ICCBBA
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January 18, 2019

Dear European Commission,

In accordance with Article 27(2) of Regulation (EU) 2017/745 and Article 24(2) of Regulation (EU) 2017/746, ICCBBA is applying for designation as a UDI Issuing Entity. We understand the following information must be submitted for our application:

1. Name, address, and phone number of the applicant;
2. Detailed information regarding the applicant's organization, including the description of any financial or other relationship between the applicant and any manufacturer or governmental institutions or organization;
3. Detailed description of its system for the assignment of UDIs, including description of any standard or criteria applied;
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;
5. Detailed description of the applicant's policies and procedures for determining whether manufacturers may use the applicant's system;
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;
7. Description of business model and fee system, with an explanation and rationale of any fee waiver or reduction available;
8. Detailed description of the applicant's electronic data management system;
9. Description of the tools or services made available by the applicant allowing to check data quality in the EU database (Eudamed);
10. The form "Applicant's undertakings," signed by the applicant organization's legal representative in the European Union; and
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.

We have provided this information on the attached pages. Please let us know if you have any questions or need clarification regarding the information presented. We will be pleased to provide any additional information you may require.

Sincerely,

Global Development Director, ICCBBA

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

Global Development Director
ICCBBA

Street Address:

Representative in the European Union:

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

ICCBBA is an international standards development organization and a non-governmental organization (NGO) in official relations with the World Health Organization (WHO) that manages, develops, and licenses ISBT 128: the international information standard for the terminology, coding, and labeling of medical products of human origin (MPHO). ICCBBA manages the allocation of globally unique identifiers to licensed facilities and maintains the ISBT 128 Standard, international databases for Facility Identification Numbers and Product Description Codes, supporting documentation, and educational materials.

The ISBT 128 Standard was established in 1994 and is now used for the identification and coding of MPHO by more than 5,300 facilities in 89 countries worldwide, including 385 facilities in 23 EU Member States.

ICCBBA is governed by a volunteer Board of Directors comprised of leading experts in blood transfusion, cellular therapy, and tissue transplantation from around the world. Board positions are advertised publicly and Board members normally serve six-year terms. The current Board of Directors has members from Australia, Bhutan, China, Germany, the Netherlands, Saudi Arabia, the United Kingdom, and the United States.

ICCBBA has a small staff (13 persons) that manages the technical documentation and databases, promotes and supports the global implementation of the standard, organizes technical meetings, and administers registration and licensing. In addition, ICCBBA is supported by an extensive network of volunteer subject matter experts (299 persons) who are organized into a Standards Committee and multiple Technical Advisory Groups (TAGs).

ICCBBA Standards Committee is the panel that reviews and guides ICCBBA technical policies. The group also reviews all documents prior to publication.

ICCBBA Technical Advisory Groups (TAGs) are formed to provide stakeholder input to the ongoing development of the ISBT 128 Standard and to provide educational and technical support to facilities implementing ISBT 128. TAGs are made up of four categories of participants:

- Representatives: Appointed by countries, professional bodies, or major user groups at the invitation of ICCBBA.
- Technical Experts: Appointed by ICCBBA for their particular expertise.
- Liaisons: Appointed by Regulatory Authorities, Government, and supra-governmental organizations.
- Observers: Vendors, observers from user communities not currently using ISBT 128, and other interested parties, all at the discretion of the TAG Chair.

Apart from the fees paid by facilities and vendors to use the ISBT 128 Standard as described in section 7, there is no financial relationship between ICCBBA and any manufacturer or government entity.

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

ICCBBA has developed a UDI system that is compliant with ISO/IEC 15459-2, ISO/IEC 15459-4, and ISO/IEC 15459-6. The system is specifically designed for use only with medical devices that contain MPHO. It uses data elements that are compatible with the ISBT 128 coding and labeling system used for MPHO and thus provides an effective traceability mechanism for all the MPHO products derived from a single donor whether regulated as medical devices, tissues and cells, or advanced therapy medicinal products.

Manufacturers using the ICCBBA UDI system are required to register and be licensed by ICCBBA. As part of the registration process, the manufacturer is assigned a globally unique facility identification code. This code uniquely identifies the manufacturer and is contained within the UDI device identifiers assigned by the manufacturer.

Manufacturers are required to follow the ISBT 128 Standard Technical Specification (ST-001), the primary standards document for ISBT 128. It describes the data structures and the bar code symbologies that may be used.

The document ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO (ST-017) provides requirements for the use of ISBT 128 that are specific to the use of the ICCBBA UDI system for medical devices. Please see attachment A.

