MedTech Europe
from diagnosis to cure

European Unique Device Identification Database (EUDID)

Background paper
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Introduction

Unique Device Identification will become a mandatory requirement for medical devices over the next few years. The US Food and Drug Administration (FDA) has put in place legislation for identifying and tracking Medical Devices. The European Commission has released proposed legislation for the same purpose which will be finalised and come into effect over the next few years. In addition to this the International Medical Device Regulators Forum (IMDRF) has recently released guidance notes on this subject.

An essential part of all regulation, proposals and guidance documents mentioned above is a database that shall store information on devices and some key characteristics. Manufacturers shall submit information into this database prior to selling a device into a specific market.

This document is intended primarily to provide guidance from MedTech Europe to any regulatory agency (national or supranational) intending to develop a pan-European database, identified within this document as "EUDID". It further presents some information about the processes which may be necessary for submitting data to the database for device Manufacturers in Europe who will be responsible for providing data to the EUDID. The document reflects industry requirements and is based on current databases and recommendations from regulators i.e. FDA and organisations i.e. IMDRF.

In this context the document should also provide useful advice for governmental authorities and healthcare systems needing to respond to the challenge of Unique Device Identification.

Within this document, the word "should" denotes that the requirement is good practice/highly recommended, but is not mandatory; the word "shall" indicates that the requirement is mandatory.

Unique Device Identifier (UDI)

The “Unique Device Identifier” (UDI) will be created and maintained by the device manufacturer based on global device identification standards. The standard formats for the three prospective issuing agencies are provided in ***Appendix C***.

With certain exceptions, a UDI will be required to appear on the label of a medical device and be composed of two parts:

- Device Identifier (DI) - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device; and
- Production Identifier(s) (PI) – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device. This will be dependent upon the manufacturer’s internal quality system.
    - the lot or batch number within which a device was manufactured;
    - the serial number of a specific device;
    - the expiration date of a specific device;
    - the date a specific device was manufactured;

Therefore, **UDI = DI + PI.**

Within the EUDID only the static part (DI) of a UDI will be stored. The DI will be used to look up information about the device in the EUDID.

European Unique Device Identification Database (EUDID)

The EUDID should serve as the repository of key device identification information. The EUDID contains only the DI, which serves as the primary key to obtain device information in the database. PIs are not submitted to or stored in the EUDID; the EUDID will contain only production identifier flags to indicate which PI attribute(s) are on the device label.

The EUDID should contain only data elements which are necessary for the main purpose of UDI ('unambiguous device identification to support traceability'). The EUDID should also contain certain ancillary administrative data used to develop and maintain the EUDID, as well as to facilitate integration of DI information with other EU databases/link to other EU Member States (MS) databases/pillars of the Eudamed database. A complete list of EUDID attributes and descriptions are provided in ***Appendix B***. It is important to note that a majority of the data attributes in the EUDID appear on the medical device labelling/packaging (see example in ***Appendix D***). Data attribute values in the EUDID are intended to be consistent with their representation on the label. Furthermore, the data attribute values should be language neutral.

The design principles guiding EUDID development shall include the following:

- Standards-based submission with two options:
  - Structured input via the EUDID Web Interface
  - Health Level 7 (HL7) Structured Product Labelling (SPL)
- Standards-based data repository with controlled vocabularies including:
  - Dun & Bradstreet (D&B) Number (DUNS)
  - Global Medical Device Nomenclature (GMDN)
- Harmonisation with the IMDRF guidance list of attributes and as a minimum correspond to the US FDA GUDID
- Free and public access to the device information in EUDID via public search and web service capability.

EUDID Key Concepts

The EUDID key concepts should apply to both EUDID submission options – Web Interface and HL7 SPL XML file submission.

EUDID Account

Manufacturers which are required to submit information to the EUDID shall first request a EUDID account.

- A manufacturer may have one or more EUDID accounts. It is at the manufacturer's discretion to determine how many EUDID accounts are needed.
- Each EUDID account is identified by a DUNS Number; this DUNS number represents the manufacturer. It may be the headquarters DUNS number, or the parent DUNS number for the manufacturers included in the EUDID account. EUDID shall contain a real time mirror of the DUNS data code set, in order to ensure that recently edited company data within DUNS may be used immediately. EUDID data relating to DUNS information which is edited shall itself be updated in real time.
- Each account should have only one Regulatory Contact. A regulatory contact:
    - Is the individual responsible for management of EUDID submission requirements for the manufacturers in a given EUDID account?
    - Shall be contacted by EU Commission on matters pertaining to EUDID regulatory submission requirements.
- Each EUDID account shall have one or more Coordinators; the coordinator administrates EUDID account information and entries on behalf of the manufacturer.
    - Each Coordinator shall be assigned one or more manufacturing site, each identified by a DUNS number, in a given EUDID account.
    - Coordinators should manage the EUDID account for their designated manufacturing sites. Responsibilities include:
        - Creation of User account(s) using DUNS numbers (see below);
        - Creation of user role for a third-party (see below), as required;
        - Serving as User, as required.
- Each EUDID account shall have one or more manufacturing sites
    - Manufacturers shall be identified by DUNS numbers; device information would be submitted for the manufacturers identified in the EUDID account.
    - The manufacturer's name and address retrieved from D&B database and the name and address on the label should correspond.
- Each EUDID account shall have one or more Users.
    - Each User shall be assigned one or more manufacturing site, each identified by a DUNS number, in a given EUDID account.
    - Each User should be responsible for data entry, submission, and management of device identification information for their designated manufacturing site DUNS into the EUDID.

The manufacturer should have the option to designate third-party submitters for EUDID submissions. Third-party submitters are companies/individuals (contractors, vendors) authorised to submit EUDID information on behalf of the manufacturer.

Each EUDID account may have more than one third-party submitter.

- In order to enable third parties to submit to EUDID:
  - Manufacturers should identify the third-party in their EUDID account by providing third-party DUNS number(s) to the European Commission during EUDID account request.By identifying the third-party, the manufacturer authorises the third-party to submit EUDID information on its behalf.
  - EUDID HL7 SPL submissions by third-parties not identified in a EUDID account should be rejected.
- EUDID Coordinators may provide third parties with User accounts, as required.

The EUDID account user contact information should be used for internal European Commission purposes only; this information shall not be made public.

Submission of device information to EUDID shall require an established EUDID account, regardless of the submission option chosen – via web interface or electronic submission gateway as HL7 SPL XML files. The EUDID account shall not be submission type-specific, e.g. a separate EUDID account shall not be needed for each submission option. The account identifies the manufacturer in EUDID and enables submission of device information via both options.

Search and retrieval of EUDID information, both via web interface and web service, should not require a EUDID account.

Device Identifier Record

The Device Identifier (DI), together with associated data attributes, constitutes a DI Record in the EUDID which shall contain identifying information for a particular device version or model.

