GS1 AISBL APPLICATION

to the

EUROPEAN COMMISSION

for

designation as an issuing entity for Unique Device Identifiers (UDIs)

GS1 Global Office ("GS1") hereby submits its application for designation as an issuing agency for the assignment of UDIs in accordance with Article 27(2) of Regulation (EU) 2017/745 and Article 24(2) of Regulation (EU) 2017/746.

GS1 welcomes the opportunity to apply for designation.

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I. CONTACT INFORMATION

GS1 is a neutral, international not-for-profit organisation dedicated to the development and implementation of global standards and solutions to improve the efficiency and visibility of supply chains. The GS1 System of Standards is used by over 1 million companies worldwide. The head office of GS1 is located in Brussels (Belgium). GS1 has local Member Organisations with offices in 112 countries, including in all EU Members States.

Note that the Member Organisations in Europe are grouped under GS1 in Europe, who is not the applicant for designation as Issuing Entity.

[redacted]

[redacted]

Links:

GS1 website: http://www.gs1.org
GS1 Healthcare website: http://www.gs1.org/healthcare
GS1 webpage on UDI: http://www.gs1.org/healthcare/udi
GS1 in Europe website: http://www.gs1.eu/

II. INFORMATION ABOUT GS1

To support this application, information regarding GS1's organisation, including the description of any financial or other relationship between GS1 and any manufacturer or governmental institutions or organisation, is provided below:

1. Not-for-Profit Information

GS1 is organised as an international not for profit association, incorporated under Belgian law (*Association Internationale Sans But Lucratif – AISBL*, registered in the register of legal entities (*Registre des Personnes Morales*), district of Brussels, under number 419.640.608 ("**GS1**"). An extract of the registration in the Belgian Crossroads Bank for Entreprises (*Banque Carrefour des Entreprises – BCE*) is included as Appendix A.

GS1 is a private and non-governmental organisation.

GS1 has 112 members, named "**GS1 Member Organisations**" (or in short "**GS1 MOs**" or "**MOs**") in 112 countries. Having adopted the legal form of an association, there is no ownership right or capital link between the association and its members (both ways). Each of the GS1 MOs has voting rights as well as specific membership rights (and obligations) under the statutes (bylaws) of the association, a recent copy of which (English free translation) is included as Appendix B (the "**Statutes**"). Per article 18 of the Statutes, in case of dissolution of the association all of its assets would have to be assigned to another not-for-profit organisation. There have never been and will never be any distributions of monies or assets now or in case of dissolution by the association to its members.

GS1 also has three non-profit, non-stock subsidiaries in the USA that respectively employ staff, own certain patents and operated the Global Data Synchronisation Network (GDSN). GS1 together with these three subsidiaries is most often designated under the name "**GS1 Global Office**" or "**GS1 GO**".

2. GS1 governance:

GS1 has, by law and pursuant to its Statutes, a **General Assembly** composed of representatives of all the GS1 MOs with the broadest powers in order to achieve the purpose of GS1. Reporting into the General Assembly, by law and pursuant to its Statutes, is the **GS1 Management Board**, composed of 2/3 of user organisations and the 1/3 representatives of the GS1 MOs (currently, in total, 34 members) and which has the widest powers of management and administration necessary for the operation of GS1. The **President and CEO** (currently, Mr Miguel A. Lopera) reports to the GS1 Management Board and manages GS1 on a day-to-day basis.

3. GS1 Member Organisations, admission to membership, local governance and members

To be admitted as a GS1 MO, the applicant organisation must be an **independent** national or pluri-national organisation. It is also required (for as long as it remains a GS1 MO) to operate on a **not-for-profit basis** and to have a Board (or local equivalent body) composed of a majority of users of the standards (i.e. organisations both on demand-side and supply-side) but may also comprise, in some cases, regulators or associations or federation of users, other not for profits, etc. Indeed, in order to ensure proper oversight and accountability towards the users of the GS1 System, GS1 operates on a "**user-governed, user-driven**" principle. Accountability is very important as, per applicable competition law and antitrust regulations, the fees charged by the GS1 MO are set locally by the GS1 MO and not by GS1 Global Office.

Once admitted, each GS1 MO is granted a license to administer a unique number bank for the purpose of allocating identification numbers to users of the standards and to administer the standards system in its country by supporting users.

In many countries, where the local legal system allows for membership-based legal entities, the users to whom the GS1 MO licenses GS1 identification numbers are also "members" and part of a General Assembly-like body of the GS1 MO, which further enhances accountability towards the GS1 system users. This is not the case in all countries though, in some countries they are "licensees" or "subscribers", but within GS1 we tend nevertheless tend to designate them by the term "**members**".

4. Federation model

As appears from sections 2 and 3 above, GS1 operates *de facto* as a federated network, where GS1 MOs (through their leadership) participate at several levels in the governance structure. This allows for a global approach with local input from the network.

5. Healthcare

The bodies mentioned in section 2 above are the decision-making bodies of GS1, but GS1 also has a few advisory bodies composed of experts that feed strategy recommendations, advice and information into the governance bodies and support the implementation of the strategies. In particular, the healthcare sector has its own "**Healthcare User Group**" which has a key role in designing, driving and implementing GS1's healthcare strategy.

6. Potential conflicts of interests

While business practices may change over time, GS1's commitment to the highest standards of integrity remains constant. Conducting business ethically and in a neutral way is critical to GS1's success.

Between the GS1 and its GS1 MOs, the foundational document is the Statutes, in which the not-for-profit and "user-driven, user-governed" principles are embedded (articles 2 and 6.g). Compliance with the Statutes, internal regulations and policies, as well as, more generally, the decisions of the General Assembly and GS1 Management Board is overseen by a committee of the GS1 Management Board named the "Internal Compliance Committee". It operates according to an internal regulation attached as Appendix C.

