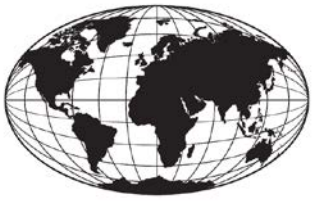

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT
(for Annex E and F)

Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

Authoring Group: IMDRF Adverse Event Terminology Working Group

Date: 12 July 2018

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Preface

This guidance document was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

1. Introduction

This document has been prepared by the IMDRF Adverse Event Working Group, charged with developing a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).

Widespread use of a single, appropriate adverse event terminology and coding system is expected to improve signal detection by adverse event management systems enabling a faster response by both industry and regulatory authorities.

Use of defined **terms** as well as associated **codes** to describe problems encountered with medical devices provides several benefits:

(1) it improves the accuracy of capturing and reporting of medical device related adverse events;

(2) it reduces ambiguity and hence increases effectiveness of the evaluation process; and

(3) it is readily usable, in contrast to narrative text, for more sophisticated approaches to signal detection (i.e. the identification of potential novel risks) and trending analysis by incident management systems including advanced querying functions and data visualization. Thus enabling a faster response by both regulatory authorities and device manufacturers.

A globally harmonized terminology and associated codes also has the following benefits:

- **For manufacturers (including local distributors/authorized representatives):** it provides **consistency for manufacturers** reporting to multiple jurisdictions, reducing the burden of managing multiple coding systems when preparing medical device adverse event reports for multiple jurisdictions;
- **For regulatory authorities:** by providing common terms and definitions, it supports analysis of safety, quality and performance information in a manner that can readily be shared globally: common terms will increase accuracy and reliability of information exchanged about medical device adverse events between regulatory

authorities, and may facilitate more rapid detection of potential safety signals when pooled at inter-regional levels;

- **For patients:** it protects patients by **enabling faster local and international response** to medical device adverse events including those related to medical device malfunctions/deteriorations;
- **For healthcare providers:** the use of common terms with manufacturers and regulators may enhance accuracy, reliability and utility of the reports, especially when larger datasets can be pooled and analyzed. It may also, provide terms and definitions, some of which are within a hierarchical form, to be used for adverse event reporting within or between healthcare facilities.

2. Scope

2.1 Use of the adverse event reporting terminology

This document provides the IMDRF terms, definitions and IMDRF alpha-numerical codes to be used for Adverse Event (AE) reporting concerning medical devices and in vitro diagnostics both pre and post market as described in section 5.

Notably, the precise criteria for reporting adverse events are defined by each regulatory authority and are not subject to this guidance document. Reference is made to the relevant guidance documents of each jurisdiction and the GHTF document on Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF, 2006).

2.2 Intended end-users of the adverse event reporting terminology

The set of terminologies outlined in this document are intended for use by:

(1) *reporters* of adverse events which are obligated to be reported to the authorities in accordance with the relevant regulations of each jurisdiction;

(2) *regulatory authorities*, collecting and processing such information and related data in databases and other electronic systems to monitor and analyze adverse events to

improve the protection of patients and public health. Regulatory authorities may be national competent authorities (NCAs) or supranational bodies charged with these tasks.

3. References

The following documents were used in the development of this document.

- ISO /TS 19218-1 Medical device- Hierarchical coding structure for adverse event – Part 1 Event –type codes
- ISO /TS 19218-2 Medical device- Hierarchical coding structure for adverse event – Part 2 Evaluation codes
- GHTF/SG1/N70:2011 Label and Instructions for Use for Medical Devices
- GHTF/SG2/N54R8:2006 Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
- GHTF/SG2/N87:2012 Medical Devices: Post Market Surveillance: An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities
- GHTF/SG5/N5:2012 Reportable Events During Pre-Market Clinical Investigations
- Event Problem Codes of the US FDA, which is available at:
- Manufacturer Evaluation Codes of the US FDA, which is available at:

4 Adverse event terminology

4.1 Adverse Event Reporting

GHTF/SG2/ N54R8:2006 outlines GHTF global guidance for **post-market adverse event reporting**. The GHTF guidance covers: what to report; to whom to report; when to report; and how to report (content, including dataset elements). While it does not provide a definition of an adverse event or an incident or a serious incident involving a medical device (and IVD) it does outline the types of adverse events that that should be reported to regulatory authorities.

Notably, the term "**adverse event**" in the context of clinical trials (i.e. in the pre-market space) has a more restricted meaning (c.f. GHTF/SG5/N5:2012) than in the post-market space (see above and GHTF/SG2/ N54R8:2006).

Finally, it should also be noted that, depending on jurisdictions, the term **adverse event** (in its post-market meaning) and **incident** can typically be used interchangeably.

4.2 Adverse event terminology used in adverse event reporting

This adverse event terminology is intended to serve as a tool for addressing reporting needs identified in previous guidance (e.g. GHTF/SG2/N54R8:2006) and relating to the occurrence of adverse events in the post-marketing period. The terminology may also be used for events and incidents occurring during the pre-market period (e.g. during clinical trials GHTF/SG5/N5:2012).

The adverse event terminology outlined here consists of four main sets of specific terminologies (see section 4.4 for more details) and is intended to facilitate the reporting of:

- **observations** at the level of the ***medical device***
- its ***components*** including accessories,
- **observations** (typically adverse effects on health) at the level of subjects, i.e. ***patients, users or other persons,***
- **investigations** into possible ***causes*** of the event as well as ***causal links*** between use of the device (independent of whether malfunctioning or not) and adverse health effects.

For the time being the adverse event terminology does not include subsets such as actions taken by manufacturers (e.g. field safety corrective action/ recall) or regulatory authorities, and extent of problem (e.g. case restricted to a single case, many devices, or systematic problem).

4.3 Basic considerations regarding terms, codes and hierarchical coding structure

To ease the use of these terminologies (in particular in databases) and to reduce possible ambiguities of meaning, each term is uniquely identified by an alphanumerical code and is further explained by a definition and, in some cases, examples. The set of terminologies is based on currently available terminologies which have been reviewed, improved, and as appropriate, either expanded or simplified.

The four keywords (term, terminology, code and hierarchical coding structure) are briefly explained in the following:

- **Term/Terminology:** The use of terminologies (i.e. a controlled set of well-defined terms) can aid in the description of events by reducing ambiguity of narrative text through categorization of events.
- **Code/coding:** Ambiguity can be further reduced by the use of alphanumerical *codes*, assigned to a predefined *term* from a given pre-defined and controlled *terminology*. The assignment of these codes is known as "*coding*".
- **Hierarchical coding structure** refers to the logical arrangement of such coded terms in branching structures comprising several levels, i.e. comparable to a logical decision tree.

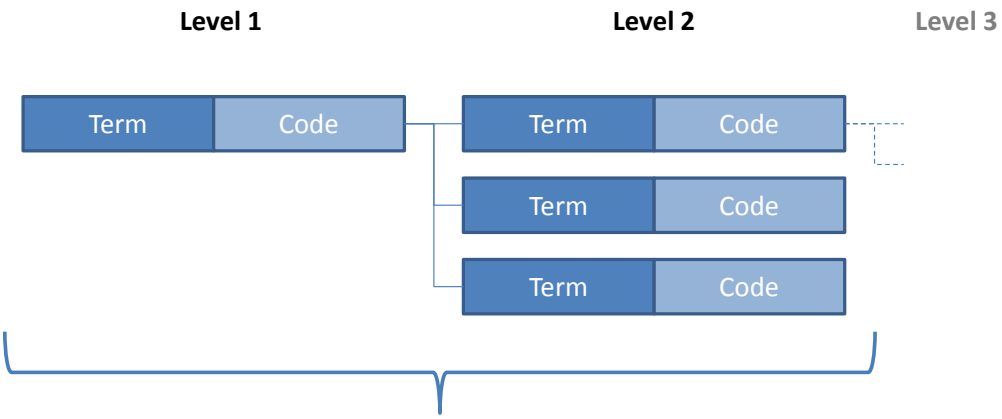
Although the hierarchical arrangement has been referred to as a "coding structure" (e.g. ISO TS 19218), it is important to note that it is primarily the *terms* and their descriptions that are of interest, while the codes are merely used to unambiguously identify the terms. In such a hierarchical term structure (coding structure), more general terms comprise the entry level (e.g. Level 1). From each level 1 term, second and in some cases third level terms (Level 2 and 3) branch-off which allow various more detailed options of finer description of the level 1 term. Therefore, with an increasing number of levels, the resolution and descriptive power of the hierarchical system grows. The advantage of a hierarchically arranged terminology ("coding structure") is that a large variety of terms can be utilized by users in a relatively accessible way, i.e. without the need to know all terms before using the system. Developing an effective hierarchical coding structure however requires that;

(1) level 1 terms are kept to a small number so as to ease entry into the hierarchical coding structure;

(2) that the arrangement of second and third and any other levels follows intrinsically and/or maps logical options; and

(3) avoids duplication of codes which would be confusing.

Inevitably, there is a trade-off between *resolution* (i.e. number of levels and number of terms/codes) and *practicability* of such systems for users, including health care workers, manufacturers and regulatory authorities.



Coding =	The act of assigning a alphanumerical code to a term
Terminology =	Totality of terms used
Hierarchical Coding Structure =	Arrangement of terms in a hierarchical (logical tree-like) structure with various "levels"

Figure 1: *Schematic summary of relevant keywords with respect to adverse event terms: "term", "terminology", "code", "coding", "hierarchical coding structure" and associated "levels".*

4.4 The four sets of terminologies and coding system comprising the complete adverse event reporting terminology

The complete adverse event terminology is comprised of four distinct sets of terminologies and their associated alphanumeric codes (***Figure2, Table 1***). Reporters should be encouraged to code to the most detailed level as possible, and use as many codes as necessary, in agreement with requirements of relevant jurisdictions.

An overview of the terminologies and associated codes is given in Table 1.