The following shall be key characteristics of a DI Record in EUDID (regardless of the submission option):

- EUDID shall only contain the DI; the PI is never part of the EUDID. However, the EUDID shall contain production identifier *flags*, which indicate the PI attribute(s) used according to the manufacturer's quality system (lot or batch number, serial number, expiration date, and manufacturing date).
- Primary DI: Each DI record shall have a Primary DI, which is the primary key for the record. This is the DI of the lowest level of a medical device package containing a full UDI. The lowest packaging level is also the base package.

- The DI record may also contain additional device identifiers:
  - Unit of Use DI: A virtual identifier assigned to an individual medical device when a UDI is not labelled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device. The package configuration example in ***Appendix A***, Figure 1 includes a Unit of Use DI.
  - Direct Marking DI: An identifier that is marked directly on the device; only required if different from the Primary DI.
  - Package DI: A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).
- All DIs shall be checked for uniqueness in the EUDID; although the same 'Unit of Use DI' should be allowed to be allocated to more than one DI Record. Once used, a DI shall not be reused for another product, even if the product is no longer in commercial distribution.
  - When the *Manufacturing End Date* is in the past, the device shall be considered no longer held or offered for sale by the manufacturer. The device may or may not still be available for purchase in the marketplace until stock is depleted or expiration date is reached
  - The device shall still be in the database and available via public search, but shall be noted as "no longer manufactured"
- Package information for a particular version or model of a device is part of the DI record.

Package Information in EUDID

A device package is a package which contains a fixed quantity of a particular version or model of a device. In order to adequately identify a device throughout distribution and use, the various package configurations, i.e. each different type of package, must have a unique identifier. Thus, if a device is sold in individual device packages, which are sold in boxes of thirty (30) device packages, which are sold in cartons that contain twelve (12) boxes of thirty (30) device packages, a different DI would be required on the individual device package, on the box of thirty packages, and on the carton of twelve boxes of thirty device packages. The DI assigned to the individual device package will remain the same independent of the packaging hierarchy. See ***Appendix A*** for reference.

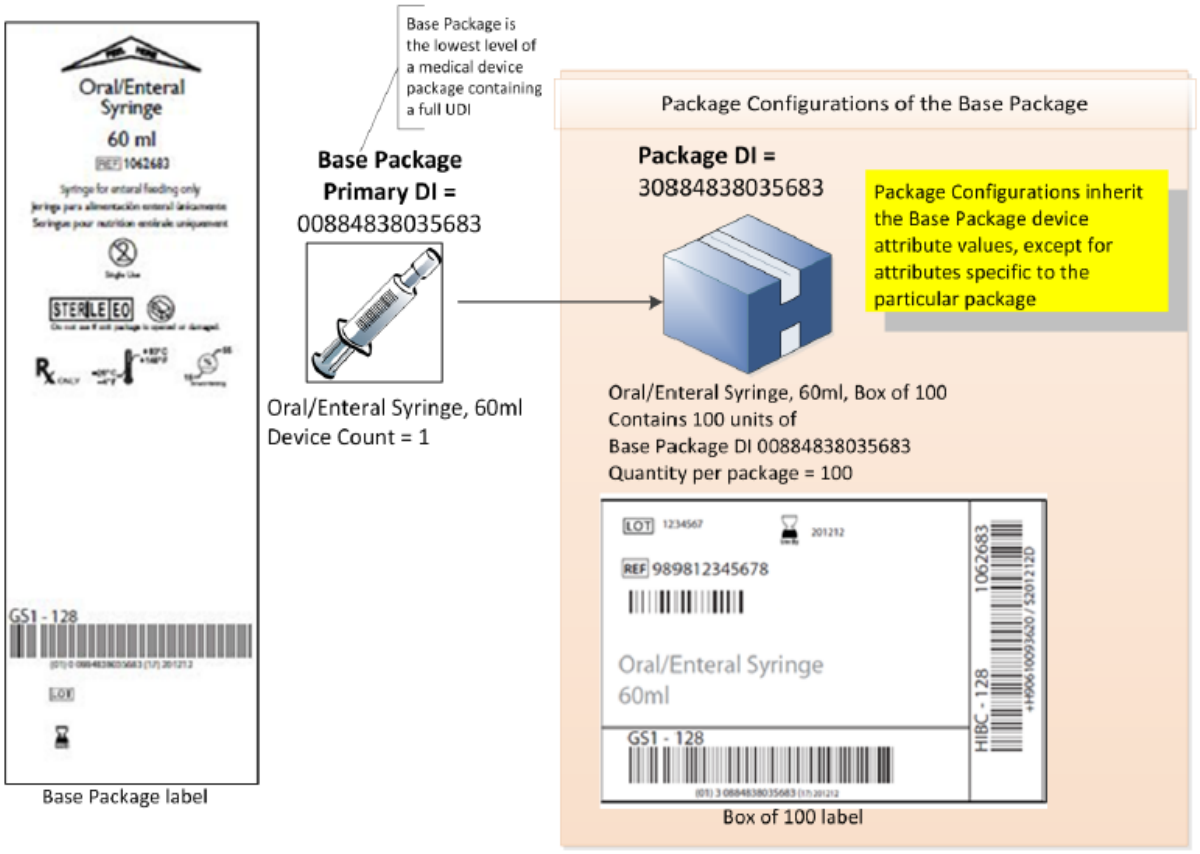
The following are key points to note regarding package information in EUDID:

- The Primary DI number identifies the base package.
- The Device Count attribute provides the number of medical devices in the base package.
- Package configurations of the base package are part of the base package DI record.
- Package configurations inherit base package attribute values, except for attributes specific to that particular package. Therefore, attribute information needs to be provided only once and applies to all packages. The attributes specific to a package include:
  - Package Device Identifier – DI for the particular package configuration. Contains DI Package: what is the DI for the package inside this package?
  - Quantity per Package - how many packages of the next lower level are inside this package?
  - Package Type - optional text that describes the type of packaging of the product (box, carton, etc.) and assists users to understand the higher-level packaging configurations.

The following figure provides a package configuration example for EUDID where the DI is on the individual device with one package level.

- Oral/ enteral syringe, each with Primary DI 00884838035683 and *Device Count* = 1.
- Box of 100 syringes, with Package DI 30884838035683 (contains 100 units of Primary DI 00884838035683).

Package 30884838035683 inherits all attribute values of base package 00884838035683, except for the attributes specific to 30884838035683, as shown in the table below.



Base Package

Primary DI	Device Count
00884838035683	1

Package Information

Package DI	Quantity per Package	Contains DI Package	Package Type
30884838035684	100	00884838035683	Box

Global Medical Device Nomenclature (GMDN)

Each DI record in EUDID should require entry of one or more GMDN Preferred Term (PT) codes.

GMDN is a system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency. GMDN has been developed over the past 20 years as a vocabulary that represents the whole medical device arena, including such specialties as dental products, laboratory equipment, in vitro diagnostics, and biologic devices with cellular or tissue origins.
The following should be ensured:

- EUDID shall only allow active Preferred Terms (PTs) to be submitted.
- EUDID shall contain a real time mirror of the GMDN data code set, in order to ensure that newly assigned GMDN codes may be used immediately for EUDID entry.
- EUDID entries containing GMDN codes which are withdrawn by GMDN, shall trigger a communication to the regulatory contact of the DI record to allow update the EUDID.