To promote those standards within the staff of GS1, there is also a formal "Code of Conduct Policy" that governs GS1 and its subsidiaries. The full policy is provided in Appendix D of this document. Key points include:

- GS1 requires all employee to avoid entering into any relationship or activity, which may result in a conflict of interest with, or be prejudicial to the business of GS1.

- Information obtained during the course of work must always be kept as confidential. It must never be discussed with any unauthorised person either within or outside the organisation, or used to the employee's own advantage, or in a way that could harm others.

The employee Code of Conduct applies to every employee within GS1. These standards form an expressed condition of employment, which if substantially breached may lead to counselling or termination of employment.

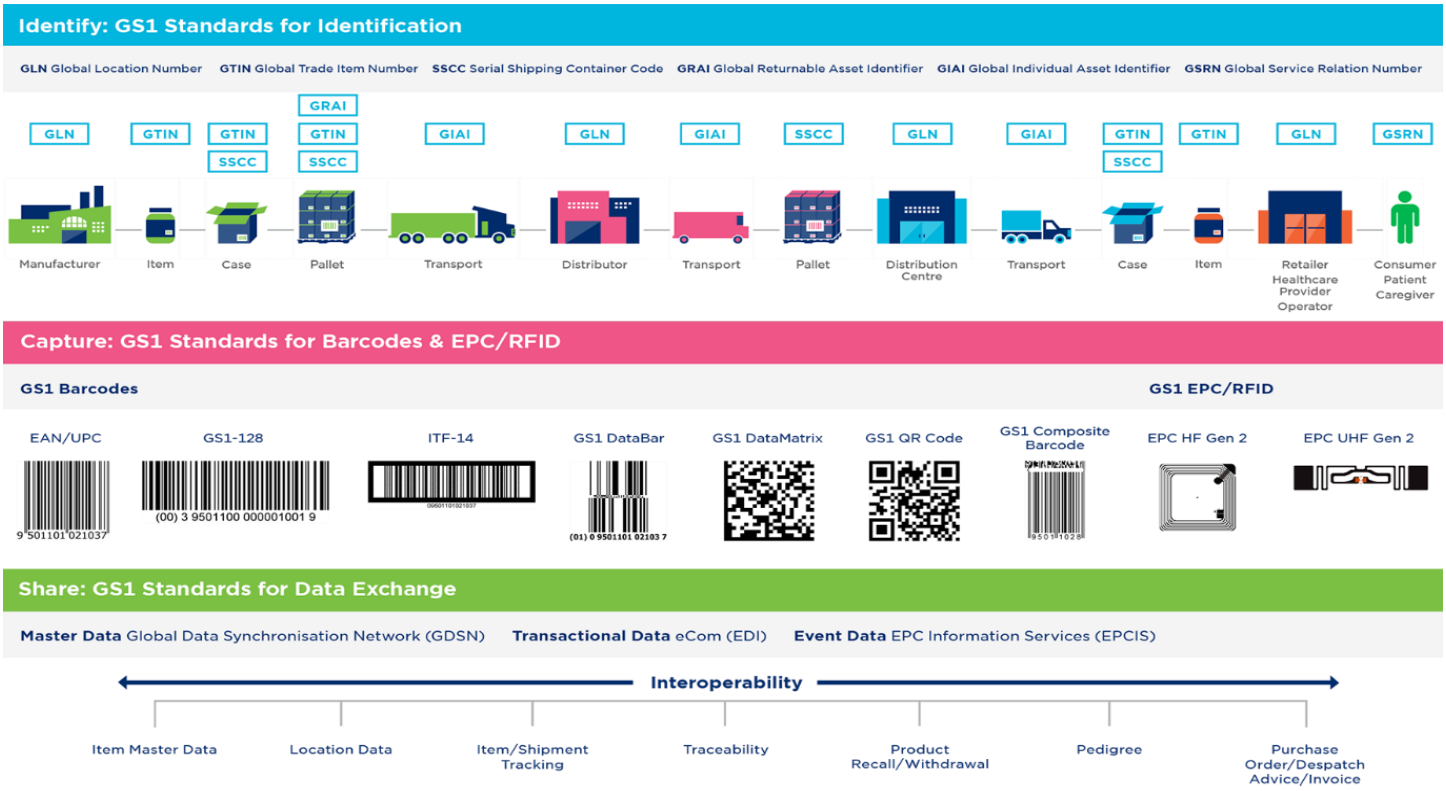
III. INFORMATION ABOUT THE GS1 SYSTEM

To support this application, a description of the GS1 system for the assignment of UDIs, including description of any standard or criteria, are provided below:

Description of the GS1 system:

The GS1 system (formerly the EAN/UCC system) is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. The system is designed to overcome the limitations of using company, organisation or sector specific coding systems, and to make trading more efficient and responsive to customers. By using GS1 identification numbers (also referred to as GS1 Keys) companies around the world are able to uniquely and unambiguously identify physical things like trade items, assets, logistic units, shipments, and physical locations, as well as logical things like corporations or a service relationship between provider and recipient. GS1 identification numbers can be represented in barcode symbols or in RFID tags to enable electronic data capture wherever required in business processes. In addition, the GS1 system provides for the encoding of supplementary information, such as expiration date, batch/lot number and serial number, to facilitate the communication of product-specific information wherever the data carrier is read. GS1 identification numbers are also used in electronic data exchange standards.

The graphic below illustrate the GS1 Standards used in Healthcare:



The GS1 system of standards is designed for use globally in any industry or trade sector, and any changes to the system are facilitated in the user-driven, user-focused standards development process known as the "Global Standards

Management Process" ("**GSMP**"). The GSMP brings together users from all industries and from around the world to identify needs for standards, gather business requirements, document best practices, obtain consensus on solutions, and then develop and implement the resulting standards. Changes take place only after wide consultation and are subject to a significant transition period so as not to negatively affect current users. The GSMP is an open and transparent process made possible by the participation of companies who seek to improve the efficiency of supply chains. It is the pre-eminent worldwide collaborative forum where GS1 Standards are built and maintained. For more details, the GMSP manual is provided in Appendix E.