The code structure for the nomenclature is as follows and has been used for the medical device problem terminology (Annex A):

X|nn[nn][nn]

X is a placeholder for the annex in which the relevant nomenclature is reproduced (i.e. A to F):

Annex A: Medical Device Problem Terms and Codes

Annex B: Cause Investigation – Type of Investigation Terms and Codes

Annex C: Cause Investigation – Investigation Findings Terms and Codes

Annex D: Cause Investigation – Investigation Conclusion Terms and Codes

Annex E: Health Effects – Clinical Signs, Symptomsand Conditions Terms and Codes

Annex F: Health Effects – Health Impact Terms and Codes

Annex G: Component Terms and Codes

Each letter n is a placeholder for an Arabic number which together uniquely identify the term with Level 1 terms populating digits 1-2 only, Level 2 terms populating digits 3 to 4 (maintaining the Level 1 parent term digits), Level 3 terms using digits 5 to 6 – again maintaining the level 1 and 2 parent term digits.

Each code thus reflects the relationship to the parent / child term and the body of nomenclature it belongs to. Having two digits per level allows for changes in the future (deletion of terms / introduction of terms), which requires assignment of *new* codes so as to allow *backward compatibility* with existing terms/codes from previous reporting and as compiled in databases.

In Annex E, level 1 terms are used as categories only and these codes cannot be selected as a term for reporting.

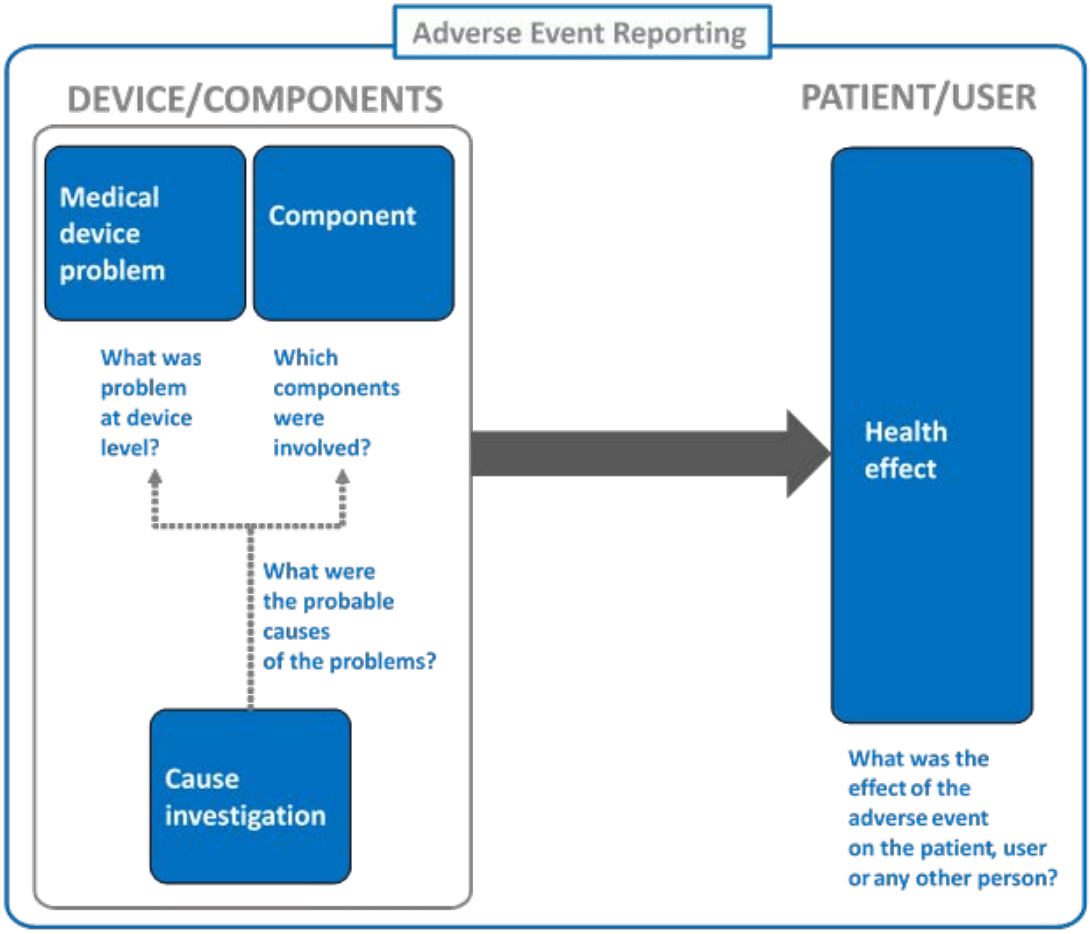


Figure 2: *The Adverse Event Reporting terminology is composed of four sets of terminologies: (1) Medical device problem terminology, (2) components terminology, (3) cause investigation terminology and (4) Health Effects terminology. Note that for an effective monitoring of adverse events, means of effectively identifying devices as well as the category they belong to (e.g. GMDN) are important.*

Table 1: *Overview of the four sets of terminologies comprising the complete terminology for adverse event reporting.*

No.	Name of terminology	Description	Annex	Coding system
1	Medical device problem	Terms/codes for describing problems (malfunction, deterioration of function, failure) of medical devices that have occurred in pre- or post-market contexts (e.g. clinical studies, clinical evaluation or post-market surveillance)	A	A|00[00][00]
2	Cause investigation - Type of Investigation	Terms/codes for describing the type of investigation of the device involved in the reported event.	B	B|00
	Cause investigation - Investigation Findings	Terms/codes for describing the findings of the device involved in the reported event.	C	C|00[00][00]
	Cause investigation - Investigation Conclusion	Terms/codes for describing the conclusion of the device involved in the reported event.	D	D|00[00]
3	Health Effects - Clinical Signs, Symptoms and Conditions	Terms/codes for describing the clinical signs, symptoms and conditions of the affected person appearing as a result of the medical device adverse event/incident.	E	E|00[00][00]
	Health Effects - Health Impact	Terms/codes for describing the consequences of the medical device adverse event/incident on the person affected.	F	F|00[00][00]
4	Component	under development	G – to be developed	G|… (to be defined)

4.5 Description of the four sets of terminologies

1. **Medical Device Problem terms/codes (Annex A):** these terms allow capturing of the problems encountered at device(s) level through observational language without yet describing possible reasons or causes for the problems or failures observed. Annex A provides a comprehensive list of medical device problem terms and codes. It is recognized that not all jurisdictions may want to code to such detailed levels. The hierarchical structure will allow jurisdictions to choose the level of coding to use. These terms are largely based on FDA's device issue terms and are harmonized with ISO Technical Specifications 19218-1, where possible.

2. **Cause investigation terms/codes (Annex B-D):** these terms allow capturing of the type of investigation conducted and the findings in the investigation and the conclusion of root cause from the investigation *(Figure3)*. These terms are largely based on FDA's device issue terms and are harmonized with ISO Technical Specifications19218-2, where possible.

    i. **Type of Investigation terms/codes (Annex B):** Annex B provides what was investigated and what kind of investigation was conducted to specify the root cause of the adverse event.

    ii. **Investigation Findings terms/codes (Annex C):** Annex C provides the findings in the specific investigation that are the keys to identify the root cause. This annex has hierarchical levels, allowing jurisdictions to choose the level of coding to use.

    iii. **Investigation Conclusion terms/codes (Annex D):** Annex D provides the conclusions derived from the investigation. The conclusion specifies the root cause of the specific adverse event. This annex has hierarchical levels, allowing jurisdictions to choose the level of coding to use.

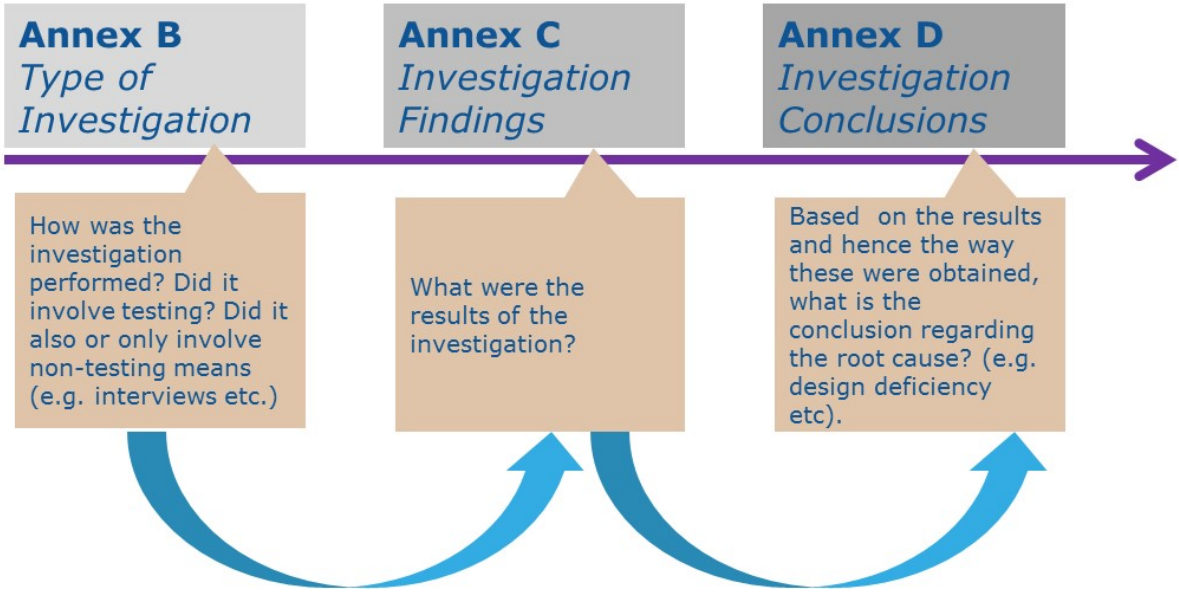


Figure 3: *The three annexes (Annex B: Type of Investigation, Annex C: Investigation Findings, and Annex D: Investigation Conclusion) for Cause Investigation.*

3. **Health Effects terms/codes (Annex E and F):** these terms allow capturing of the patient signs and symptoms observed and the outcomes related to the medical device adverse event through observational language without using diagnostic specifics (*Figure* 4). Annex E provides a list of clinical signs, symptomsand conditions that are granular enough to capture the health effect for the purposes of medical device adverse event/incident reporting, while being general enough to avoid rebuilding other comprehensive terminology systems. Annex F provides a list of potential outcomes and consequences of the medical device adverse event/incident. Terms from these two annexes together will provide a description encompassing both the clinical observation and the impact on the person affected.

    i. **Clinical Signs, Symptoms and Conditions terms/codes (Annex E):** Annex E provides terminology to describe the observed condition of the affected persons after the medical device adverse event occurs. These terms are largely based on a subset of MedDRA terms. This annex is organized along organ systems as well as physiological problems.

ii. **Health Impact terms/codes (Annex F):** Annex F provides terminology to describe the resulting consequences of the medical device adverse event/incident on the person affected.