Device Identifier Record Life-Cycle

The EUDID DI Record Life-Cycle should comprise the various states of a DI record and the associated business rules and functionality available to a user.

DI Record States

A DI record shall be in one of three DI record states at any given time. The DI record state determines the applicable business rules and the EUDID functionality available to Users.

A new DI record may be saved in one of the following three DI record states: *"Draft DI Record"*, *"Unpublished DI Record"*, or *"Published DI Record"*.

Draft DI Record: enables Users to create and save an incomplete DI record via the EUDID Web Interface. The Draft DI record state shall only be applicable to the EUDID Web Interface option. HL7 SPL submissions shall not be submitted as Draft DI records.

A Draft DI record:

- Should not have to pass any data validation rules prior to being saved as a draft DI record.
- Shall be able to be edited an unlimited number of times.
- Shall be able to be saved in the Draft DI record state for 180 calendar days; if the record remains in the draft DI state after 180 calendar days, it will be "purged", i.e., permanently removed from the EUDID. Please note that the 180-day cycle should be reset and start over each time the draft DI record is edited and re-saved as a draft.
- Shall be able to be viewed/edited only by the user who created the record.
- Shall not be available for public search and retrieval.

A Draft DI record shall have to pass *Review*, i.e., pass data validation rules to be eligible for promotion to other DI record states as follows:

- Unpublished state means Publish Date is in the future.
- Published state means Publish Date is today or in the past.

Unpublished DI Record: enables users to pre-populate data to complete a DI record prior to the EUDID submission date.

An Unpublished DI record:

- Shall have passed all data validation rules.
- Shall have not reached the *Publish Date*
- Shall be able to be copied to create new DI records, to enable reduction of data entry time; all attributes except for the Primary DI number can be copied.
- Shall be able to be edited an unlimited number of times; and once edited, the record shall be revalidated. Shall not be available for public search and retrieval.
- Shall be checked by an automated EUDID process, and when the *Publish Date* is reached, the record shall be published.

Published DI Record: a DI record that is available for search and retrieval by the public.

A Published DI record:

- Shall have passed all data validation rules.
- Shall be available for public search and retrieval.
- Shall have a Publish Date which is today or in the past. Please note that a DI record entered with a Publish Date of today, shall be available for public search immediately.
- Shall be able to be copied to create new DI records, enabling reduction of data entry time; all attributes except for the Primary DI number would be copied.
- Shall not be able to be moved to any other DI record state without EU Commission staff intervention.

Published DI records for devices removed from manufacture shall remain in the published state and shall be available for public search and retrieval. The *Manufacturing End Date* shall be auto-populated by the system based on *Discontinued* as shown below.

- When the Manufacturing End Date is today or in the past, the Manufacturing Status shall be “Discontinued” When the Manufacturing End Date is in the future or not populated, the Manufacturing Status shall be ”Live”

EUDID Modules

The EUDID shall provide two options for submission of device identification information:

- Manually entry (submission) of one DI record at a time via the secure EUDID Web Interface.
- Electronically submission per XML file via the HL7 SPL submission option.

Both options shall require a EUDID account.

EUDID shall allow either option to be used in order to maintain the data of the same device record (e.g. data submitted via HL7 SPL can be changed via Web Interface and vice versa).

EUDID shall provide at least the two following information retrieval options for published DI information:

- Search and retrieval of device information via the web interface
- System to system search and retrieval via web service

EUDID accounts shall not be required for search and retrieval of published information.

EUDID Web Interface

The EUDID Web Interface module shall have the following functions:

EUDID Account Management Module

The Account Management module shall enable the creation and management of EUDID accounts.
The EUDID account concept shall be based on DUNS numbers (similar to the US FDA's guidance on GUDID).

A EUDID account shall be required for submitters of device information, e.g. manufacturers, regardless of the submission option chosen, EUDID Web Interface or HL7 SPL XML file submission.

EUDID Device Identifier Module

The DI module shall enable the creation and management of DI records.

Functions:

- The creation DI records.
- Saving, editing, and managing Draft DI records.
- Reviewing and validation of DI records against system validation rules.
- Copying of Unpublished and Published DI records.
- Editing and management of Unpublished and Published DI records.
- Searching and retrieval of all attributes of DI records for their assigned DUNS numbers.
- Downloading in bulk of the manufacturers own data

HL7 SPL Submission

The HL7 SPL Submission option shall enable companies to electronically submit device information one DI record at a time as an HL7 SPL XML file. Detailed technical specifications on the HL7 SPL submission option should be described in separate document.

In order to minimize the risk of technical errors during productive data exchange the European Commission should:

- provide a test environment (Test-EUDID and data exchange gateway)
- and to describe the testing process and requirements.

Companies that choose the HL7 SPL submission option would need to do the following:

- Establish a EUDID account.
- Perform tests via the EUDID test environment and achieve successful results.

Search/Retrieval of Device Information

The EUDID Search and Retrieval module shall allow various user types e.g. from regulators to general public to access data relevant to their requirements. Published data shall include all DI record attributes with the exception of a few such as: DUNS Number, Company Physical Address, GMDN Preferred Term Code, registration numbers, etc.

There shall be two Search and Retrieval options available in EUDID:

- Search and retrieval of device information via the web Interface
- System to system search and retrieval via web service

There shall be no EUDID accounts required for search or download of published information.

EUDID Web Interface Search and Retrieval

The EUDID Web Interface search and retrieval module shall provide the ability to:

- Search published EUDID data
- View results
- Export results as XML files

Two search options shall be available via the EUDID Web Interface:

- Quick Search – should allow search on the following fields: DI, Company Name, Brand Name, and Model or version.
- Advanced Search – should allow search on all EUDID attributes relevant to the specific user types.

All EUDID web based functionalities shall be platform independent, and not affected by operating system or browser choice.

EUDID System to System Search and Retrieval via Web Interface

EUDID shall provide basic web service functionality to access published device information. Key characteristics of the web service shall be:

- Simple Object Access Protocol (SOAP) based web service accessible via a secure interface such as HTTPS.
- The web service input shall accept only one DI number per request. The following types of DI numbers shall be supported: Primary DI, Secondary DI, Unit of Use DI, Direct Marking DI, and Package DI.
- The web service shall return attributes that are available for retrieval in XML format for the requested DI number type.