The following parts of the GS1 system are relevant for the implementation of the UDI system:

Global Trade Item Number® (GTIN®) – i.e. UDI-DI: The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a box of 15 Brand X tissues; a carton of six boxes of Brand X tissues; etc.). The GTIN is the foundation of the GS1 system.

Global Model Number (GMN) – i.e. Basic UDI-DI: A product model is a base product design or specification from which a trade item is derived. The trade item inherits major features/functions from the base model. The GS1 Global Model Number (GMN) is the GS1 identification key used to identify product models from which trade items are derived. The GMN comprises the GS1 Company Prefix and a model reference. The model reference is alphanumeric and its structure is left to the discretion of the brand owner who assigns it.

GS1 Application Identifiers (AIs) – i.e. UDI-PIs: In addition to the product identification number (i.e., GTIN), there may be certain *item-specific information* that manufacturers or supply chain partners want marked on products to enable communication of that information *wherever the bar code is scanned* (e.g., expiration date; lot/batch number; etc.). The GS1 system provides "Application Identifiers" to support this need. GS1 Application Identifiers (AIs) are a finite set of specialised identifiers encoded within barcodes to indicate the type of data represented in the various barcode data segments. There are approximately 100 AIs, including an AI for each GS1 Identification Number (e.g., GTIN; SSCC; GLN; etc.) as well as AIs for various types of secondary information (e.g., expiration date; lot/batch number; etc.). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number. GS1 AIs are standard throughout the world and are familiar to IT system developers.

GS1 Data Carriers – i.e. UDI carriers: GS1 Data Carriers provide machine-readable representations of GS1 identification numbers that facilitate automatic identification and data capture (AIDC). AIDC is a term used to describe various technologies used to identify items, collect data about them and enter that data electronically into computer systems in a fully automated way. In order to accommodate a variety of environments and applications, the GS1 system supports eight AIDC data carriers: six barcode symbologies (i.e., GS1 BarCodes) and RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)]. Changes in the use of AIDC data carrier technology are made using a well-defined standards development process, taking into account the implementation impact of the changes.

Global Data Synchronisation Network (GDSN): The Global Data Synchronisation Network (GDSN) provides an efficient and effective way to (1) exchanging GS1 Global Trade Item Numbers (GTINs) and synchronise their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with trading partners. The GDSN is a network of interoperable certified data pools connected by the GS1 Global Registry. The GDSN certified Data Pools enable the synchronisation of product

information, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data synchronisation that ensures that product information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

Standards and criteria for the assignment of UDIs:

GS1 will apply the same standards and criteria as those applied to use the GS1 system in general, with the GS1 Global Trade Identification Number® (GTIN®) and the Global Model Number (GMN) in particular.

The GTIN is the foundation of the GS1 system.

The GMN has been developed and published in September 2017 in order to support the implementation of the Basic UDI-DI in the EU UDI system, based on the EU Regulations as adopted in April 2017. The EU requirements on the structure of the Basic UDI-DI have been amended in November 2018. The GMN Standard is currently under revision in order to include these new requirements. The updated GMN standard will be adopted in May 2019.

The standards and criteria used are detailed in the GS1 General Specifications, as well as ISO and ISO/IEC standards. By following the standards, architectural principles and guidelines of the GS1 system, users can design applications to automatically process GS1 system data for the assignment of UDIs.

GS1 GENERAL SPECIFICATIONS

Every organisation using GS1 Standards is requested to conform fully to the GS1 General Specifications. The GS1 General Specifications provide detailed information and guidance with regard to syntax, identifier assignment, allocation, and AIDC standards within the GS1 system. The sections of the GS1 General Specifications are:

GS1 General Specifications Section	Description of Contents
Section 1 Basics & Principles	Provides an introduction to the core components of the GS1 system.
Section 2 Application Identification	Provides a definition for each GS1 application using a template format. Each application is uniquely identified and contains a description, the associated GS1 Key, its definition and links to relevant data structures and attributes, rules, carrier specifications, placement, and unique processing requirements.
Section 3 Application Identifier Definitions	Describes the meaning, structure, and function of the GS1 element strings so they can be correctly processed in users' application programs.
Section 4 Application Rules	Provides the rules for use of GS1 Keys in their application environments. Differences in industries are included as well as the data relationship rules for Application Identifier use.

Section 5 Data Carriers	Provides a detailed description of the data carriers that are endorsed by GS1. It includes symbol specification tables for use in the supply chain operational environment as well as the related bar code production and quality assessment required to achieve excellent scan rates.
Section 6 Symbol Placement Guidelines	Provides guidance on symbol placement as well as transport label standards and tag standards.
Section 7 AIDC Validation Rules	Provides rules for validating and processing GS1 Element Strings without human intervention. Check digit and calendar date algorithms are also included.
Section 8 GS1 Standards Glossary	

ISO AND ISO/IEC STANDARDS

The following ISO and ISO/IEC standards, which are required in the UDI Final Rule, are directly referenced within the GS1 General Specifications for use within the GS1 system:

- ISO/IEC 646 Information technology -- ISO 7-bit coded character set for information interchange
- ISO/IEC 15459-2 Information technology -- Unique identifiers -- Part 2: Registration procedures
- ISO/IEC 15459-4 Information technology -- Unique identifiers -- Part 4: Individual items
- ISO/IEC 15459-6 Information technology -- Unique identifiers -- Part 6: Unique identifier for product groupings

In addition to those standards, the following ISO and ISO/IEC standards are also directly referenced within the GS1 General Specifications:

- ISO 1073-2 Alphanumeric character sets for optical recognition -- Part 2: Character set OCR-B -- Shapes and dimensions of the printed image
- ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code symbol 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 15420 Information technology -- Automatic identification and data capture techniques -- EAN/UPC bar code symbology specification
- ISO/IEC 15424 Information technology -- Automatic identification and data capture techniques -- Data Carrier Identifiers (including Symbology Identifiers)