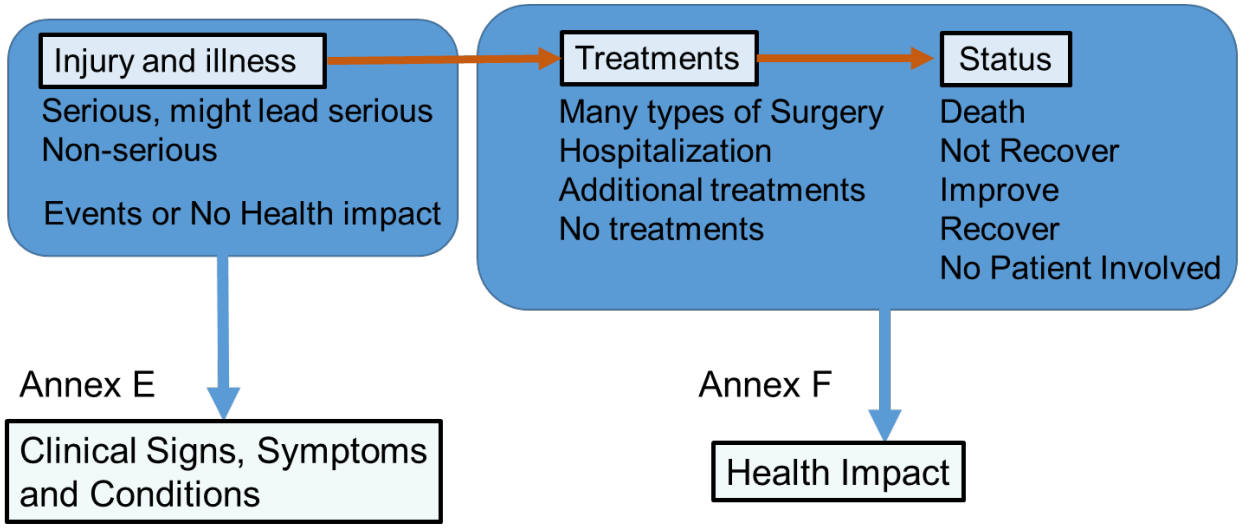


Figure 4: *The two annexes (Annex E, Clinical Signs, Symptoms and Conditions, Annex F: Health Impact) for Health Effect.*

4. **Component terms/codes (Annex G – currently under development)**

5. Maintenance of adverse event terminology

Due to the nature of the medical device industry and the implementation of new technologies, materials, designs, procedures etc., the medical device problem terms, and its associated component terms are expected to require updating to adapt to technical progress. For this reason there is need for periodic review and maintenance of the constituting terminologies and codes in view of adding, modifying or removing terms as required.

However, it is important that changes to the AE terminology should be restricted to the absolute necessary, i.e. mainly reserved for adaptation to technical progress (new terms as new devices, designs and materials emerge). Frequent changes to the terminology are not anticipated. Any change for involved parties and end users will require re-programming of existing coding systems at the level of industry, healthcare facilities and regulators alike so needs to be managed with this in mind.

The detailed maintenance plan of IMDRF AE terminology can be found in IMDRF/AE WG/N44 - Maintenance of IMDRF AE Terminologies.

Annexes

Annex A: Medical Device Problem Terms and Codes

Annex B: Cause Investigation – Type of Investigation Terms and Codes

Annex C: Cause Investigation – Investigation Findings Terms and Codes

Annex D: Cause Investigation – Investigation Conclusion Terms and Codes

Annex E: Health Effect – Clinical Signs, Symptoms and Conditions Terms and Codes

Annex F: Health Effect – Health Impact Terms and Codes

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Principles of Labeling for Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 12 July 2018

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

Introduction

The purpose of this IMDRF guidance is to provide globally harmonized labeling principles for medical devices and IVD medical devices and support the IMDRF Essential Principles of Safety and Performance. Specifically, this document provides guidance on the content of the label and instructions for use in order to support the correct, safe, and effective use of medical devices and IVD medical devices by their users.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs), industry, and others, and will provide benefits in establishing consistent labeling requirements in various jurisdictions.

Labeling[1] serves to identify a device and its manufacturer, and to communicate information on safety, use and performance. In some jurisdictions, Labeling is referred to as 'Information Supplied by the Manufacturer'. Labeling includes the label, instructions for use, and information related to the identification, technical description, intended purpose and proper use of the medical device and IVD medical device, as applicable (Figure 1). It is intended for users of medical devices, including IVD medical devices, both professional and lay persons, as appropriate, and for relevant third parties.

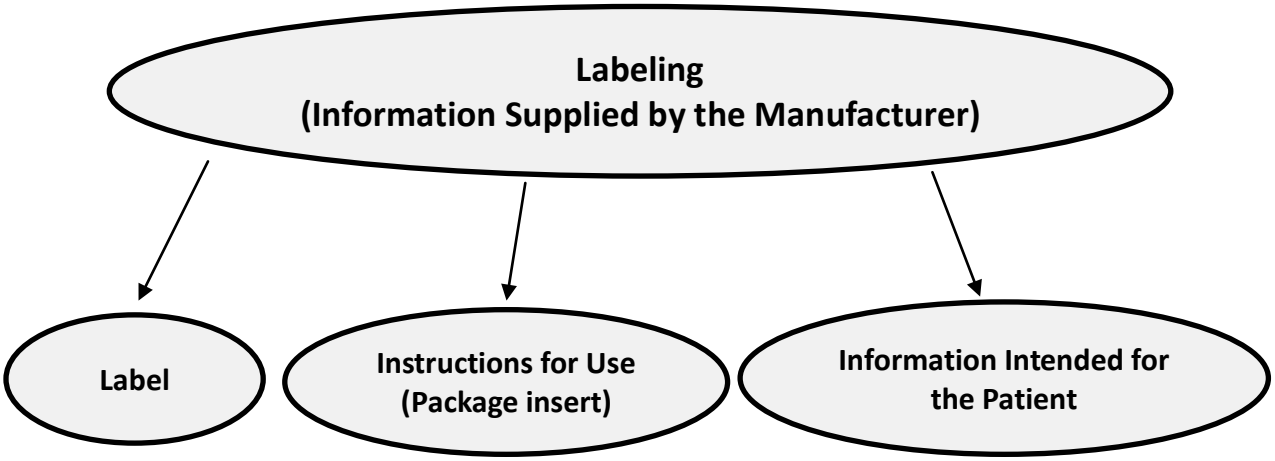

Figure 1. Components of Medical Device and IVD Medical Device Labeling

RAs require and specify information that manufacturers are expected to incorporate in the labeling when the device is placed onto the market, to ensure the correct, safe, and effective use of their product. This guidance provides some of those basic expectations, although RAs may have additional labeling requirements beyond the scope of this guidance.

[1] Some regional and national regulations use the term 'information supplied by the manufacturer' rather than 'labeling'. This document uses the term 'labeling'.

This guidance document describes the general labeling principles for medical devices and IVD medical devices and supersedes an earlier version produced under the Global Harmonization Task Force (GHTF) entitled "Label and Instructions for Use" dated September 16, 2011 (GHTF/SG1/N70:2011). The intent of this document is to outline the foundational labeling principles that are globally harmonized. It is important to note that many jurisdictions have additional specific labeling requirements which sometimes also depend on the particular medical device or IVD medical device.

1.0 Scope

This document applies to all medical devices and IVD medical devices and is intended to specify the general content and format of medical device and IVD medical device labeling. This document specifies the general labeling principles, including specific sections on the label, instructions for us, and information intended for the patient. The requirements of any relevant medical device or IVD medical device-specific standards should also be considered.

While this document includes general labeling principles, it does not include sections that address other possible components of labeling. Individual jurisdictions may have their own regulations or requirements regarding other labeling components.

Advertising and promotional materials are outside the scope of this document.

