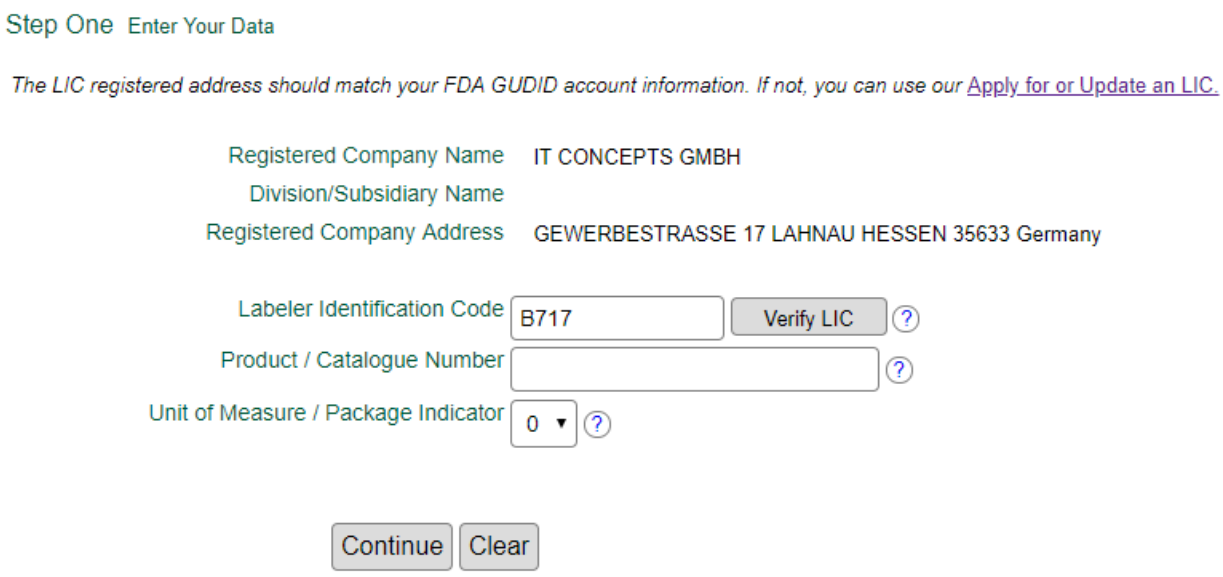
As has always been the case, any company seeking a new LIC that registers directly with HIBCC incurs no such recurring charges, regardless of the location of the applying company. The LIC assignment is global and there is no territorial exclusivity associated with the source of the assignment.

Health Industry Business Communications Council (HIBCC)
2525 E. Arizona Biltmore Circle #127
Phoenix, AZ 85016
(602) 381-1091 . info@hibcc.org