- ISO/IEC 15426-1 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 1: Linear symbols
- ISO/IEC 15426-2 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 2: Two-dimensional symbols
- ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification
- ISO/IEC 16390 Information technology -- Automatic identification and data capture techniques -- Interleaved 2 of 5 bar code symbology specification
- ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification
- ISO/IEC 24723 Information technology -- Automatic identification and data capture techniques -- GS1 Composite bar code symbology specification
- ISO/IEC 24724 Information technology -- Automatic identification and data capture techniques -- GS1 DataBar bar code symbology specification

The following ISO/IEC standards are also important references to note when using the GS1 system:

- ISO/IEC 15418 Information technology -- Automatic identification and data capture techniques -- GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance
- ISO/IEC 15423 Information technology -- Automatic identification and data capture techniques -- Bar code scanner and decoder performance testing
- ISO/IEC 15459-1 Information technology -- Unique identifiers -- Part 1: Unique identifiers for transport units
- ISO/IEC 15459-3 Information technology -- Unique identifiers -- Part 3: Common rules for unique identifiers
- ISO/IEC 15459-5 Information technology -- Unique identifiers -- Part 5: Unique identifier for returnable transport items (RTIs)
- ISO/IEC 15459-8 Information technology -- Unique identifiers -- Part 8: Grouping of transport units
- ISO/IEC TR 24720 Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)
- ISO/IEC 29158 Information technology -- Automatic identification and data capture techniques -- Direct Part Mark (DPM) Quality Guideline

JOINT INITIATVE COUNCIL (JIC)

GS1 is a member of the Joint Initiative Council (JIC).
The Joint Initiative on Standards Development Organisations (SDO) Global Health Informatics Standardisation enables common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counterproductive standardisation efforts.
The purpose of the Joint Initiative Council is to foster the highest level of cooperation among its member standard development organisations (SDO) that include Health Level Seven International (HL7), Clinical Data Interchange Standards Consortium (CDISC), International Health Terminology Standards Development Organisation (IHTSDO), European Committee for Standardisation Technical Committee on Health Informatics (CEN/TC 251) and International Standards Organisation Technical Committee on Health Informatics (ISO/TC 215) and GS1 (supply and demand chain standards).

This Council, operating as a council of equals and as a liaison group under ISO/TC 215.
For more information, please visit: http://www.jointinitiativecouncil.org/.

LINKS

- *GS1 General Specifications*: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
- GS1 Global Data Synchronisation Network https://www.gs1.org/services/gdsn
- Copies of ISO and ISO/IEC standards can be secured from ISO (the International Organisation for Standardisation) at http://www.iso.org/iso/home/store.htm

IV. DESCRIPTION OF THE MATERIALS SENT TO USERS FOR THE ASSIGNMENT OF UDI

To support this application, copies of application forms, guidelines, instructions and other materials send by GS1 to users, are provided below:

ASSIGNMENT PROCESS

Upon joining a GS1 Member Organisation ("**GS1 MO**"), organisations receive a GS1 Company Prefix. The GS1 Company Prefix is part of the data structure for all GS1 Identifiers (e.g., GTIN, GMN, etc.) and provides the foundation for generating all of the GS1 identification numbers. With membership, organisations also receive comprehensive documentation on how to allocate GMNs (i.e., the "Basic UDI-DI"), GTINs (i.e., the "Device Identifier" of a UDI) to their products as well as how to utilise GS1 Application Identifiers (i.e., the "Production Identifier" of a UDI).

For concrete examples, please see Appendix F.

The GS1 system provides clear, structured data standards and allocation rules designed to ensure that GMNs and GTINs are globally unique and in a consistent format. Manufacturers assign/allocate their own GMNs and GTINs based on their GS1 Company Prefix, and the GS1 General Specifications and GS1 Healthcare GTIN Allocation Rules.

Manufacturers who hold the specifications of a medical device must properly allocate and maintain their GMNs and GTINs to enable trading partners to distinguish products effectively for regulatory, supply chain and patient safety concerns, and in accordance with EU requirements. The integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders. GS1 Healthcare GTIN Allocation Rules help manufacturers determine when a product should have a new unique GTIN assigned.

Assignment of GS1 Company Prefixes

GS1 Member Organisations assign GS1 Company Prefixes to their own members. A GS1 Company Prefix is a globally unique number used exclusively within GS1 identification standards. A GS1 Company Prefix assigned to a member of any GS1 Member Organisation entitles that member to create any of the GS1 Identification Keys (e.g., GTIN, GMN, etc.).

GS1 Company Prefixes are assigned in varying lengths (depending on the company's needs) and in random order.
A GS1 Company Prefix consists of two segments: a GS1 Prefix and a Company Number.

- GS1 Prefix is a number with two or more digits, administered by the GS1 Global Office. The GS1 Global Office assigns GS1 Prefixes to GS1 Member Organisations and/or for Restricted Circulation Numbers. The main purpose of the GS1 Prefix is to enable decentralisation of the administration of identification numbers (i.e., each GS1 MO allocates GS1 Company Prefixes under their own GS1 Prefix).
- Company Numbers are assigned by GS1 MOs. Each GS1 MO assigns Company Numbers to its own members.

Pre the GS1 General Specifications, GS1 Company Prefixes may not be sold, leased, or given, in whole or in part, for use by any other company. The GS1 General Specifications also include additional guidelines that apply when a company changes legal status as a result of an acquisition, merger, partial purchase, split, or "spin-off".

The GS1 Company Prefix is part of the GS1 data structures and provides the foundation for generating all of the GS1 Identification Keys. With a GS1 Company Prefix and the GS1 General Specifications and Allocation Rules, user companies can create any of the GS1 Identification Keys.

UDIs Using the GS1 system

Using the GS1 system, the Basic UDI-DI is represented by a Global Model Number (GMN), the UDI device identifier (DI) is represented by a GTIN, and UDI production identifiers (PI) are represented by GS1 Application Identifiers (AIs).