2.0 References

- GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices*
- GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*
- GHTF/SG1/N046:2008 *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*
- GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*
- IMDRF/UDI WG/N7:2013 *UDI Guidance Unique Device Identification (UDI) of Medical Devices*
- IMDRF/GRRP WG/N47:2018 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
- IMDRF/UDI WG/N7:2013 *UDI Guidance: Unique Device Identification (UDI) of Medical Devices*
- IMDRF/RPS WG/N19:2016 *Common Data Elements for Medical Device Identification*
- GS1 General Specification: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
- Health Industry Business Communications Council (HIBCC)UDI and Labeling Resource Center: http://www.hibcc.org/udi-resources/
- International Council for Commonality in Blood Banking Automation (ICCBBA) - Technical Specification

https://www.iccbba.org/tech-library/iccbba-documents/technical-specification

Standards

- ISO 639-1:2002 *Codes for the Representation of Names of Languages – Part 1: Alpha-2 Code*
- ISO 3864-1:2011 *Graphical Symbols. Safety Colours and Safety Signs. Part 1: Design Principles for Safety Signs and Safety Markings*
- ISO 15223-1:2016 *Medical Devices -- Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied -- Part 1: General Requirements*
- ISO 14971:2007 *Medical Devices – Application of Risk Management to Medical Devices*
- IEC 62366-1:2015 *Medical Devices – Part 1: Application of the Usability Engineering Process to Medical Devices*
- ISO/IEC 646:1991 *Information Technology - ISO 7-bit Coded Character Set for Information Interchange*
- ISO/IEC 15415:2011 *Information Technology - Automatic Identification and Data Capture Techniques. Bar Code Symbol Print Quality Test Specification - Two-Dimensional Symbols*
- ISO/IEC 15416:2016 *Automatic Identification and Data Capture Techniques - Bar code Print Quality Test Specification - Linear Symbols*
- ISO/IEC 15426-1:2006 *Information Technology- Automatic Identification and Data Capture Techniques - Bar Code Verifier Conformance Specification — Part 1: Linear Symbols*
- ISO/IEC 15426-2:2015 *Information Technology-Automatic Identification and Data Capture Techniques - Bar code verifier conformance specification — Part 2: Two-Dimensional Symbols*
- ISO/IEC 15459-2:2015 *Information technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 2: Registration Procedures*
- ISO/IEC 15459-4:2014 *Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 4: Individual Products and Product Packages*
- ISO/IEC 15459-6:2014 *Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 6: Groupings*
- ISO/IEC 16022:2006 *Information Technology- Automatic Identification and Data Capture Techniques-Data Matrix Bar Code Symbology Specification*
- ISO/IEC TR 29158:2011 *Information technology - Automatic identification and data capture techniques - Direct Part Mark (DPM) Quality Guideline*
- ISO/IEC 18000-6:2013 *Information Technology -- Radio Frequency Identification for Item Management -- Part 6: Parameters for Air Interface Communications at 860 MHz to 960 MHz*
- ISO 18113:2009 *In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling)*

3.0 Definitions

3.1 *Accessory:* An article intended specifically by its manufacturer to be used together with a particular medical device or IVD medical device to enable or assist that medical device or IVD medical device to be used in accordance with its intended use. (GHTF/SG1/N71: 2012)

3.2 *Analytical Performance of an IVD Medical Device:* The ability of an IVD medical device to detect or measure a particular analyte. (GHTF/SG5/N6:2012)

3.3 *Catalog number*: The value given by the manufacturer to identify the specific medical device as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for the end user). (Adapted from IMDRF/RPS WG/N19:2016)

3.4 *Conformity Assessment Body (CAB):* A body other than a Regulatory Authority engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. (IMDRF/GRRP WG/N040:2017)

3.5 *Contraindication:* Labeling elements that describe situations, such as patient populations, medical reasons, or clinical conditions, in which the device should not be used because the risk of use clearly outweighs any possible benefit.

3.6 *Clinical Investigation:* Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device. Explanation: This term is synonymous with 'clinical trial' and 'clinical study'. (GHTF/ SG5/N1R8:2007)

3.7 *Clinical Performance:* The ability of a medical device to achieve its intended purpose as claimed by the manufacturer. (GHTF/SG5/N1R8:2007)

3.8 *Clinical Performance of an IVD Medical Device:* The ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user. (Adapted from GHTF/SG5/N6:2012)

NOTE 1: Clinical performance can include diagnostic sensitivity and diagnostic specificity based on the known clinical/physiological state of the individual, and negative and positive predictive values based on the prevalence of the disease.

3.9 *Device Identifier (UDI-DI)*: The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a Unique Device Identification Database (UDID). Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBCC-UPN (Universal Product Number), ISBT 128-PPIC (Processor Product Identification Code). (GHTF UDI WG/N7: 2013).

3.10 *Electronic Labeling:* Any form of electronically accessible information supplied by the manufacturer related to a medical device or IVD medical device.

3.11 *Expected Lifetime/Expected Service Life:* Time-period specified by the manufacturer during which the medical device or IVD medical device is expected to maintain safe and effective use.

NOTE 1: The expected lifetime can be determined by stability.

NOTE 2: Maintenance, repairs, or upgrades (e.g. safety or cybersecurity modifications) can be necessary during the expected lifetime.

3.12 *Expiry Date/Expiration Date:* Upper limit of the time interval during which the safety and performance characteristics of a material stored under specified conditions can be assured.

NOTE 1: This also applies to medical devices whose physical, chemical or functional properties are maintained during a specified and known period, such as for capital equipment.

NOTE 2: Expiry dates are assigned to IVD reagents, calibrators, control materials and other components by the manufacturer, based on experimentally determined stability properties.

(Adapted from ISO 18113-1:2009)

3.13 *Hazard:* Potential source of harm. (ISO/IEC Guide 51:2014)

3.14 *Indications for Use:* A general description of the disease or condition the medical device or IVD medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the medical device or IVD medical device is intended.

3.15 *Information for Safety*: Information provided to the user or responsible organization that is used as a risk control measure or disclosure of a residual risk.

NOTE 1: Examples can include warnings or precautions, instructions in the use of a medical device or IVD medical device to prevent use error or avoid a hazardous situation, or explanation of a safety feature of a medical device or IVD medical device.

3.16 *Intended Use / Intended Purpose*: The objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. (Adapted from GHTF/SG1/N77:2012)

NOTE: The intended use can include the indications for use.

3.17 *Instructions for Use:* General and technical information provided by the manufacturer to inform the device user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use. (GHTF/SG1/N70:2011)

NOTE 1: Instructions for use can also be referred to as "package insert."

3.18 *In Vitro Diagnostic (IVD) Medical Device:* 'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

NOTE 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

NOTE 2: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

(GHTF/SG1/N071:2012)

3.19 *Label:* Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices. (GHTF/SG1/N70:2011)

NOTE: The definition above refers to the human readable label.

3.20 *Labeling:* The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. (GHTF/SG1/N70:2011)

NOTE 1: Labeling can also be referred to as "information supplied by the manufacturer."

NOTE 2: Labeling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labeling information can be accessed (such as through a website).

3.21 *Lay User:* Individual who does not have formal training in a relevant field or discipline. (Adapted from GHTF/SG1/N045:2008)

NOTE 1: Principles for lay person(s) may also apply to self-testing for a medical device or IVD medical device.

NOTE 2: For an IVD medical device used outside of a laboratory setting, the user of the IVD medical device will be considered a lay user.

NOTE 3: For an IVD medical device for self-collection/self-testing, a self-tester is considered a lay user.

3.22 *Lot number*: A distinctive set of numbers and/or letters that specifically identifies a medical device or IVD medical device batch and permits its manufacturing, packaging, labeling and distribution history to be traced. (Adapted from ISO 18113-1: 2011)

NOTE 1: This can also be referred to as the lot code, batch number, or batch code.

3.23 *Manufacturer:* "Manufacturer" means any natural or legal person[2] with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s). (GHTF/SG1/N055:2009)

NOTE 1: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

NOTE 2: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

NOTE 3: 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

NOTE 4: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

NOTE 5: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

NOTE 6: An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.

[2] The term "person" that appears here and in the other definitions of this document, includes legal entities such as a corporation, a partnership or an association.

NOTE 7: To the extent that an accessory is subject to the regulatory requirements of a medical device[3], the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

3.24 *Medical Device*: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

(Adapted from GHTF/SG1/N071:2012)

NOTE 1: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

NOTE 2: For clarification purposes, in certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

[3] See GHTF/SG1/N29 *Information Document Concerning the Definition of the Term "Medical Device"*

3.25 *Packaging*: Product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary. (ISO 21067-1:2016)

3.26 *Patient:* An individual under the care of a healthcare provider who may benefit from the action of a medical device. A patient may also be a user of a medical device.

3.27 *Performance:* The ability of a medical device to achieve its intended purpose as stated by the manufacturer. Performance may include both clinical and technical aspects.

3.28 *Performance of an IVD Medical Device:* The ability of an IVD medical device to achieve its intended use/intended purpose as claimed by the manufacturer. The performance of an IVD medical device consists of the analytical and, where applicable, the clinical performance supporting the intended use of the IVD medical device. (GHTF/SG5/N6:2012)

3.29 *Precaution:* Information regarding any special care users should exercise for the safe and effective use of the device or IVD device, or to avoid damage to the device or IVD medical device that could occur as a result of use, including misuse (Adapted from ISO 18113-1).

3.30 *Production Identifier (UDI-PI)*: The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date. (GHTF UDI WG/N7: 2013)

3.31 *Regulatory Authority (RA):* A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (IMDRF/GRRP WG/N040:2017)

3.32 *Risk:* Combination of the probability of occurrence of harm and the severity of that harm. (ISO/IEC Guide 51:2014)

3.33 *Safety:* Freedom from unacceptable risk. (ISO/IEC Guide 51:2014)

3.34 *Self-Testing:* A medical device or IVD medical device used by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves.

3.35 *Shelf-Life*: Period of time until the expiry date during which a medical device in its original packaging maintains its stability under the storage conditions specified by the manufacturer.

NOTE: Stability (3.38) and expiry date (3.12) are related concepts

(Adapted from ISO 18113-1:2009)

3.36 *Single Use Device*: A medical device or IVD medical device that is intended to be used on an individual patient during a single procedure and then disposed of. It is not intended to be reprocessed and used again.

3.37 *Stability*: Ability of a medical device and IVD medical device to maintain its safety and performance characteristics within the manufacturer's specifications over a specified period of time.

NOTE 1: Stability applies to

- Sterile and non-sterile medical devices whose physical, chemical or functional properties may be altered or compromised over a stated time interval;
- IVD reagents, calibrators and controls, when stored, transported and used in the conditions specified by the manufacturer,
- Reconstituted lyophilized materials, working solutions and material removed from sealed containers, when prepared, used and stored according to the manufacturer's instructions for use,
- Measuring instruments or measuring systems after calibration.

NOTE 2 Stability of an IVD reagent or measuring system is normally quantified with respect to time and specified conditions

- In terms of the duration of a time interval over which a measured property changes by a stated amount or
- In terms of the change of a property under specified conditions.

(Adapted from ISO 18113-1:2009)

3.38 *Unique Device Identifier:* The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific model or version of medical device on the market along with its associated production information. The UDI is comprised of the UDI-DI and UDI-PI. (Adapted from GHTF UDI WG/N7: 2013)

NOTE 1: The word "Unique" does not imply serialization of individual production units.