Certain data structures are required for medical devices containing MPHO labeled with ISBT 128. These are:

For the Device Identifier (DI):

Data Structure 034 (Processor Product Identification Code) is used to encode the DI. This data structure includes three elements:

- Facility Identification Code (assigned by ICCBBA to uniquely identify the labeler)
- Facility Product Code
- Standardized Product Description Code

For Production Identifiers (PIs):

ICCBBA requires that all medical devices containing MPHO carry a minimum set of production identifiers that are critical to ensure effective traceability back to the donor. The required PIs and their corresponding data structures are:

- Donation Identification Number (Data Structure 001)
- Serial Number (Data Structure 032 (Product Divisions))

Other production identifiers (expiration date, manufacturing date, and lot number), if they appear on the label, must also be included in the UDI bar code.

Because a standardized Product Description Code must be used, manufacturers must also be familiar with tissue or cellular therapy Product Description Code terminology. This is found in the ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002).

The following documents contain detailed instructions regarding the assignment of unique manufacturer codes and requirements for the creation of UDIs:

Standards:

ISBT 128 Standard Technical Specification (ST-001)
The purpose of this document is to provide standards and guidance for the coding and labeling of MPHO.

ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO (ST-017)
This standard is specific for medical devices and gives detailed instructions regarding the requirements and formation of UDIs. Please see attachment A.

Guidance Documents:

Attachment B: Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)
This guidance document assists users and software developers to implement Data Matrix two-dimensional (2-D) symbology for delivery of ISBT 128 data structures for labeling of MPHO.

Attachment C: Implementation Guide: Use of Product Divisions [Data Structure 032] (IG-023)
This guidance document provides information about the format and use of the Product Divisions [Data Structure 032] when used in conjunction with the Product Code [Data Structure 003].

Attachment D: Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)
This guidance document provides guidance for the use of the Donation Identification Number [Data Structure 001].

Attachment E: Implementation Guide: ISBT 128 Facility Identification Number (IG-034)
This guidance document provides guidance for the use of the Facility Identification Number, including how it is assigned, maintained, and the databases supporting it.

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.

The following documents and instructions are provided to manufacturers who plan to use ICCBBA's UDI system:

Forms:

Attachment F: Facility Registration Form (FM-025) (for HCT/P facilities)

Attachment G: License Holder Agreement (FM-086) (for HCT/P facilities)

Attachment H: Facility Annual Return - General (FM-066) (for HCT/P facilities)
Facilities are asked to update ICCBBA on an annual basis of their activities.

Letters and Emails:

When HCT/P facilities register with ICCBBA, they are sent an email outlining where information about ISBT 128 may be found on the ICCBBA website. Please see:

Attachment I: Collection Facility Letter (email) and

Attachment J: Email to New Facilities.

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

Applicants must be facilities that manufacture medical devices that contain medical products of human origin.

Facilities must first be registered with ICCBBA to use ISBT 128 and be assigned a unique Facility Identification Number (FIN).

ICCBBA licensees are permitted to make use of the ISBT 128 Standard according to their type of license. Users must submit annual updates.

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.

It is essential that facilities using ISBT 128 comply with the standard to meet its requirements and to ensure traceability. Should ICCBBA become aware of a facility utilizing ISBT 128 for UDI that is not in compliance with the Standard, it will work with the facility to bring it into compliance. It will follow-up with the facility by discussing the deficiency(ies) in their use of the standard and provide educational materials as needed. If appropriate, an agreed Corrective Action Plan will be developed.

A facility's license to use ISBT 128 will be suspended if it is unable to substantially comply with the standard in a reasonable period of time following notification of a problem. ICCBBA staff will work with facilities to resolve issues prior to suspending a license. If a facility has a suspended license for more than 12 months and no attempt is made to come into compliance, the license to use ISBT 128 will be revoked. ICCBBA will notify a facility in writing via email or standard mail if its license to use ISBT 128 will be, or has been, suspended or revoked. ICCBBA will notify appropriate regulatory authorities that a facility's license to use ISBT 128 will be, or has been, suspended or revoked.

The following are ICCBBA's policies/procedures for dealing with manufacturers' deficiencies in using ISBT 128 for the assignment of UDIs:

Medical Devices: Notification of Nonconformities in the Use of ISBT 128 (PP-058)
This procedure defines how ICCBBA will notify facilities that they are not in substantial compliance with the standard.

Medical Devices: Monitoring Facility Compliance with Corrective Action Plan (PP-059)
This procedure outlines the process to monitor the progress of facilities in correcting deficiencies in the implementation or use of ISBT 128.