Information about assigning and using these standards is provided below.
For more information, consult the GS1 General Specifications: https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications.

UDI Segment	GS1 Standard	Data Type	Length in software	Length in barcode
Basic UDI-DI	GMN	Alphanumeric	Variable – max. 25 digits	Not used in AIDC
UDI-DI	GTIN	Numeric	Fixed – 14 digits	16 digits
UDI-PI: lot number	AI (10)	Alphanumeric	Variable – max. 20 digits	22 digits
UDI-PI: expiry date	AI (17)	Numeric	Fixed – 6 digits	8 digits
UDI-PI: serial number	AI (21)	Alphanumeric	Variable – max. 20 digits	22 digits
UDI-PI: production date	AI (11)	Numeric	Fixed – 6 digits	8 digits

Assigning GTINS

GS1 members assign their own GS1 Identification Keys based on GS1 Standards and allocation rules. The principles of GS1 Identification Key allocation ensure non-significant, secure and globally unique numbers that can be used by all trading partners, independent of industry sector or location. Each company's GS1 Company Prefix serves as the foundation for any GS1 Identification Key that the member assigns. GS1 member companies can assign GS1 Identification Keys manually, or use a number-generator software from one of their vendors or their GS1 MO (if provided).

Each labeler will assign their own GTINs. GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively).

However, regardless of how they are assigned and encoded, GTINs are always represented in software applications as 14 digits by right justifying and zero-filling to the left as appropriate (i.e. GTIN-14, or GTIN-8, GTIN-12 or GTIN-13 in 14-digit format using leading zeros.) In order to preserve any leading zeros that may be present, the GTIN field should be represented in databases and software applications as a text field, not as a numeric field. For more information, consult the GS1 Healthcare GTIN Allocation Rules: https://www.gs1.org/1/gtinrules/en/healthcare.

Batch/Lot Number - AI (10)

A Batch/Lot Number is typically assigned at the point of manufacturer using a production lot number, a shift number, a machine number, a time or an internal production code. Batch/Lot Number is represented by Application Identifier (10).

- The two-digit AI (10) is used to indicate Batch/Lot Number.
- A variable-length field of up to 20 alphanumeric characters of Batch/Lot Number data follows the AI.
- The data syntax for the Batch/Lot Number component is n2 + a 20.
- EXAMPLE: (10)987654321GFEDCBA

Production Date - AI (11)

Production Date can also be referred to as production date. It indicates the production or assembly date determined by the manufacturer. Production Date can also be referred to as Manufacturing Date. It is represented by Application Identifier (11).

- The two-digit AI (11) is used to indicate Manufacturing Date.
- A fixed-length field of 6 numeric characters representing Manufacturing Date follows the AI.
    - YY = the tens and units of the year (e.g., 2003 = 03).
    - MM = the number of the month (e.g., January = 01).
    - DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for the Manufacturing Date component is n2 + n6.
- EXAMPLE: (11)130726

Expiration Date - AI (17)

Expiration Date is often referred to as expiry date or maximum durability date. It indicates the limit of consumption or use of a product. Expiration Date is represented by Application Identifier (17).

- The two-digit AI (17) is used to indicate Expiration Date.
- A fixed-length field of 6 numeric characters representing the Expiration Date as YYMMDD follows the AI.
    - YY = the tens and units of the year (e.g., 2003 = 03).
    - MM = the number of the month (e.g., January = 01).
    - DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for the Expiration Date component is n2 + n6.
- EXAMPLE: (17)101231

Serial Number - AI (21)

Serial Number is represented by Application Identifier (21). The data is alphanumeric and the length is variable up to 20 alphanumeric characters.

- The two-digit AI (21) is used to indicate the Serial Number.
- A variable-length field of up to 20 alphanumeric characters of Serial Number data follows the AI.
- The data syntax for the Serial Number component is n2 + a 20.
- EXAMPLE: (21)ABCDEFG123456789

A UDI comprises a Device Identifier (DI) and Production Identifier(s) (PIs). In the GS1 system, GTINs uniquely identify items that are traded in the supply chain, such as medical devices. GTINs can be utilised as the "Device Identifier" in a UDI. GS1 Application Identifiers (AIs) are used to communicate item-specific/production information in a bar code (e.g., batch/lot number, serial number, expiration date, etc.). GS1 AIs can be utilised as the "Production Identifier(s)" where required in a UDI. Thus, the GTIN and GS1 AIs can be used for UDI. In the GS1 system, the GMN can be utilised as the "Basic UDI-DI".

NOTICE RE: CHANGES TO UDI-RELATED STANDARDS

GS1 will notify the EU Commission of any changes to any GS1 Standards related to UDI, and will propose that the EU Commission participate in the development of any new standard or modifications related to UDI.

The GS1 Healthcare GTIN Allocation Rules are currently under review. The updated version should be adopted end of 2019.

LINKS

- *GS1 General Specifications:*
  https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
- *GS1 Healthcare GTIN Allocation Rules*:
  https://www.gs1.org/1/gtinrules/en/healthcare
- *GS1 AIDC Healthcare Implementation Guide*:
  http://www.gs1.org/sites/default/files/docs/gsmp/healthcare/AIDC_Healthcare_Imp_Guide.pdf

V. PROCESS TO DETERMINE WHETHER A MANUFACTURER MAY USE THE GS1 SYSTEM

The GS1 system is open (i.e. non-proprietary) and voluntary.

Manufacturers who wish to use the GS1 system apply to license a GS1 Company Prefix from a GS1 Member Organisation and thus become a "**member**". Regardless of its location, a manufacturer may contact any of the 112 GS1 MOs in order to become a member.

Applicable competition and antitrust laws preclude the alignment of terms between members of a network. Therefore, apart from certain fundamental terms that are based in the standards, regulation or policies on non-competitive aspects, each GS1 MO sets its own fees and defines its own licensing terms (e.g. license duration, payment process, etc).