3.39 *User:* The person, professional or lay, who uses a medical device. The patient may be that user. (GHTF/SG1/N070:2011)

3.40 *Warning:* Information describing a situation for which there is a foreseeable serious hazard with the use of the device.

4.0 Principles for Medical Device and IVD Medical Device Identification

Medical devices and IVD medical devices may be identifiable in multiple ways, as described below. The ways in which identifier information should be included in the labeling are discussed in subsequent sections of this document.

4.1 The medical device or IVD medical device should be identifiable via a method that allows differentiation from other products of the same type, such as through the use of a brand or trade name.

4.2 A medical device or IVD medical device should be identified with a catalogue number. A combination of medical devices or IVD medical devices or accessories may also be so identified. Each catalogue number should only involve one defined product specification.

4.3 If required by the relevant authority, a medical device or IVD medical device should be identified with Unique Device Identifier (UDI) and the UDI-DI should be linked to a catalogue number in the UDID. UDI should be issued under a system operated by an accredited issuing agency/entity and conform to relevant international standards.

For guidance on the information to be incorporated within the label for UDI purposes, refer to the IMDRF guidance document on this subject[4].

5.0 General Labeling Principles for Medical Devices and IVD Medical Devices

This section describes the general principles that apply equally to all medical devices and IVD medical devices. The primary purpose of labeling is to identify the medical device or IVD medical device and its manufacturer, and provide essential information about its safety, performance and appropriate use to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on packaging or as instructions for use. These documents should be developed and evaluated using risk management principles[5] and usability engineering processes[6]. Certain jurisdictions may require the inclusion of additional information.

The following principles are recommended.

[4] For additional guidance refer to IMDRF/UDI WG/N7 FINAL:2013 *Unique Device Identification (UDI) of Medical Devices*

[5] For additional guidance refer to ISO 14971: 2007 *Medical Devices – Application of Risk Management to Medical Devices*

[6] For additional guidance refer to IEC 62366-1:2015 *Medical Devices – Part 1: Application of the Usability Engineering Process to Medical Devices*

5.1 Labeling

5.1.1 The medium, format, content, legibility, and location of the labeling should be appropriate to the particular medical device or IVD medical device, its intended purpose, and intended users to ensure safe and appropriate use, taking into consideration the following:

- user education;
- user training;
- any special needs of the persons for whom the device is intended; and
- the location and environment in which the device can be used.

5.1.2 Country-specific requirements for the content of the labeling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.

5.1.3 Depending on the requirements of the RA having jurisdiction, labeling may be provided in one or more language(s). Languages may be identified using the plain text name of the language or a language code[7].

5.1.4 The use of internationally recognised symbols[8] in labeling should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.

5.1.5 Residual risks that are to be communicated to the user and/or other persons should be included in the labeling.

5.1.6 If required by the RA having jurisdiction, the labeling should include a summary of the performance studies and clinical investigations used to demonstrate conformance with regulatory review principles and that demonstrate the safety and clinical performance of the medical device or IVD medical device for its intended use. This summary should include but may not be limited to a summary of the investigation, clinical performance and outcome data, clinical safety information, and a summary of the clinical benefit. If not contained in the instructions for use, a reference should be included as to where such information may be accessed.

[7] For additional guidance refer to ISO 639-1:2002.

[8] Such as those found in ISO 15223-1:2016 *Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements*

5.2 Label

The label should contain the following, which may appear on the medical device or IVD medical device itself, on the packaging of each unit, or on the packaging of multiple medical devices or IVD medical devices. It is important to note that medical device and IVD medical device kits may include individual reagents, articles, or medical devices that may be made available as separate medical devices or IVD medical devices. In this situation, those individual medical devices and IVD medical devices contained in the kit should comply with the label content principles in this section.

5.2.1 The information required on the label should be provided on the device itself. If this is not practicable or appropriate (for example, contact lenses, bone cement, software, etc.), some or all the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. If UDI is required by the RA having jurisdiction, it should be on the label and on all device packages, and, for reprocessed devices intended to be used more than once, it should be provided on the device itself.

5.2.2 The label on the outside packaging should include any special handling measures or permissible environmental conditions for storage and transport of the medical device or IVD medical device. Where premature unpacking of a medical device or IVD medical device or its parts could result in an unacceptable risk, the packaging should be marked appropriately. If UDI is required by the RA having jurisdiction, the UDI-DI record should include the storage condition.

5.2.3 Where relevant, the label on the packaging should include an indication of the net quantity of contents, expressed in terms of weight or volume (including volume after reconstitution), numerical count, or any combination of these or other terms which accurately reflects the contents of the package. If UDI is required by the RA having jurisdiction, the net quantity should be included in the UDID.

5.2.4 The label should contain the brand or trade name of the medical device or IVD medical device. If UDI is required by the RA having jurisdiction, the brand or trade name should also appear in the UDID.

5.2.5 The details strictly necessary for a user to identify the device and its use, e.g. 'cardiac ablation catheter 10 French / 20 cms' or 'paediatric thermometer' or 'Blood Glucose Meter' or 'HIV-1/HIV-2 Antibody Test'. If UDI is required by the RA having jurisdiction, this information should match and be stored in the appropriate field(s) of the UDID.

5.2.6 The label should be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes [9]. If UDI is required by the RA having jurisdiction, please follow the requirements of the appropriate UDI issuing agency/entity.

5.2.7 In jurisdictions that have implemented a UDI system, the UDI of the medical device or IVD medical device in human-readable format and machine readable form should be on the label of the medical device or IVD medical device. There should be only one machine readable format on the label; if there are multiple, there should be a clear indication to anyone relying on capture/use of this format throughout distribution and use, including the provider of care, which machine readable format to scan when and for what purpose.

[9] For additional guidance refer to IMDRF/UDI WG/N7 FINAL:2013 *Unique Device Identification (UDI) of Medical Devices*

5.2.8 If a catalogue number is used to identify the medical device or IVD medical device, the label should include this catalogue number. In jurisdictions that have implemented a UDI system, a UDI should be used to identify the device and the catalogue number should be linked in the UDID to a UDI.

5.2.9 The label should contain the name and full address of the manufacturer or authorized representative in a format that is recognizable and allows the location of the manufacturer to be established. A full address should contain information related to the physical location such as street/road, number/floor/house, city, state/region, postal code, country, etc. An abbreviated version of the address may be sufficient on the label if the device is accompanied by instructions for use that provide a full address. If UDI is required by the RA having jurisdiction, the name of the manufacturer should also appear in the UDID.

5.2.10 For imported medical devices or IVD medical devices, the label should contain the name and postal address of the authorised representative (such as the importer or distributor) in the importing country/jurisdiction, if such information is required by the RA having jurisdiction. This information may be added by the authorised representative within the country of import, rather than be provided by the manufacturer, in which case, the additional information should not obscure any of the manufacturer's labels.

5.2.11 If the label includes symbols and safety-related identification colors[10], the marking should be described and explained, where necessary.

5.2.12 The label should include the batch code, batch number, lot code, lot number, serial number, control number, or version number of the medical device or IVD medical device, as appropriate. If UDI is required by the RA having jurisdiction, the UDI would include the appropriate UDI-PI.

5.2.13 The label should include an unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month (e.g. on devices supplied sterile or single use disposable devices), where this is relevant. Where there is no indication of the date until when it may be used safely, the year of manufacture should be provided. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable. If UDI is required by the RA having jurisdiction, the UDI would include the expiry date and manufacturer date in the UDI-PI.

5.2.14 If the medical device or IVD medical device is supplied sterile, the label should include an indication of the device's sterile state and, where applicable, the sterilization method. If UDI is required by the RA having jurisdiction, the sterilization information on the label would be included in the UDI-DI record of the UDID.

[10] For additional guidance see ISO 3864-1:2011 *Graphical Symbols. Safety Colours and Safety Signs. Part 1: Design Principles for Safety Signs and Safety Markings*

5.2.15 Where appropriate, the label should state that the medical device or IVD medical device contains or incorporates a medicinal or biological substance, e.g. heparin-coated catheter or drug-coated stent.

5.2.16 The label should include any warnings or precautions to be taken that need to be brought to the immediate attention of the user of the medical device or IVD medical device as relevant, and to any other person where appropriate (e.g. 'CAUTION – HOT SURFACE' or 'THIS PRODUCT CONTAINS LATEX' or 'CONTAINS POTENTIALLY INFECTIOUS MATERIAL'). This information may be kept to a minimum, in which case more detailed information should appear in the instructions for use.

5.2.17 If the medical device or IVD medical device is intended by the manufacturer for single-use only, reuse on a single patient, and/or reuse on more than one patient, the label should indicate this.[11] If UDI is required by the RA having jurisdiction, the UDI-DI record should indicate the sterility information in the UDID.

5.2.18 If the medical device or IVD medical device is intended only for premarket clinical investigational, premarket performance evaluation, non-clinical research, or presentation or demonstration purposes, the label should indicate this specific use. In these situations, some of the principles listed in this document may not apply.

5.3 Instructions for Use

5.3.1 Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams near the corresponding text. Some medical devices or IVD medical devices may include separate information for the professional user and the lay person.

5.3.2 Where the manufacturer supplies multiple medical devices or IVD medical devices to a single user and/or location, it may be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer should provide further copies upon request or make the electronic format available.

5.3.3 Instructions for use may not be needed or may be abbreviated for certain medical devices or IVD medical devices if they can be used safely and as intended by the manufacturer without any such instructions for use. Justification for any omission should be described in the manufacturer's risk analysis for the medical device or IVD medical device.

5.3.4 Instructions for use may be provided to the user either in paper or non-paper format (e.g. electronic). They may be supplied by various means either with the medical

[11] According to Note 5 of GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer,* any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. As a consequence, a reprocessor of a single use device would be subject to the same requirements as those applicable to a manufacturer.

device or IVD medical device or separate from it. Examples of other means are information displayed on a screen incorporated into the medical device or IVD medical device, information downloaded from the manufacturer's web site using the internet, and machine-readable sources. The means chosen should be appropriate for, and accessible to, the anticipated user population. Any updates to the IFU need to be consistent across paper and electronic formats whether they are retrospective or batch specific.