Additional considerations:

- We encourage the European Commission to establish rules in relation to mergers / acquisitions and data in EUDID, in conjunction with industry.
- The information entered in EUDID, shall remain the intellectual property of the manufacturer and shall not be used for any commercial purposes by any third party (or prior authorisation from the intellectual property owner)

Appendix A - EUDID Package Information Examples

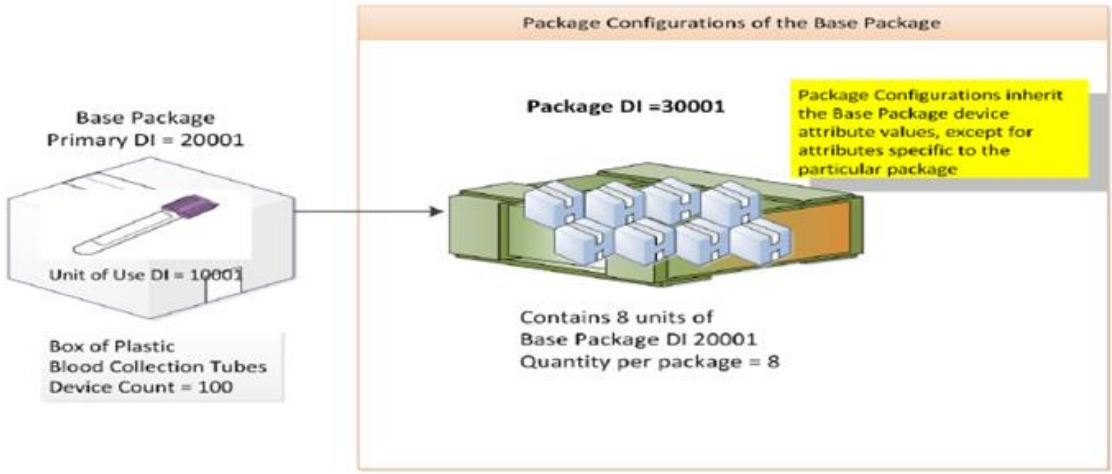
The examples below illustrate how package information should be entered into the EUDID along with attribute values pertinent to packages.

Example 1: Unit of Use DI with one Package Level

The figure below provides a package configuration example for EUDID where the medical device has Unit of Use DI Number and one package level.

- Box of 100 single use blood collection tubes with the Primary DI 20001 and Device Count = 100. Note that the tubes themselves do not have the DI on them; therefore each tube gets a virtual Unit of Use DI 10001.
- Carton of 8 boxes (800 total), with Package DI 30001 (contains 8 of Primary DI 20001), Quantity per Package = 8.
- Package Discontinue Date is blank, therefore system auto-populates Package Status to “In Commercial Distribution.”

Package 30001 inherits all attribute values of base package 20001, except for the attributes specific to 30001 such as Quantity per Package, as shown in the table below.



Base Package

Primary DI	Device Count
1001	1

Package Information

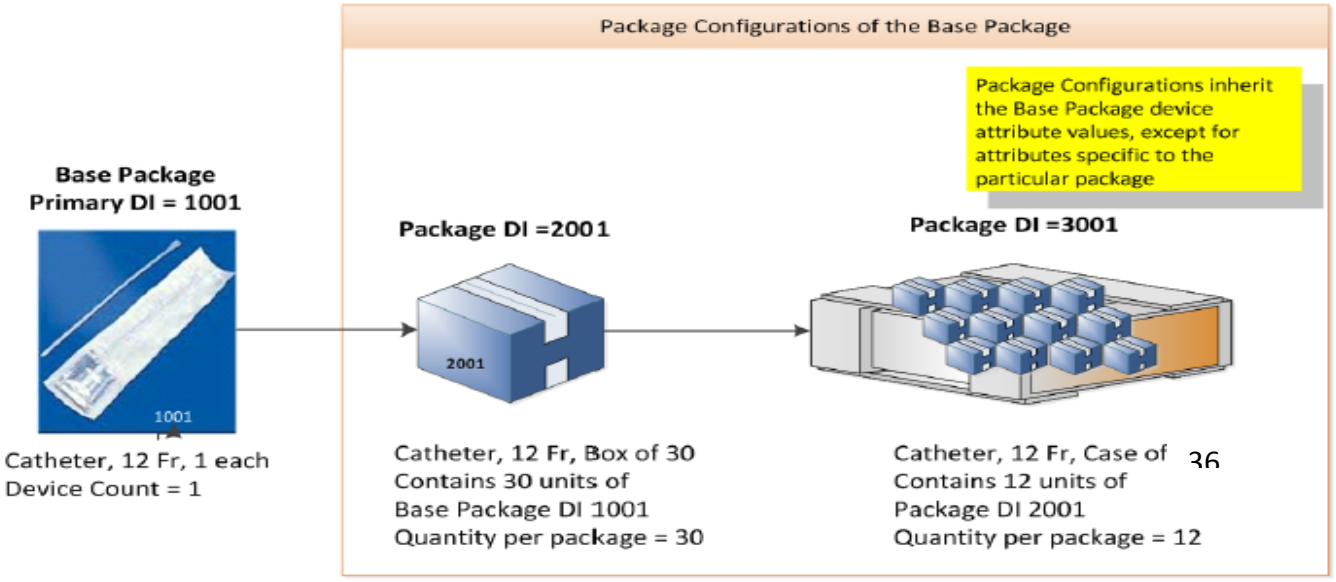
Package DI	Quantity per Package	Contains DI Package	Package Type
30001	8	2001	Carton

Example 2: DI on individual device with two Package Levels

The figure below provides a package configuration example for EUDID where the DI is on the individual device with two package levels.

- Catheter, 12 Fr, each with Primary DI 1001 and Device Count = 1.
- Box of 30 catheters with Package DI 2001 (contains 30 of Primary DI 1001).
- Carton of 12 boxes, with Package DI 3001 (contains 12 of Package DI 2001).
- Package Discontinue Date is blank, therefore system auto-populates Package Status to “In Commercial Distribution.”

Package 2001 and 3001 inherit all attribute values of base package 1001, except for the attributes specific to 2001 and 3001, as shown in the table below.