The GS1 MO's website will describe the steps for obtaining a GS1 Company Prefix and becoming a member, which can be generally summarised as follows:

1. **Estimate the bar code needs and fees.**
   The applicant has to estimate how many trade items need to be identified, based on the number of products as well as the number of variations for each—sizes, colours, packages, etc. The licensing fees are based on the numbering capacity of the barcode, as well as other factors such as the estimated annual sales revenue, the amount of share capital, … (GS1 MOs use such factors to ensure a pricing that is fair and proportionate to the size of the organisation seeking a license, cf. above).

2. **Fill out the membership application and accept licensing terms.**
   The applicant will need to provide certain information, which may include its estimated annual sales revenue or a similar factor (cf. above), the approximate number of product variations needing bar codes, and its contact information, and accept the GS1 MO membership or licensing terms.

3. **Submit related payment online or by mail.**
   Most GS1 MOs offer a license on an annual basis but they may also offer multi-year licenses. Upon registration, the initial fee becomes payable.

4. **Get a GS1 Company Prefix.**
   Once payment is received, the GS1 Company Prefix is sent by email.

As part of the membership and license, the GS1 MO will provide support to the member (e.g. training, bar code creation, quality verification, etc.).

VI. POLICIES AND PROCEDURES FOR DEALING WITH DEFICIENCIES

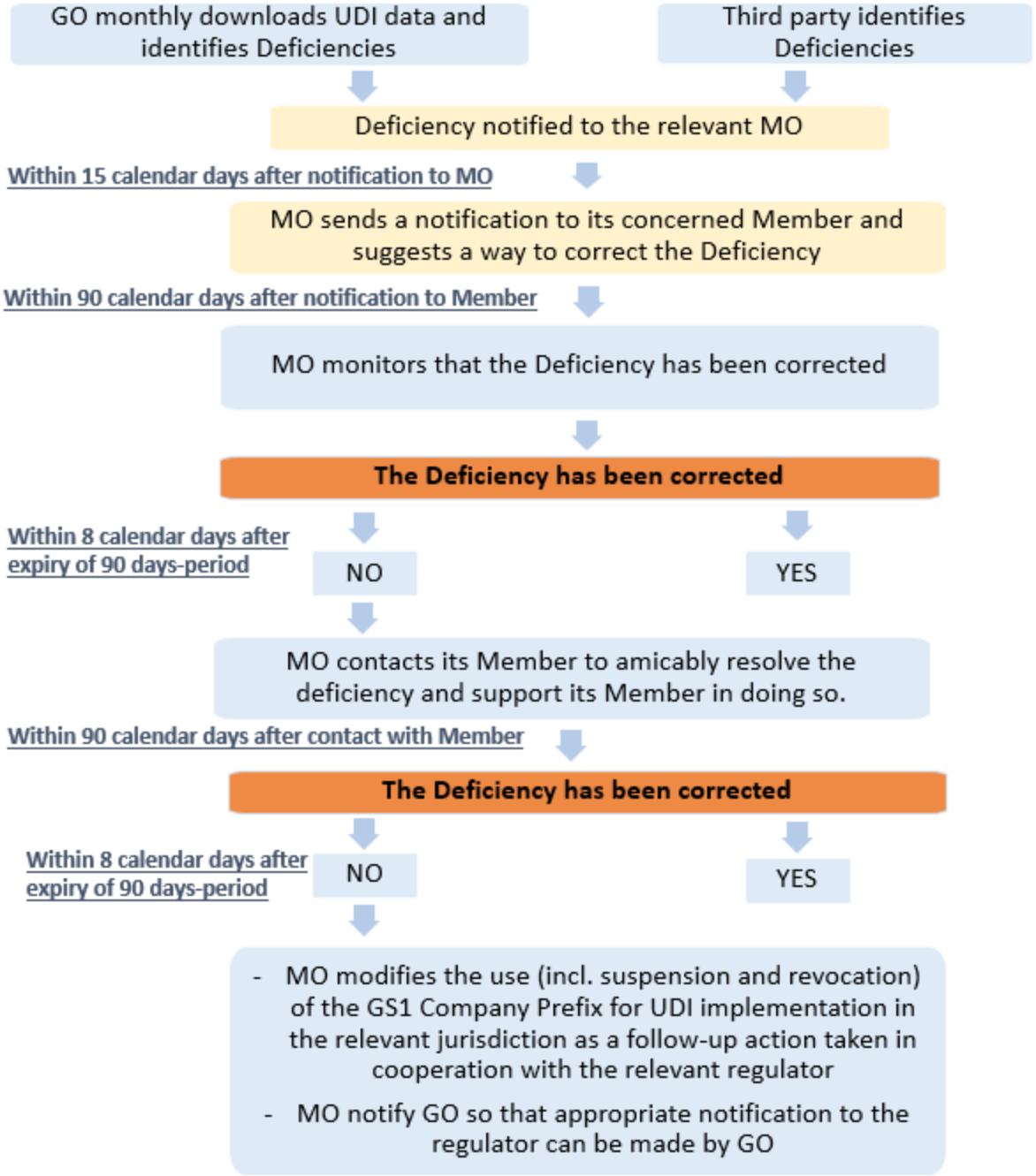
To support this application, description of GS1's policies/procedures for dealing with manufacturers' deficiencies in using correctly the system for the assignment of UDIs, including for monitoring corrections, are provided below:

GS1 has developed a specific "GS1 UDI Policy" to identify, notify and monitor corrections of deficiencies in using the GS1 system for UDI assignment. Below are the main points. See the full GS1 UDI Policy in Appendix G.