5.3.5 If the manufacturer has a website, the instructions for use may also be made available on that website. In this situation, the medical device or IVD medical device packaging should include a means for the user to easily access the electronic instructions for use via inclusion of a web address or other information. For jurisdictions that have a UDID and capture the link, the link should be recorded in the UDID.

5.3.6 Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to:

- view the instructions for use;
- access the correct version of the instructions for use; and
- obtain a paper version of the instructions for use.

NOTE: The RA having jurisdiction may set the conditions under which such non-paper format should be provided to guarantee a high level of protection of health. Those conditions may specify the types of medical devices or IVD medical devices that can use a non-paper format and the requirements the manufacturer needs to respect, such as, that the manufacturer should upon request provide a paper version of the instructions for use free of charge.

5.3.7 The instructions for use should contain the name or trade name of the medical device or IVD medical device.

5.3.8 The instructions for use should include a description of the medical device or IVD medical device. This description should include but may not be limited to a summary of the design of the medical device or IVD medical device and how it is intended to be used.

5.3.9 The instructions for use should contain the name and address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established (e.g., street/road, number/floor/house, city, state/region, postal code, country, etc.), together with contact information (e.g., a telephone number and/or fax number and/or website address) to obtain technical assistance.

5.3.10 The instructions for use should state the medical device's or IVD medical device's intended use/purpose, including the intended user (e.g. professional or lay person), as appropriate.

5.3.11 The instructions for use should state the performance of the medical device or analytical performance of the IVD medical device claimed by the manufacturer.

5.3.12 The instructions for use should include any specifications the user requires to use, process, and maintain the device appropriately. For example, if the medical device or IVD medical device performs any measurements, the instructions for use should include the claimed limits of accuracy.

5.3.13 The instructions for use should include information that allows the user and/or patient to be sufficiently informed of any warnings, precautions, measures to be taken and limitations of use regarding the medical device or IVD medical device. This information should cover, where appropriate:

a) warnings, precautions and/or measures to be taken in the event of malfunction of the medical device or IVD medical device or changes in its performance that may affect safety;

b) warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

c) warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the medical device or IVD medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);

d) precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.

e) precautions related to potentially infectious material that is included in a medical device or IVD medical device.

f) warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into or included with the medical device or IVD medical device.

5.3.14 The instructions for use should include any recommended quality control procedures to be taken to verify that the medical device or IVD medical device performs as intended, including the following if applicable:

a) the procedure for using the available controls;

b) instructions recommending the frequency of use;

c) the limitations of the quality control procedure, clearly delineated;

d) how the user should interpret the quality control procedure results, including a description of whether test results can or cannot be accepted when a quality control procedure fails; and

e) the actions to be taken if there is a failure of any of the controls.

5.3.15 If the medical device or IVD medical device incorporates or includes a medicinal substance and/or material of biological origin, the instructions for use should identify that substance or material, and list any warnings, precautions and/or limitations related to this substance.

5.3.16 The instructions for use should include any relevant residual risks, contraindications, and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.

5.3.17 The instructions for use should include the details of any preparatory treatment or handling of the medical device or IVD medical device before it is ready for use (e.g., sterilization, identification of other necessary equipment not provided with the medical device or IVD medical device, final assembly, reconstitution, calibration, etc).

5.3.18 The instructions for use should include any requirements for special facilities (e.g. clean room environment), or special training, or particular qualifications of the user and/or third parties.

5.3.19 The instructions for use should include any information needed to verify whether the medical device or IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, including (where relevant) details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection; identification of any consumable components and how to replace them; information on any necessary calibration to ensure that the device operates properly and safely during its intended life span; and methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing medical devices or IVD medical devices.

5.3.20 The instructions for use should include an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions that apply.

5.3.21 The instructions for use should include any warnings or precautions to be taken related to the disposal of the medical device or IVD medical device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

a) infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);

b) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);

c) physical hazards (e.g. from sharps).

5.3.22 If the medical device or IVD medical device is supplied sterile, the instructions for use should include instructions to be followed in the event of the sterile packaging being damaged or unintentionally opened before use.

5.3.23 If the medical device or IVD medical device is supplied non-sterile with the intention that it is sterilized before use, the instructions for use should include appropriate instructions for sterilization and should also include instructions for cleaning the device prior to sterilization, if cleaning is required.

5.3.24 If the medical device or IVD medical device is reusable, the instructions for use should include information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

5.3.25 For medical devices or IVD medical devices intended for use together with other medical devices, IVD medical devices, and/or general purpose equipment, the instructions for use should include information sufficient to identify such devices or equipment, in order to obtain a safe combination, and/or information on any known restrictions to combinations of medical devices or IVD medical devices and equipment.

5.3.26 If the medical device or IVD medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes, the instructions for use should include detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and/or the means of protecting the patient, user, or third party from unintended radiation during use of the device.

5.3.27 The instructions for use should state the date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

6.0 General Labeling Principles for Medical Devices other than IVD Medical Devices

6.1 Label

6.1.1 If the medical device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is patient-specific), the label should indicate this fact. For jurisdictions that have a UDID and capture whether a medical device or IVD medical device is only available via prescription from a medical professional, this designation should be indicated in the UDI-DI record of the UDID.

6.2 Instructions for Use

6.2.1 If the medical device administers medicinal or biological products, the instructions for use should indicate any limitations or incompatibility in the choice of substances to be delivered.

7.0 General Labeling Principles for IVD Medical Devices

7.1 Label

7.1.1 The label should include an indication that the device is for in vitro diagnostic use. If UDI is required by the RA having jurisdiction, the label should include the UDI.

7.2 Instructions for Use

7.2.1 The description of the intended use should include the following, where applicable:

- what the device measures or detects;
- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostics);
- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
- whether it is automated or not;
- what the device reports (e.g., qualitative test, semi-quantitative, quantitative test);
- the type of specimen(s) (e.g. serum, plasma, whole blood, tissue biopsy, urine) required including the specimen source(s) (e.g. capillary whole blood from arm), matrix (e.g. EDTA tube), time (e.g. 8 hours after injury) and collection method (e.g. self-collected urine); and

- target population (on whom the IVD medical device is used).

7.2.2 The instructions for use should include a statement of the test principle(s), such as the general biological, chemical, microbiological, immunochemical and other principles on which the IVD medical device is based. Proprietary information need not be disclosed, but provide enough detail to allow the user to understand how the IVD medical device is able to carry out its function.

7.2.3 The instructions for use should include a description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only).

NOTE: IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.

7.2.4 The instructions for use should include a list of materials provided and a list of special materials required but not provided.

7.2.5 The instructions for use should include a description of in-use stability. This may include the storage conditions prior to opening and shelf-life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.

7.2.6 The instructions for use should list the conditions for collection, shipping, handling, and preparation of the specimen.

7.2.7 Where relevant, the instructions for use should include the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

7.2.8 The instructions for use should describe the assay procedure including calculations and interpretation of results, any additional software or reference database required, and where relevant, if any confirmatory testing should be considered.

7.2.9 The instructions for use should list the analytical performance characteristics, such as precision, sensitivity, specificity, and accuracy (which is a combination of trueness and precision).

7.2.10 Where relevant, the instructions for use should list the clinical performance characteristics (e.g. diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations, etc.).

7.2.11 Where relevant, the instructions for use should include the reference intervals in normal and affected populations.

766 **7.2.12** The instructions for use should include information on any interfering substances
767 or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of
768 specimen/sample) that may affect the performance of the assay.

769 **7.2.13** Where relevant, the instructions for use should include a bibliography.

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8.0 Labeling Principles for Software as a Medical Device

8.1 Software that is incorporated into a medical device or IVD medical device or that is intended for use as software as a medical device (SaMD) should be identified with a unique identifier, such as version, revision level or date of release/issue and should be available to the intended user.

8.2 For software embedded into a medical device or IVD medical device, the identification need not be on the outside of the medical device or IVD medical device.

8.3 For SaMD without a physical form or packaging, the label may be available electronically. In this situation, the medical device should incorporate a means for the user to easily access the electronic label via inclusion of a web address or other information.

9.0 Labeling Principles for Medical Devices and IVD Medical Devices Intended for Use by Lay Persons

9.1 The information and instructions provided by the manufacturer should be easy for the intended lay user to understand and apply, in order to correctly interpret the result provided by the device.

9.2 Instructions for use intended to be used principally by lay users should be available in a format appropriate and accessible to the lay user.

9.3 Some devices may include separate information for the professional user and the lay person, e.g. a simplified job aid for lay persons. This information should agree with the instructions for use, and should state the clearly the version it relates to where applicable. It should be written at a level consistent with the education, training and any special needs of its intended readers

9.4 The language of the intended use statement may be simplified in an instructions for use used by lay persons (including self-testing), provided key messages remain. In addition, instructions for use for home use medical devices or self-testing IVD medical devices may omit some of the recommended elements, provided this does not affect safety or performance. Justification for any omission should be described in the manufacturer's risk analysis for the product.

9.5 Interpretation of results should include pictorial representations of all possible test results (including when a device has failed to provide a valid result) for medical devices or IVD medical devices that give a visual readout, where possible.

9.6 For medical devices or IVD medical devices intended for use by lay persons, the instructions for use should clearly and concisely describe the circumstances when the user should consult with a healthcare professional.

9.7 For IVD medical devices intended for self-testing, the instructions for use should clearly state this.

10.0 Labeling Principles for Information Intended for the Patient

The following principles describe general considerations for information intended to be provided to the patient before or after use of the medical device. Note that the principles below may only apply to certain types of products, and depend on the particular medical device and RA having jurisdiction as to what principles may apply.