Base Package

Primary DI	Device Count
1001	1

Package Information

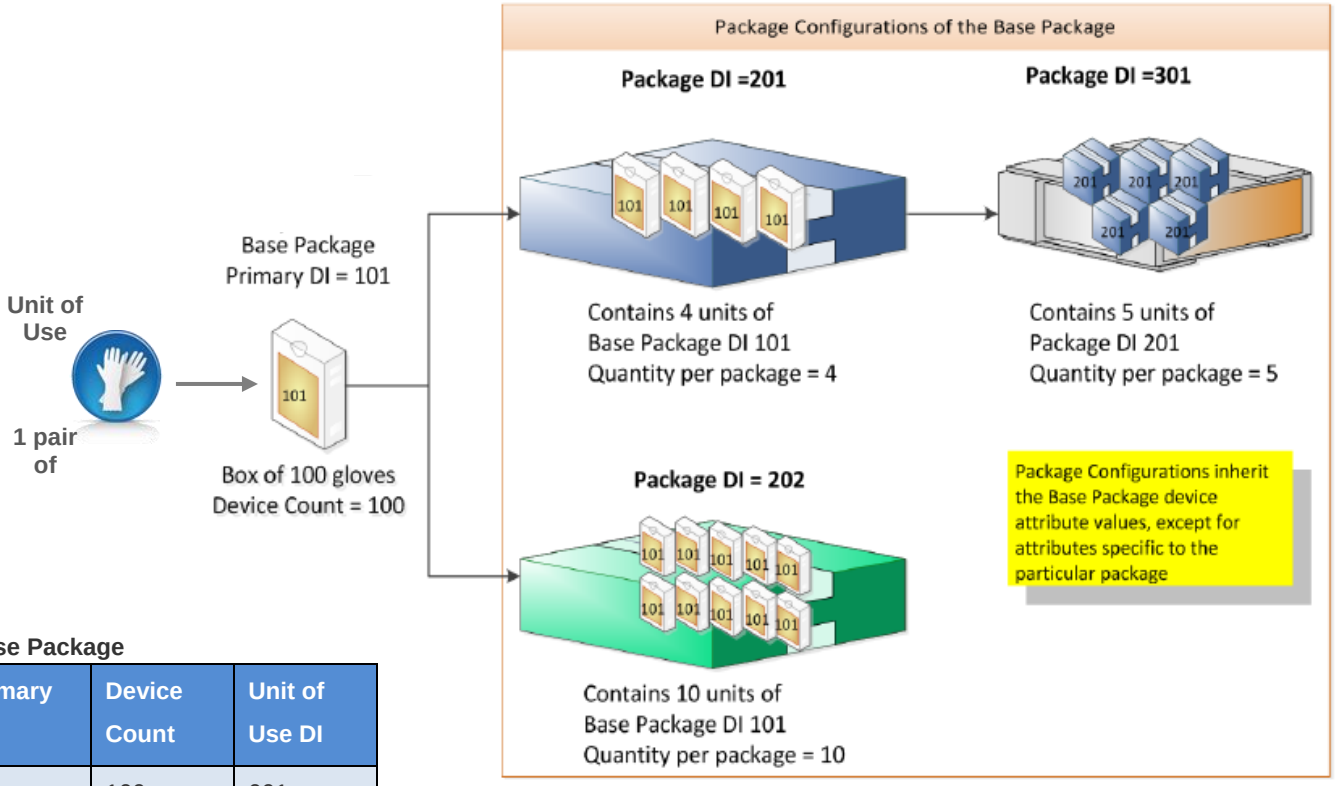
Package DI	Quantity per Package	Contains DI Package	Package Type
2001	30	1001	Box
3001	12	2001	Carton

Example 3: DI not on individual device with Multiple Package Levels

The figure below provides a package configuration example for EUDID where the DI is NOT on the individual device with multiple package levels.

- Gloves, box of 100, Primary DI 101 and Device Count = 100.
- Carton of 4, with Package DI 201 (contains 4 of Primary DI 101).
- Case of 5, with Package DI 301 (contains 5 of Package DI 201).
- Carton of 10, with Package DI 202 (contains 10 of Package DI 101).
- Package Discontinue Date is blank, therefore system auto-populates Package Status to "In Commercial Distribution."

Packages 201, 301 and 202 inherit all attribute values of base package 101, except for the attributes specific to 201, 301 and 202, as shown in the table below.



Base Package

Primary DI	Device Count	Unit of Use DI
101	100	001

Package Information

Package DI	Quantity per Package	Contains DI Package	Package Type
201	4	101	Box
301	5	201	Case
202	10	101	Carton

Appendix B - EUDID list of attributes

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Issuing Agency	Organization accredited by EU to operate a system for the issuance of UDIs.	Choose a value from the drop down.	single	MAN	alphanum, 30	GS1; HIBCC; ICCBBA	Yes
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing a full UDI.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	single	MAN	numeric or alphanum. 6-23 characters		Yes
Device Count	Number of medical devices in the base package. For example : Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	Enter a numeric value.	single	MAN	numeric, 7		Yes
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.	single	MAN - if device count is > than 1	numeric or alphanum. 6-23 characters		No
Manufacturer DUNS Number	Business number issued by Dun & Bradstreet (D&B) that matches the Labeler (Company) name on device label.	Choose appropriate DUNS Number from drop down.	single	MAN	numeric, 9	from DUNS in real time	No

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Manufacturer Name	Company name associated with the manufacturer DUNS Number entered in the DI Record. This name should match the company name on the device label.	System populated	N/A	N/A	N/A		N/A
Manufacturer physical Address	Company physical address associated with the DUNS Number entered in the DI. This address should match the address on the device label.	System populated	N/A	N/A	N/A		N/A
Authorised Representative/ Importer DUNS Number	Business number issued by Dun & Bradstreet (D&B) that matches the Authorised Representative/Importer (Company) name label.	Choose appropriate DUNS Number from drop down.	N/A	OPT	numeric, 9	from DUNS in real time	No
Authorised Representative/ Importer Name	Company name associated with the Authorised Representative/Importer DUNS Number entered in the DI Record.	System populated	N/A	N/A	N/A		N/A
Authorised Representative/ Importer physical Address	Company physical address associated with the Authorised Representative/Importer DUNS Number entered in the DI.	System populated	N/A	N/A	N/A		N/A
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered and have the ® and/or TM symbol.	Enter the name of the device. Only the ® and ™ symbols will be supported for the production release.	N/A	OPT	alphanum and symbols, 80		No
Device Version or Model Number	The version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model means all devices that have specifications, performance, size, and composition, within limits set by labeler.	Enter an alphanum. value.	single	MAN - if Software (standalone)	alphanum, 40		Yes

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
REF Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter an alphanum. value.	single	OPT	alphanum, 40		No
DI Record publish Date	Indicates the date the DI Record gets published and is available via Public Search.	Choose date from calendar or manually enter in format (dd/mm/yyyy).	single	MAN	numeric date format, 8		No
Manufacturing End date	Indicates the date the device is no longer manufactured.	Choose date from calendar or manually enter in format (dd/mm/yyyy).	single	OPT	numeric date format, 8		No
Manufacturing Status	Indicates whether the device is currently manufactured	System populated	N/A	N/A		Discontinued / Live	No
DM DI different from Primary DI	Indicates that the DM DI Number is different from the Primary DI Number.	Select checkbox if appropriate.	single	OPT	Boolean		No
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements .	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	single	MAN - if check box for 'DM DI different from Primary DI'	numeric or alphanum. 6-23 characters		No

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers). For example: 4 glove boxes in a Carton -- Package DI =201 (the UDI on the Carton) 5 Cartons in a Case -- Package DI=301 (the UDI on the Case) contains a 5 cartons (with DI 201) with 4 glove boxes in a carton 10 glove boxes in a Carton -- Package DI=202 (the UDI on the Carton).	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	multiple per package higher the base pack	MAN - if Package Configuration is entered	numeric or alphanum. 6-23 characters		No
Quantity per Package	The number of packages with a unique primary DI within a given packaging configuration. For example: Package configuration Carton with Package DI=201 contains 4 boxes of the base package DI=101, the quantity per package is 4; Package configuration Case with Package DI=301 contains 5 cartons of Package DI=201, the quantity per package is 5. Package configuration Carton with Package DI=202 contains 10 boxes of the base package DI=101; the quantity per package is 10.	The quantity of a package configuration needs to be greater than 1.	multiple per package higher the base pack	MAN - if Package Configuration is entered	numeric, 9		Yes
Contains DI Package	The primary DI for the base package or any lower level package configuration contained within a given package configuration. For example: Package DI=201 and Package DI=202 contain the base package Case with primary DI=101; Package DI=301 contains lower level package configuration of a Carton with Package DI=201.	Choose a value from the drop down.	multiple per package higher the base pack	MAN - if Package Configuration is entered	numeric or alphanum. 6-23 characters		No
Package Type	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	Choose a value from the drop down.	multiple per package higher the base pack	OPT	alphanum, 20		No