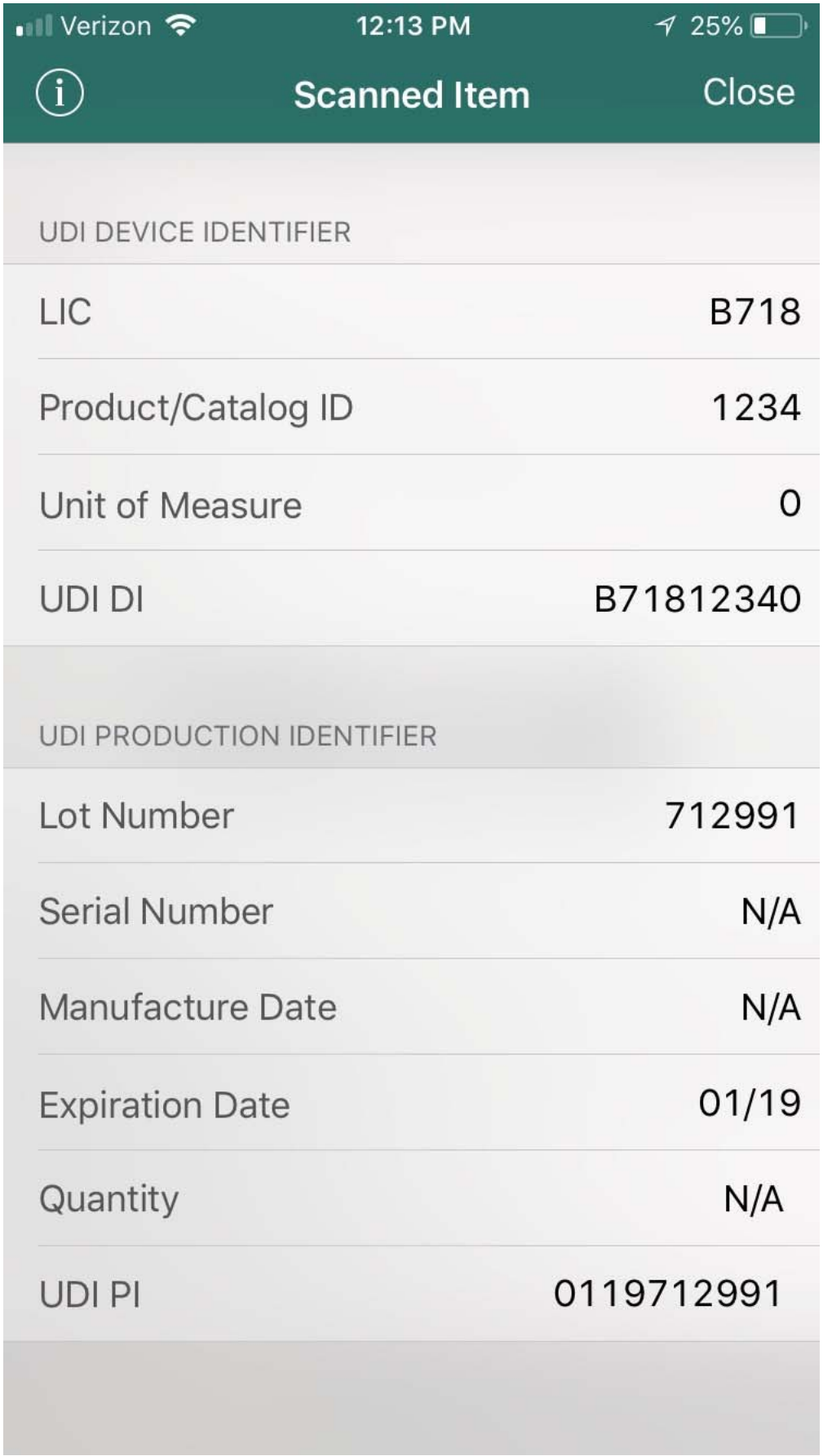
1. Unrecognized LIC Entered



2. Correct LIC Entered



Sample of HIBCC UDI Decoder Mobile App



Ref. Ares(2018)6590301 - 20/12/2018

Call for applications in the view of the designation of UDI issuing entities in accordance with Article 27(2) of Regulation (EU) 2017/745 on medical devices (MDR) and Article 24(2) of Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR).

Form - Applicant's undertakings

Date: 23 January 2019

I, Kirk Kikirekov, in my quality of legal representative in the European Union of Prospitalia h-trak, Building 2, Walton Street, Ayelesbury HP21 7QW, United Kingdom confirm that Health Industry Business Communications Council intends to submit an application for being designated as an issuing entity in accordance with Article 27(2) of Regulation (EU) 2017/745 on medical devices (MDR) and Article 24(2) Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR). In this context, Health Industry Business Communications Council, having read the conditions for designation as laid down in Section II of the call for application, undertakes to:

(i) operate its system for the assignment of UDIs for at least ten years after its designation;

(ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

(iii) remain in compliance with the criteria for designation and the terms of designation

Date and signature of the applicant organisation's legal representative within the European Union

[redacted]

23 January 2019