10.1 Information that is specifically intended for the patient should be provided with the medical device.

10.2 If the information intended for the patient includes an implant card, the card should clearly identify the medical device or, if UDI is required by the RA having jurisdiction, the UDI of the implant should be identifiable prior to implantation, be available to be scanned, parsed into DI + PI and the DI should be used to pull data from the relevant UDID into the patient's health record. In addition, the data recorded on the implant card should include the following:

a) The name or trade name of the medical device. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to UDID.

b) The details strictly necessary for a user to identify the medical device and its use, e.g. 'transcatheter heart valve' or 'synthetic hernia mesh'. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to UDID.

c) The information should be provided in a human-readable format but may be supplemented by machine-readable forms, such as bar codes. If UDI is required by the RA having jurisdiction, human readable and machine-readable format should following requirements of accredited issuing agency/entity.

d) If a catalogue number is used to identify the medical device, the number should be included. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to this field in UDID.

e) The card should contain the name and full address of the manufacturer or authorized representative in a format that is recognizable and allows the location of the manufacturer to be established. A full address should contain information related to the physical location such as street/road, number/floor/house, city, state/region, postal code, country, etc. An abbreviated version of the address may be sufficient if the device information leaflet provides a full address. If UDI is required by the r RA having jurisdiction, obtained from UDI-DI linked to this field in UDID.

f) The card and/or data recorded in the health record should include the batch code, batch number, lot code, lot number, serial number, or control number of the medical device, such that it is uniquely identified. If UDI is required by the RA having jurisdiction, obtained from parsing the UDI into UDI-DI + relevant UDI-PI.

10.3 If the information intended for the patient includes an information leaflet, the information in the leaflet should be written in a way that is readily understood by patients. In addition, the leaflet should include the information mentioned in the following table, as well as information established in specific standards, as applicable. Note that the following table is only a suggestion of the structure and content of the patient information leaflet.

Item	Information to be included
1	(a) the UDI-DI (b) the name of the medical device; and (c) the model of the medical device.
2	(a) the intended purpose; and (b) the kind of patient on whom the medical device is intended to be used.
3	Any special operating instructions for the use of the medical device.
4	(a) the intended performance of the medical device; and (b) any undesirable side effects that could be caused by use of the medical device.
5	Warnings about any residual risks that may remain due to any shortcomings of the protection measures adopted.
6	(a) warnings about risks that could arise from the interaction of the medical device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional. Example 1: The risk of electrical interference from electro-surgical medical devices. Example 2: The risk of magnetic field interference from magnetic resonance imaging medical devices.
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance that should be undertaken; and (b) symptoms that could indicate that the medical device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the medical device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected lifetime; and (e) anything that could shorten or lengthen the expected lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the medical device.

Item	Information to be included
8	(a) the materials and substances included in the medical device; and (b) any manufacturing residuals that could pose a risk to the patient.
9	(a) a notice that any serious incident that occurs in relation to the medical device should be reported to the manufacturer.

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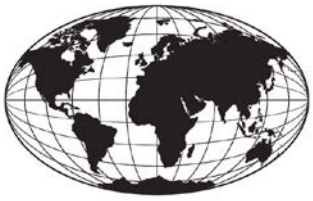


IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Unique Device Identification system (UDI system) Application Guide

Authoring Group: IMDRF UDI WG

Date: 12 July 2018

Table of Contents

Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

Introduction

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) provides a framework for the regulatory authorities that intend to develop their UDI systems in a globally harmonized approach. This UDI system Application Guide is to be used as a supplement to the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) which was developed as a high-level conceptual framework containing the basic core concepts of a UDI system. The document further acknowledges that additional guidance may be necessary.

This UDI system Application Guide, together with the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013), provide a harmonized approach to UDI system implementation. Each is primarily intended for medical device regulatory authorities and manufacturers that plan to develop and implement UDI systems.

However, the benefit and purpose of a UDI system will only be realized, if healthcare stakeholders integrate and obtain value in their systems from UDIs and data in associated Unique Device Identification Databases (UDIDs). This guide is therefore also intended to assist all relevant stakeholders within the healthcare supply chain and clinical care systems to gain a better understanding of their role and impact on the UDI system.

1.0 Scope

This Application Guide is intended to provide the details and specifications necessary to ensure consistency for enabling a harmonized approach in the application of the requirements set forth in the IMDRF UDI Guidance Document (IMDRF/UDI WG/N7Final:2013).

It is recognized that national regulation could differ in relation to certain specific aspects dealt with in the text.

2.0 References

- IMDRF/UDI WG/N7 Final: 2013 - UDI Guidance: Unique Device Identification (UDI) of Medical Devices
- IMDRF/RPS WG/N19 Final: 2016 - Common Data Elements for Medical Device Identification
- GS1 General Specification: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
- Health Industry Business Communications Council (HIBCC) UDI and Labelling Resource Center: http://www.hibcc.org/udi-resources/
- International Council for Commonality in Blood Banking Automation (ICCBBA) - Technical Specification: https://www.iccbba.org/tech-library/iccbba-documents/technical-specification

- ISO/IEC 646:1991, Information technology - ISO 7-bit coded character set for information interchange

- ISO/IEC 15415:2011, Information technology - Automatic identification and data capture techniques. Bar code symbol print quality test specification - Two-dimensional symbols

- ISO/IEC 15416:2016, Automatic identification and data capture techniques - Bar code print quality test specification - Linear symbols

- ISO/IEC 15417:2007, Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

- ISO/IEC 15420:2009, Information technology -- Automatic identification and data capture techniques -- EAN/UPC bar code symbology specification

- ISO/IEC 15426-1:2006, Information technology- Automatic identification and data capture Techniques - Bar code verifier conformance specification — Part 1: Linear symbols

- ISO/IEC 15426-2:2015, Information technology-Automatic identification and data capture techniques - Bar code verifier conformance specification — Part 2: Two-dimensional symbols

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

- ISO/IEC 15459-4:2014, Information technology - Automatic identification and data capture techniques - Unique identification, Part 4: Individual products and product packages

- ISO/IEC 15459-6:2014, Information technology - Automatic identification and data capture techniques - Unique identification, Part 6: Groupings

- ISO/IEC 16022:2006, Information technology- Automatic Identification and Data Capture Techniques-Data Matrix Bar Code Symbology Specification

- ISO/IEC 18000-6:2013, Information technology -- Radio frequency identification for item management -- Part 6: Parameters for air interface communications at 860 MHz to 960 MHz

- ISO/IEC 18004:2015, Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification

- ISO/IEC TR 24720:2008, Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)

- ISO 28219:2017, Packaging -- Labelling and direct product marking with linear bar code and two-dimensional symbols

- ISO/IEC TR 29158:2011, Information technology - Automatic identification and data capture techniques - Direct Part Mark (DPM) Quality Guideline

3.0 Definitions

The following terms are used throughout the text. Definitions are derived from GHTF, IMDRF or other authoritative sources. Special notes indicate when a definition is not consistent across all regulatory jurisdictions.

Accessory
Accessory means an article intended specifically by its manufacturer to be used together with a specific medical device(s), to enable the medical device to be used in accordance with its intended use [modified draft GHTF definition –GHTF/SG1/N071:2012].

Alphanumeric
Consisting of both letters and numbers and often other symbols (such as punctuation marks and mathematical symbols).

Automatic Identification and Data Capture (AIDC)
A technology used to automatically capture data. AIDC technologies include bar code, smart cards, biometrics and RFID.

Base Package
Lowest packaging level.

Checksum Digit
Digital calculated from data and appearing as part of the data string to ensure that the data is correctly composed and transmitted.

Configurable medical device system
A configurable medical device system consists of several components which can be assembled in multiple configurations. Those individual components may be medical devices themselves and/or non-medical devices.

Examples are Computed Tomography (CT) systems, Ultrasound systems, Anesthesia systems, Physiological Monitoring systems, Radiology Information System (RIS).

Configuration
Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a medical device. The combination of items may be modified, adjusted or customized to meet a customer need.

Examples:

1. CT: gantry, tube, table, console are items of equipment that can be configured/combined to deliver an intended function.
2. Anesthesia: ventilator, breathing circuit, vaporizer are items of equipment that can be configured/combined to deliver an intended function.

Data delimiter
Within a UDI, a defined character or set of characters that identifies specific data elements.

Device Identifier (UDI-DI)
The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code). GS1, HIBCC and ICCBBA are accredited issuing agencies/entities in some jurisdictions.

Direct marking
Direct marking, for purposes of UDI requirements, is affixing a UDI permanently on the device itself.

Human Readable Interpretation (HRI)
Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.

Implantable device
Any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. [GHTF SG1/N77:2012]

Issuing Agency/Entity:
An organization accredited by a regulatory authority to operate a system for the issuance of UDIs.

Kits
Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as medical devices. These could also be called procedure packs or convenience kits.
Note: Jurisdictions may differ in their definition of kit.

Label
Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices [GHTF/SG1/N070:2011].

Manufacturer
Manufacturer means any natural or legal person [1] with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s) [GHTF SG1/N55:2009]. This includes reprocessors and remanufacturers that take responsibility for the device and reintroduce it into commercial distribution.

NOTE: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer. For the specific purpose of compliance with UDI requirements, some jurisdictions might consider certain entities other than the manufacturers (e.g. labellers) in the same way as manufacturers.

Own Brand/Private Labelers
An Own Brand or Private Labeler relabels a device from a third party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

Packaging
Product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary. (ISO 21067-1:2016)

Packaging Levels
Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g. each, carton, case.
Note: This does not include shipping containers.

Production Identifier (UDI-PI)
The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production.

The different types of Production Identifier(s) include serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date.

Radio Frequency Identification (RFID)
RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers
Shipping container is a container, where the traceability is controlled by a process specific to logistics systems.

Software as a Medical Device (SaMD)

[1] The term “person” that appears here includes legal entities such as a corporation, a partnership or an association.

The term SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. [IMDRF SaMD WG/ N10R4FINAL:2013]

Standard
Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. [GHTF/SG1/N044:2008]

Third party
A third party is referred to in this text as a company/individual, other than the original manufacturer of a device, that, based on a contract with that manufacturer, is authorized by the manufacturer to carry out certain operations on his behalf, such as submission of data to the UDI database and/or placing of the UDI carrier on the device label.