2.3.2. Identifying, Notifying and Correcting Deficiencies. *GS1 Global Office (GO) will download the content of the relevant UDI Database monthly and analyse the data. If incorrect usage of GS1 standards (a Deficiency) is noted, the relevant MO will be notified and shall take the following actions. Upon such notification by GO or upon discovering a Deficiency in other ways (e.g. through a third party), the MO shall notify the member in writing of the Deficiency within 15 calendar days after becoming aware of it, suggesting a way to correct the Deficiency and asking the member to correct such Deficiency within 90 calendar days from the date of the notification (the Correction Period).*

2.3.3. Monitoring corrections of Deficiencies. *The MO shall monitor whether a member has corrected a Deficiency within the Correction Period (e.g. by using the GO monthly report or consulting the UDI Database). Failing such correction, at the latest 8 calendar days after expiry of the Correction Period, the MO shall contact the member again and seek to amicably resolve the Deficiency and support the member in correcting the Deficiency.*

2.3.4. Suspension and Revocation on grounds of a repeated and/or deliberate misuse of the GS1 Standards. *If the Deficiency is not corrected within an additional period of 90 days from the expiry of the Correction Period and pertains to a repeated and/or deliberate misuse of the GS1 Standards related to UDI, MO shall modify the use (incl. suspension and revocation) of the GS1 Company Prefix for UDI implementation in the relevant jurisdiction, as a follow-up action taken in cooperation with the relevant regulator (see also Recommended Disclaimers of Liability above). MO shall notify GO so that appropriate notification to the regulator can be made by GO.*


GO monthly downloads UDI data and identifies Deficiencies
Third party identifies Deficiencies
Deficiency notified to the relevant MO
Within 15 calendar days after notification to MO
MO sends a notification to its concerned Member and suggests a way to correct the Deficiency
Within 90 calendar days after notification to Member
MO monitors that the Deficiency has been corrected
The Deficiency has been corrected
Within 8 calendar days after expiry of 90 days-period
NO
YES
MO contacts its Member to amicably resolve the deficiency and support its Member in doing so.
Within 90 calendar days after contact with Member
The Deficiency has been corrected
Within 8 calendar days after expiry of 90 days-period
NO
YES
- MO modifies the use (incl. suspension and revocation) of the GS1 Company Prefix for UDI implementation in the relevant jurisdiction as a follow-up action taken in cooperation with the relevant regulator
- MO notify GO so that appropriate notification to the regulator can be made by GO

VII. BUSINESS MODEL AND FEE SYSTEM OF GS1

To support this application, description of GS1's business model and fee system, with an explanation and rationale of any fee waiver or reduction available, are provided below:

GS1 Company Prefixes, which give users the capacity to create GS1 identification numbers, are issued by GS1 Member Organisations. For competition law and/or anti-trust law reasons, each GS1 MO is responsible for establishing its own fee rates and this cannot be decided centrally by GS1 Global Office. However, every GS1 Member Organisation is required to operate on a not-for-profit basis, which means that all revenues which derive from or are received in relation to the GS1 system will only be used by the local GS1 MO to further the aims and objects of GS1 as a whole and there will be no distribution of such revenue to members, owners, shareholders and directors (see Article 6.g of the Statutes in Appendix B). Furthermore, as described in section I above, the "user-driven, user-governed" principle aims to ensure that the prices are set or at least monitored by the local user community taking into account the local market and ensures accountability of the local management towards.
No waivers or reductions are available in principle. However, fee reductions are part of the terms on which GS1 MOs may not align and that are fully locally determined. In general, GS1 MOs structure their fees according to (a) number of GTINs to be allocated, (b) size of company (based on annual sales turnover or sometimes even company share capital or other financial factors), or a combination of (a) and (b). Some GS1 MOs charge additional fees in the case of additional (premium) services beyond the basic service offering. Most (but not all) GS1 MOs publish their fees on their websites. Below are examples of some of the GS1 MOs' fee structure:

Company scale		US	Belgium	Tanzania
Small		**<10 GTINs**	**<10 GTINs & Turnover<€2,500**	**Turnover<Tshs 5M (€1978)**
	Initial fee	$250	0	100,000 Tshs (€39)
	Annual renewal fee	$50	€226	80,000 Tshs (€31)
Large		**<100,000 GTINS**	**<100.000 GTINS & Turnover ≥ €125.000**	**Turnover ≥Tshs 500.1M (€197,788)**
	Initial fee	$10,500	€1,000	100,000 Tshs (€39)
	Annual renewal fee	$2,100	€1,789	2640,000 Tshs (€1044)

Data collected from MOs website in June 2017

It is important to note that the GS1 standards have been used in retails, also by very small manufacturers, for more than 40 years with no issue related to the fees to use the GS1 system.

LINKS

- GS1 Member Organisations contact details: http://www.gs1.org/contact

VIII. GS1 ELECTRONIC DATA MANAGEMENT SYSTEM

To support this application, description of GS1's electronic data management system is provided below:

The GS1 data management system is the Global Data Synchronisation Network (**GDSN**). The GDSN is an internet-based, interconnected network of interoperable data pools and a global registry that enables companies around the globe to exchange standardised and synchronised product data with their trading partners. It assures that data exchanged between trading partners is accurate and compliant with universally supported standards.

GS1 GLOBAL DATA SYNCHRONISATION NETWORK (GDSN)

The GDSN is built around the GS1 Global Registry, GDSN-Certified Data Pools, the GS1 Data Quality Framework, and GS1 Global Product Classification (**GPC**) -- which when combined, provide a powerful environment for secure and continuous synchronisation of accurate data. Trade items are identified in the GDSN using GS1 Global Trade Item Numbers (**GTIN**). Partners and locations are identified by GS1 Global Location Numbers (**GLNs**). A combination of GTIN, GLN and Target Markets (the geographical area where the catalogue item is intended to be sold) allows information to be shared in the network.

The GDSN provides a single point of truth for product information. Any changes made to one company's database can be automatically and immediately provided to all of the other companies who subscribe to the data through GDSN. When a supplier and a customer know they are looking at the same accurate and up-to-date data, doing business together is smoother, quicker and less expensive.