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Support Contact Phone	Phone number for the support contact.	For international numbers, start with "+" Does not require the use of () or -, but can enter these symbols.	multiple	MAN	numeric, 20		No
Support Contact eMail	Email for the support contact.	Enter alphanumeric email address in format ---@--.--	multiple	MAN	alphanum, 100		No
GMDN Code	Unique numerical five-digit code used to generically identify medical devices and related health care products.	Enter all applicable GMDN Preferred Term Codes.	single	OPT	numeric, 5	GMDN list	No
GMDN Name	Name associated with the GMDN Preferred Term Code.	System populated based on GMDN Preferred Term Code	N/A	OPT	alphanum	GMDN list	No
GMDN Definition	Description associated with the GMDN Preferred Term Code.	System populated based on GMDN Preferred Term Code	N/A	OPT	alphanum	GMDN list	No
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	Yes
Controlled by Lot/Batch	Flag to indicate the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Controlled by Manuf. Date	Flag to indicate the device is managed by date of manufacture; the date a specific device was manufactured.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No
Controlled by Exp. Date	Flag to indicate the device is managed by expiration date; the date by which the label of a device states that the device must or should be used.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No
Controlled by Serial No	Flag to indicate the device is managed by serial number. This number can be found on the device label or packaging. The serial number is assigned by the labeler and should be specific to each device.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No
Device containing Latex	Indicates that the device or packaging contains Latex.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No
Device containing DEHP	Indicates that the device or packaging contains DEHP.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	No
Device labeled for MRI Safety	Indicates that sufficient testing has been conducted to characterize the behavior of the device in the MR environment.	Check box if appropriate	single	MAN	Boolean	Yes/No	No
MRI Safety Status	Indicates the MR safety status of the device.	Must select one value from drop-down if selected check box for "Has the device been evaluated for MRI Safety?"	single	MAN - if selected check box for 'Device labeled for MRI Safety'	N/A	MR Safe; MR Unsafe; MR Conditional	No

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Clinically rel. Size Type	Dimension type for the clinically relevant measurement of the medical device.	Choose a value from the drop down.	multiple	OPT	N/A	Circumference; Depth; Device Size; Text, specify; French Catheter Gauge; Greatest Diameter; Height; Length; Lumen Diameter; Needle Gauge; Second Greatest Diameter; Third Greatest Diameter; Total Volume; Width	No
Clinically rel. Size Value	Numeric value for the clinically relevant size measurement of the medical device.	Enter numeric value.	multiple per Size Type or Size Type Text	MAN - if Size is provided	numeric, 40		No
Clinically rel. Size Unit of Measure	The unit of measure associated with each clinically relevant size.	Choose a value from the drop down.	multiple per Size Type or Size Type Text	MAN - if Size is provided	numeric, 20	For lengths: Centimeter; Cubic Inch; Decimeter; Feet; Femtometer; French; Inch; Kilometer; Meter; Microliter; Micrometer; Millimeter; Nanometer; Picometer; Pint; Square Centimeter; Square Feet; Square Inch; Square Meter; Square Millimeter; Ton; Yard For 'Total Volume': Centiliter; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Micrograms per Total Volume; Milligrams per Total Volume; Milliliter; Nanoliter; Picoliter; Quart; Units per liter	No
Clinically rel. Size Type Text	Additional undefined device size not represented in the EUDID clinically relevant size list.	Enter size type in addition to units and value.	multiple	OPT	alphanum, 200		No
Device packaged Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose a value from the drop down.	single	MAN	Boolean	Yes/No	Yes

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Device requires Sterilisation prior to use	Indicates that the device requires sterilization prior to use.	Choose a value fron the drop down.	single	MAN	Boolean	Yes/No	Yes
Sterilisation Method	Indicates the method(s) of sterilization that can be used for this device.	Choose a value from a drop down.	multiple	MAN - if check box for 'Dev requires Sterilisation prior to use'		Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; Hydrogen Peroxide; Microwave Radiation; Moist Heat or Steam; Ozone; Peracetic Acid; Radiation; Sound Waves; Ultraviolet Light	No
Labelled "do not re-sterilise"	Indicates whether the device can be re-sterilised	Choose a value from a drop down.	single	MAN	Boolean	Yes/No	Yes

Appendix C - UDI Specification by Issuing Agency

GS1 Issuing Agency

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
1	(01)	DI	Numeric	16	14
GS1	(11)	Manufacturing Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Lot Number	Alphanumeric	22	20
GS1	(21)	Serial Number	Alphanumeric	22	20
GS1		*Base UDI*	*Alphanumeric*	*76*	*66*
Ex of Human Readable Barcode: (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234					
The maximum number of characters in a database would be 66, while the maximum characters encoded in AIDC (barcode) would be 76. The parentheses are not encoded in the barcode. The difference is the removal of the digits in the Application Identifiers.					
This max number of characters is AIDC would require either two GS1 128s or one GS1 DataMatrix.					
None of the other GS1 standardised symbologies could carry the total number of 76.					
The average length for lot numbers is 7-9; the average length for serial number is 12.					

Health Industry Business Communications Council (HIBCC) Issuing Agency

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	+	DI	Alphanumeric	7-24	6-23
HIBCC	$	Lot Number Only	alphanumeric	19	18
HIBCC	$$	Expiration Date followed by Lot Number	Exp Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed by Lot Number	Exp Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$4	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	$$5	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	$$6	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	alphanumeric	20	18
HIBCC	$$+	Expiration Date followed by Serial Number	Exp Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	$$+2	Expiration Date followed by Serial Number	Exp Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+3	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+4	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	$$+5	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	$$+6	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	alphanumeric	20	18

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC		***Base UDI***	***alphanumeric***	***70-87***	***58-75***
Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ4567890123 45678/16D20130202C					
87 is the maximum possible data string encoded in the barcode, including the identifying symbols and the separator "/". The identifying symbols are not included in the database field size.					
The max possible data string is where expiry date is formatted as YYMMDDHH and the barcode includes a lot number and serial number and Manufacture date.					