Medical Devices: Suspending or Revoking License to Use ISBT 128 (PP-060)
This procedure defines the process to suspend or revoke the license to use ISBT 128.

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

ICCBBA is an international non-governmental organization (NGO), and its operations are funded entirely from licensing fees collected from both facilities using the ISBT 128 Standard and from vendors providing equipment or software that incorporates the standard.

As a tax-exempt, non-profit organization, all of this income is directed to achieving the ICCBBA mission: "Enhancing patient safety by promoting and managing the ISBT 128 international information standard for use with medical products of human origin."

HCT/P Medical Device Facilities

Registration Fee: One-time payment of US $200, which includes allocation of the first Facility Identification Number (FIN). Additional FINs can be requested at US $168 each.

Annual Licensing Fee: Based on the number of final labeled products produced annually that are labeled with ISBT 128.

If	Then
Your facility labels <= 1,000 HCT/P Medical Devices per year	Your annual licensing fee is US $245
Your facility labels <= 5,000 HCT/P Medical Devices per year	Your annual licensing fee is US $375
Your facility labels > 5,000 HCT/P Medical Devices per year	Your annual licensing fee will be US $375 plus US $0.1257 for each device over 5,000 For example, you label 8,000 devices per year. Fee is: 375 + (3,000 X 0.1257) = US $752.10 per year.

These fees are reduced for facilities that are located in countries with a Human Development Index (HDI) classification of Medium or Low. For facilities in Medium HDI countries, the fees are 66% of the above figures. For facilities in Low HDI countries, the fees are 33% of the above figures.

License fees are reviewed on an annual basis by the Board of Directors and adjusted to take account of inflation.

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

ICCBBA maintains a database of registered facilities using ISBT 128 for UDI. This database includes the name, facility identification number, address, country, national identification number (in the US, FDA registration number), date of registration, current status (active, suspended, revoked, or inactive), contact person, telephone number, email address, and website.

ICCBBA also maintains a database of all standardized Product Description Codes. It contains information for both current and retired Product Description Codes.

Databases are controlled documents within the ICCBBA Quality Management System, and rigorous controls are in place to ensure accuracy and consistency. Data backup and recovery systems are in place to ensure the security and availability of the data.

Copies of these databases are available to licensed organizations.

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

Service made available by ICCBBA:

- ICCBBA help desk

  The ICCBBA help desk is available to users for general inquiries and technical issues related to ISBT 128. Users can send emails to iccbba@iccbba.org or call +1 909 793 6516 for assistance.

Tools that ICCBBA provides to check specific elements of the UDI:

- Registered Facilities Database

  https://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/registered-facilities-database

  This database contains the information for facilities registered to use ISBT 128. It can be used to check the Facility Identification Number used within the UDI.

- ISBT 128 Product Description Code Database

  https://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/product-description-codes-database2

  This database contains all current and retired standardized Product Description Codes. It can be used to check the standardized Product Description Code within the UDI.

Tools that ICCBBA uses to verify the validity of the DI portion of UDIs:

- Device Identifier Checker

  https://www.iccbba.org/lookup-tools/device-identifier-checker

  This tool allows a user to parse the various elements of a single ISBT 128 Device Identifier (DI). This tool also interprets the Facility Identification Number and Product Description Code elements of the DI. It is the user's responsibility to check that the correct data has been entered into the Device Identifier field and to verify the parsed elements.

- Multiple Device Identifier Checker

  https://www.iccbba.org/lookup-tools/multiple-di-checker

  This tool allows a user to check the validity of a list of ISBT 128 Device Identifiers (DIs) provided in a data file (.txt file). This tool also interprets the Facility Identification Number and Product Description Code elements of each DI.

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

Please see attachment K.

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.

The ISBT 128 Standard requires that Code 128 must be used for linear bar codes and Data Matrix (ECC 200) must be used for 2-D bar codes. Users must follow the appropriate ISO standards for the printing of UDI carriers:

- ISO/IEC 15415:2011(E): Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols
- ISO/IEC 15416:2016(E): Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols
- ISO/IEC 15417:2007(E): Information technology — Automatic Identification and data capture techniques — Code 128 bar code symbology specification —
- ISO/IEC 16022:2006(E): Information technology — Automatic identification and data capture techniques — Data Matrix bar code symbology specification [and corrections ISO/IEC 16022:2006/Cor.1:2008(E) and ISO/IEC 16022:2006/Cor.2:2011(E)]

Some additional rules (e.g., white space and minimum X value) are defined in the ISBT 128 Standard Technical Specification.

Code 128 and Data Matrix are well-established data carriers that provide high reliability.