PROCESS OVERVIEW FOR UDI PRODUCT DATA REGISTRATION

Step 1: The medical device manufacturer registers their UDI product data with a GDSN-Certified Data Pool and instructs the data pool to submit the product data on their behalf to the UDI module of EUDAMED.

Step 2: The GDSN Data Pool registers a small subset of the data in the GS1 Global Registry. NB: The GSDN data elements will be mapped and aligned with the data elements of the UDI module of EUDAMED.

Step 3: The Data Pool converts the GDSN message to the required electronic exchange format and registers the data with the UDI module of EUDAMED.

Step 4: The Data Pool confirms the registration of the product data with the manufacturer.

LINKS

- *GDSN Roadmap* (this document provides an overview of the GDSN, including Scope, Vision, Mission, Principles and Governance):
  http://www.gs1.org/docs/gdsn/gdsn_roadmap.pdf
- *GDSN Operations Manual* (this document provides a detailed explanation of the GDSN including how to use the network):
  http://www.gs1.org/docs/gsmp/gdsn/GDSN_2_8_Operations_Manual_i1.pdf
- *GDSN Implementation Guide* (this document provides guidance on how to implement the GDSN):
  http://www.gs1.org/docs/gsmp/gdsn/GDSN_Trade_Item_Implementation_Guide.pdf

IX. GS1 TOOLS OR SERVICES ALLOWING TO CHECK DATA QUALITY IN THE EU DATABASE

To support this application, description of GS1's tools or services made available to check data quality in the EU database (EUDAMED) is provided below:

Before submission of data in the EU database:

GS1 MOs provide support, including training, to their members in order to ensure the GS1 Standards are correctly used. In particular for UDI, Appendix H provides examples of materials developed by GS1 MOs to assist users in using GS1 Standards for UDI. To ensure the manufacturers will have access to the same level of expertise across all GS1 MOs, the GS1 UDI Policy requires that at least two members of the MOs' staff follow the GS1 Certification training on UDI. See section 2.3.1. of the GS1 UDI Policy in Appendix D.

In addition, a check-digit is included in the structure of the GMN (i.e., "Basic UDI-DI") and of the GTIN (i.e., "UDI-DI"). The check-digit enables the manufacturer to avoid error in these keys.

After submission of data in the EU database:

The process described under GS1's policies for dealing for manufacturers' deficiencies (see section VI above) also aims at identifying potential errors in data registered in the EU database and at working together with the manufacturer in correcting the errors.

X. SIGNED "APPLICANT'S UNDERTAKINGS" FORM

The Global Language of Business

[redacted]

January 21, 2019

Applicant's undertakings

[redacted] in my quality of legal representative in the European Union of GS1 AISBL, confirm that GS1 AISBL 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, GS1 AISBL, 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]

GS1 AISBL
Blue Tower
Avenue Louise 326, bte 10
B-1050 Brussels
T +32 (0)2 788 78 00
F + 32 (0)2 788 78 99
E contactus@gs1.org
TVA/BTW BE – 0419 640 608
Bank account: BE14-2100-0667-6783

www.gs1.org

XI. INFORMATION ON THE READABILITY OF UDI CARRIERS COMPLIANT WITH GS1

German hospital - warehouse. Medical consumables only.
Note: both samples (2018 and 2016) are statistically relevant, but the 2018 sample is significantly larger due to more people scanning and a more efficient scanning app.

Symbologies	2018		2016		Variance
GS1	796	86%	162	70%	**17%**
No barcode	45	5%	0	8%	1%
Non-GS1 (including internal barcodes)	80	9%	12	23%	-14%
Total	921		174		

Packaging Level	2018	2016
Single unit package / Blister	42	0
Primary	267	22
Secondary	549	150
Tertiary – Case or Shipper	63	2
Total	921	174
Product Category	**2018**	**2016**
Medical Consumables	921	174
Medicinal product IV	0	0
Medical Devices	0	0
Total	921	174

UK Hospital - combined analysis of three locations, Cardiology, Orthopaedics, General Theatres stores.
Note: sample sizes were between 400 to 600 in 2016, and 500 to 1200 in 2018 due to a more efficient scanning app.

Symbologies	2018	2016	Variance
GS1	83%	70%	**13%**
No barcode	9%	8%	1%
Non-GS1 (including internal barcodes)	9%	23%	-14%

Packaging Level	2018
Single unit package / Blister	880
Primary	915
Secondary	1105
Tertiary – Case or Shipper	21
Total	2921

Product Category	2018
Medical Consumables	1995
Medicinal product IV	903
Medical Devices	23
Total	2921

UK Hospital - Cardiology only

Symbologies	2018	2016	Variance
GS1	94%	86%	**8%**
No barcode	4%	8%	-5%
Non-GS1 (including internal barcodes)	2%	5%	-3%

Packaging Level	2018
Single unit package / Blister	0
Primary	116
Secondary	446
Tertiary – Case or Shipper	1
Total	563
Product Category	**2018**
Medical Consumables	517
Medicinal product IV	23
Medical Devices	23
Total	563

UK Hospital - Orthopaedics only

Symbologies	2018	2016	Variance
GS1	80%	57%	**23%**
No barcode	6%	0%	6%
Non-GS1 (including internal barcodes)	14%	43%	-29%

Packaging Level	2018
Single unit package / Blister	880
Primary	59
Secondary	128
Tertiary – Case or Shipper	0
Total	1067
Product Category	**2018**
Medical Consumables	187

Medicinal product IV	880
Medical Devices	0
Total	1067

UK Hospital - General theatres stores only

Symbologies	**2018**		**2016**	**Variance**
GS1	1033	80%	67%	**13%**
No barcode	174	13%	17%	-3%
Non-GS1 (including internal barcodes)	84	7%	16%	-9%
Total	1291	100%	100%	

Packaging Level	**2018**
Single unit package / Blister	0
Primary	740
Secondary	531
Tertiary – Case or Shipper	20
Total	1291
Product Category	**2018**
Medical Consumables	1291
Medicinal product IV	0
Medical Devices	0
Total	1291