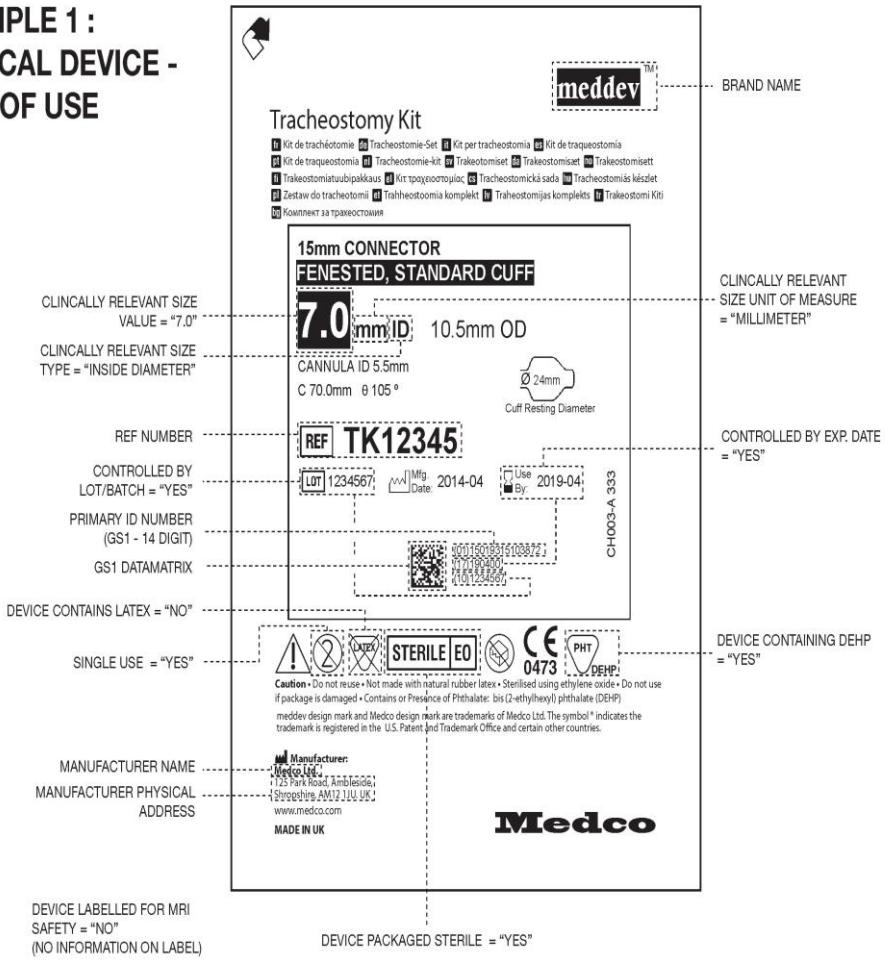
International Council for Commonality in Blood Banking Automation (ICCBBA) Issuing Agency

Issuing Agency	Identifying Symbol	Identifier	Data	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	alphanumeric	18	16
ICCBBA	=,	Serial Number	alphanumeric	8	6
ICCBBA	=	Donation Identification	alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing	numeric [YYYJJJ]	8	6
ICCBBA		***Base UDI for***	***alphanumeric***	***58***	***49***
Ex of Human Readable Barcode: =/A9999XYZNN1T7049=,000025=A99971312345600=>014032=}013032					
ICCBBA	=)	DI for blood	alphanumeric	12	10
ICCBBA	&)	Lot Number for blood	alphanumeric	12	10
ICCBBA		***Base UDI for blood***	***alphanumeric***	***24***	***20***
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					
Blood bags would have a different UDI format compared to HCT/P products regulated as a device; note that blood bags are being labelled with a DI Number and a lot number.					

Appendix D - Label samples

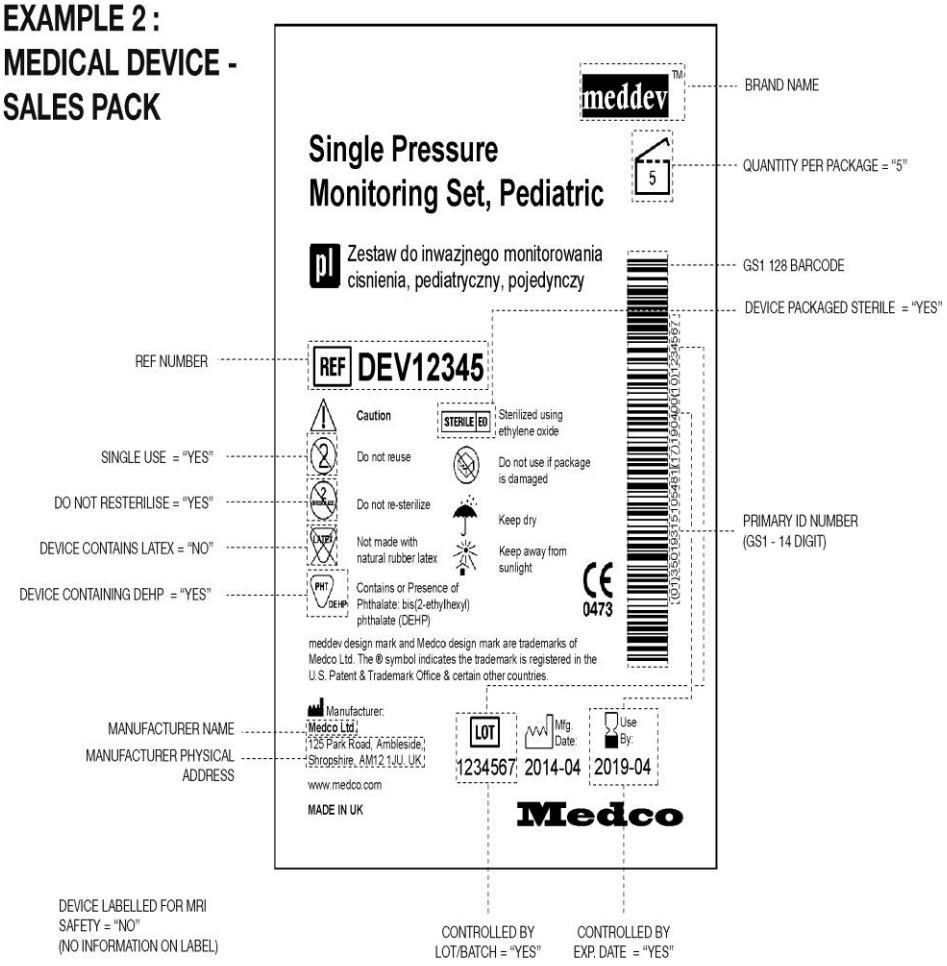
EUDID DATA ATTRIBUTES SHOWN ON TYPICAL PRODUCT LABELLING

EXAMPLE 1 : MEDICAL DEVICE - UNIT OF USE



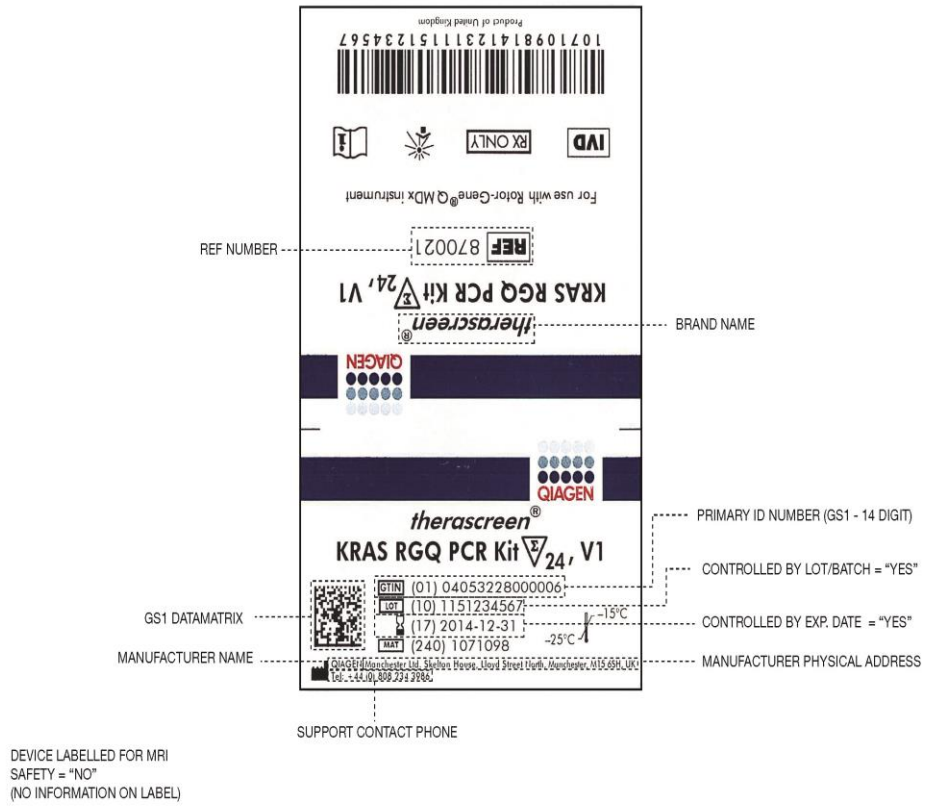
EUDID DATA ATTRIBUTES SHOWN ON TYPICAL PRODUCT LABELLING

EXAMPLE 2 : MEDICAL DEVICE - SALES PACK



EUDID DATA ATTRIBUTES SHOWN ON TYPICAL PRODUCT LABELLING

EXAMPLE 3 :
IVD - SALES PACK



Abbreviations Acronyms

Term	Description
DI	Device Identifier
D&B	Dun & Bradstreet
DUNS	Data Universal Numbering System
ESG	Electronic Submissions Gateway
GMDN	Global Medical Device Nomenclature
EUDID	European Unique Device Identification Database
GS1	GS1® – not-for-profit association dedicated to design global standards
ICCBBA	International Council for Commonality in Blood Banking Automation
HIBCC	Health Industry Business Communications Council
HL7	Health Level 7
PI	Production Identifier
GMDN PT	GMDN Preferred Term
SPL	Structured Product Labelling
UDI	Unique Device Identifier
XML	Extensible Mark-up Language

Glossary

Term	Description
Base Package	The lowest level of a medical device package containing a full UDI. The DI on the base package is the Primary DI.
Coordinator	Individual(s) responsible for management of the EUDID account, for designated Labellers.
Data Universal Numbering System (DUNS)	A unique 9-digit identification number assigned and managed by Dun & Bradstreet to business entities.
Device Identifier (DI)	A mandatory, fixed portion of a UDI that identifies the labeller and the specific version or model of a device.
Device Identifier Record (DI Record)	The DI, together with associated data attributes constitutes a DI record for a particular device version or model.
DI Record Life-Cycle	Comprises of the various states of a DI record and the associated business rules and functionality available to a user.
DI Record States	A DI Record is in one of three DI Record States at any given time: Draft DI Record, Unpublished DI Record, or Published DI Record.
Direct Marking DI	An identifier that is marked directly on the device; can be the same as or different from the Primary DI.
Device Package	A package that contains a fixed quantity of a particular version or model of a device.
Draft DI Record	Saved DI record that has not passed business rules.
Global Medical Device Nomenclature (GMDN)	A system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency.
EUDID	Global Unique Device Identification Database, the repository of device identification information for devices specified under the UDI Final Rule.
EUDID Account	A EUDID account enables companies to access and submit information to the EUDID.
EUDID Web Interface	An online interface that enables secure account creation, secure submission of DI records, and search and retrieval of device information.
Health Level 7 (HL7)	A standards development organization, whose mission is to provide messaging standards for interoperability, exchange, management, and integration of data that supports clinical patient care and the management, delivery, and evaluation of healthcare services.
Issuing Agency	Organization accredited by the EU Commission to operate a system for the issuance of UDIs.

User	Individual(s) responsible for day to day entry, submission and management of device identification information for designated DUNS into the EUDID.
New DI Trigger Attributes	Attributes, which when changed, no longer represent the same device thereby requiring the creation of a new DI.
Package DI	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).
Primary DI	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The Primary DI will be located on the base package, which is the lowest level of a medical device containing a full UDI.
Production Identifier(s) (PI)	A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured.
Published DI Record	A DI record that is published, and therefore is available for search and retrieval by the public.
Regulatory Contact	Individual responsible for management of EUDID submission requirements for the manufacturer in a given EUDID account.
Secondary DI	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.
Published DI Record	A DI record that is published, and therefore is available for search and retrieval by the public.
Regulatory Contact	Individual responsible for management of EUDID submission requirements for the manufacturer in a given EUDID account.
Secondary DI	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.
Structured Product Labelling (SPL)	A HL7 standard for the exchange of product information using extensible mark-up language.

Support Contact	Contact for consumers and healthcare providers to obtain additional information about the device.
Third-party submitters	Companies/individuals (contractors, vendors) authorised to submit EUDID information on behalf of the manufacturer.
Unique Device Identifier (UDI)	A unique numeric identifier composed of the device identifier and production identifier(s) that uniquely identify a medical device through distribution and use.
Unit of Use DI	An identifier assigned to an individual medical device when a UDI is not labelled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.
Unpublished DI Record	DI record that has passed EUDID business rules *AND* Publish Date > today.

About MedTech Europe

MedTech Europe is an Alliance of European medical technology industry associations. The Alliance was founded in October 2012 and currently has two members being EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. MedTech Europe, EDMA and Eucomed remain separate entities but are led by one joint Chief Executive and work closely together on common policy interest areas. For more information visit www.medtecheurope.org

About EDMA

Committed to raising awareness of the important role of diagnostics in the entire healthcare equation, the European Diagnostic Manufacturers Association (EDMA) provides services and activities to members engaged in the research, development, manufacturing or distribution of in vitro diagnostic (IVD) products in Europe. Founded in 1979, EDMA advocates for an appropriate regulatory system and a realistic economic environment for healthcare in Europe. For more information visit www.edma-ivd.eu.

About Eucomed

Eucomed is the European medical technology industry association. Its mission is to make modern, innovative and reliable medical technology available to more people. Eucomed represents directly and indirectly 25,000 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Small and medium sized companies make up more than 95% of this sector. The market size is estimated at roughly €100 billion while around 8% of sales revenue is ploughed back into research and development. The industry employs more than 575,000 highly skilled workers. For more information visit www.eucomed.org.