Unit of Use (UoU) UDI-DI
The UoU UDI-DI is an identifier assigned to an individual medical device. It is assigned in instances when a UDI is not labelled at the level of the device unit of use (e.g. several units contained in a plastic bag). Its purpose is to associate the use of a device to/on a patient.[2]

Unique Device Identification System (UDI system)
A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon standard, with the DI of that unique identifier being also linked to a jurisdiction-specific public UDI database. For more information on the fundamental concepts of the unique device identification system, see IMDRF/WG UDI/N7Final:2013

Unique Device Identifier (UDI):
The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. The unique identifier may include information on the lot or serial number, and be able to be applied anywhere in the world.
Note: The word "Unique" does not imply serialization of individual production units.

Unique Device Identifier Carrier (UDI carrier)
The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.
Note: Carriers can include 1D/linear bar code, 2D/Matrix bar code, RFID, etc.

Unique Device Identification Database (UDID)
The UDID contains identifying information and other elements associated with the DI of the UDI specific to the model of a medical device.

[2] Because of their nature, the Unit of Use is not appropriate to *in vitro* diagnostic medical devices.

4.0 Fundamental Elements of a Harmonized UDI System

The fundamental elements of a UDI system can be summarized as follows:

- Development of a standardized system of Unique Device Identifiers (UDIs)
- Placement of UDIs in human readable and AIDC formats/forms on package labels and in some cases, on the device itself
- Submission of core UDI data elements to a UDID
- Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation

Benefits of the UDI system strongly rely on effective integration of the UDI system to support various regulatory activities during the lifecycle of medical devices and uptake of the UDI system across the whole healthcare sector.

5.0 Guiding principles for UDI system design and operations

The UDI system is being developed to facilitate adequate device identification through distribution and use on patients. This system is newly forming across various regulatory jurisdictions at varying levels of system maturity.

When the UDI system is fully implemented, the label of most devices will include a UDI in human- and machine-readable form. In addition, globally harmonized meta-data about devices will be available in UDIDs as populated by regulated entities.

As the UDI system matures it will require ongoing process and data improvements driven by multi-stakeholder efforts to meet both submitter and user requirements. Foundational to UDI system adoption in the device ecosystem is recognition of the existence of legacy device identifiers and the need to match UDIs to these identifiers.

The UDI and metadata stored in UDIDs are intended to be the identifiers also used in the context of business and clinical transactions (e.g. purchase orders, invoices, inventory maintenance/management, clinical notes etc.).

6.0 The Unique Device Identifier (UDI)

6.1 Content, Structure and representation of a UDI

The UDI is composed of two parts: Device Identifier (DI) + Production Identifier (PI) = Unique Device Identifier (UDI). DI + PI = UDI.

- **Unique Device Identifier - Device Identifier (UDI-DI)**: The Device Identifier of the UDI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. This mandatory, fixed portion of a UDI identifies a manufacturer’s specific product and package

configuration. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code).

- **Unique Device Identifier - Production Identifier (UDI-PI)**: The Production Identifier of the UDI is a numeric or alphanumeric code that identifies the unit of device production when one or more of the following is included on the package label of the device. The different types of Production Identifier(s) include:
    a) The Lot or Batch within which a device was manufactured;
    b) The Serial Number of a specific device;
    c) The Expiration Date of a specific device;
    d) The date of manufacture (may not be required if other Production Identifiers are on the label;
    e) Software as a Medical Device (SaMD), Version[3]
    f) The Distinct Identification Code, when applicable[4]

6.2 The UDI carrier

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) stated that the UDI and UDI carrier should be based upon standards and are fundamental parts of UDI system requirements.

The UDI Carrier shall be on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

Direct marking is affixing the UDI and, potentially the full UDI carrier, permanently on the device itself.

The UDI contains the device identifier (DI) and the specific production identifiers (PI) specified in this document.

The UDI carrier may also contain other identifiers not considered part of the UDI but carried within the UDI carrier to support sharing of standardized non-UDI information between trading partners.

Figure 1 shows an example of fictitious medical device label that meets UDI requirements.

Figure 2 shows the different options for placing the UDI carrier.

[3] SaMD version might be captured in the lot Production Identifier under certain national regulations.

[4] The distinct identification code, generally referred to as a donation number or donor number, corresponds to the donation identification number in ISBT 128. This number is an essential identifier for medical products of human origin

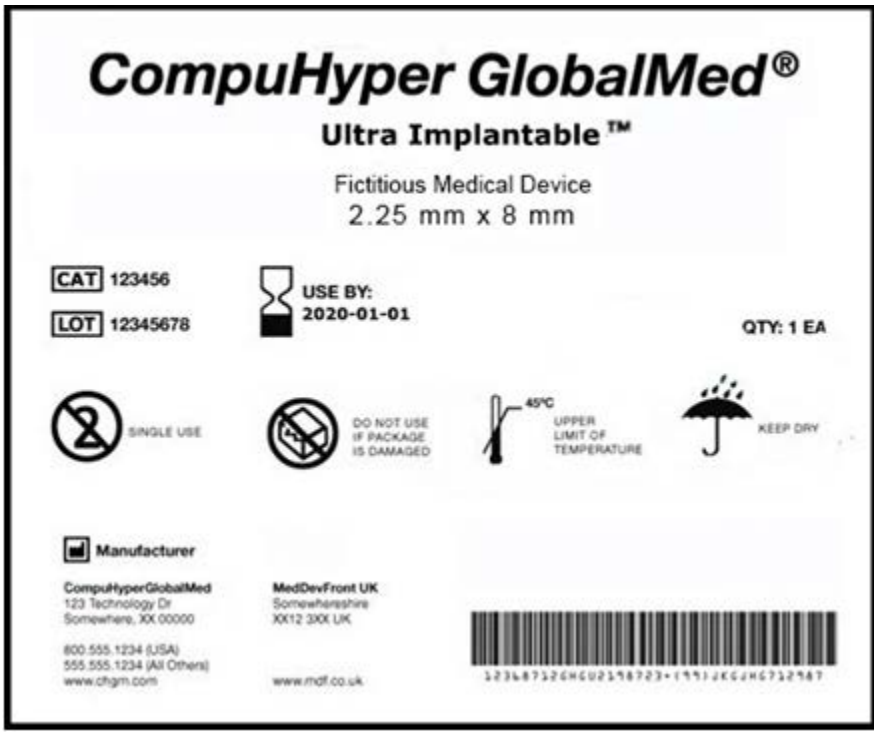


Figure 1: Example of medical device label

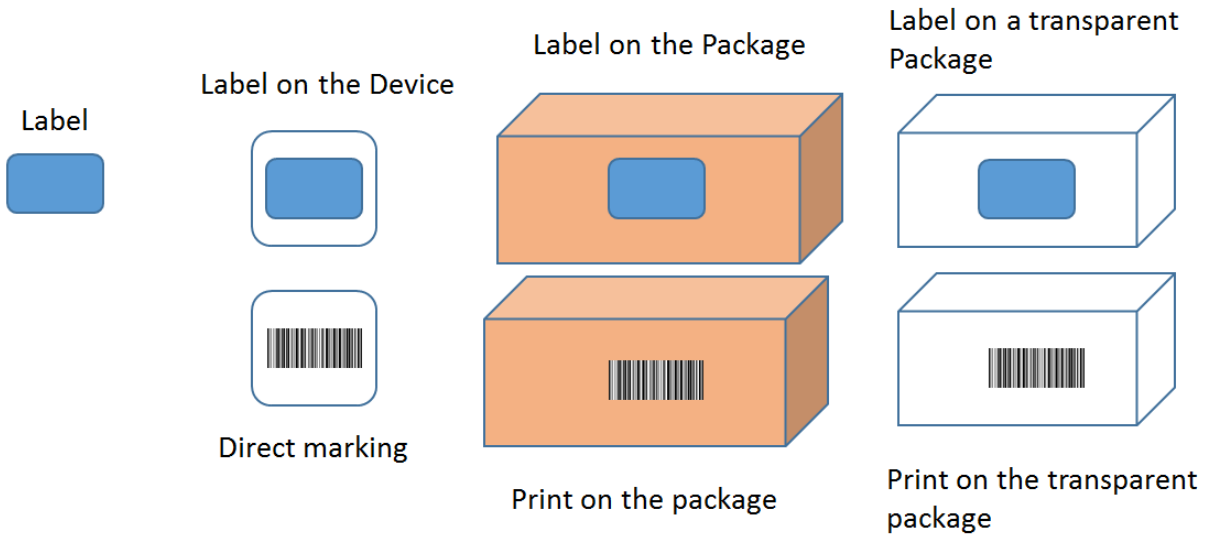


Figure 2: Option for placing the UDI carrier

6.3 UDI Human Readable Interpretation (HRI) Format, Structure and Content of Each Issuing Agency/Entity.

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) requires the HRI format to follow the specifications of the UDI issuing agency/entity as sanctioned by the regulatory authority. The tables in Appendix A contain the UDI HRI formats to be used for each of the issuing

agencies/entities with examples of the HRI alone, followed by a representation of the HRI combined with AIDC in linear and two-dimensional bar code.

The inclusion of the data delimiters is necessary in the HRI to determine what the identifiers are in the string of characters that follow the data delimiter.

6.4 Auto Identification Data Capture (AIDC) representation of UDI

There are a wide variety of AIDC carriers available; however, to meet the imperatives of the IMDRF UDI Guidance, the UDI should comply with the requirements of the global accredited issuing agencies/entities and the accepted AIDC standards, i.e., ISO/IEC 15459-2; ISO/IEC 15459-4; ISO/IEC 15459-6; ISO/IEC 646; ISO/IEC 15415; ISO/IEC 15416; ISO/IEC TR 29158.

Each issuing agency/entity has their own general technical specifications that include information on the carrier type, size, placement and quality in addition to recommendations about the human-readable presentation of the encoded data (for further information on issuing agencies/entities see Section 10.3 of this document).

Some carriers are only approved for specific applications (e.g. retail). Therefore it is imperative to understand the appropriate application of each carrier and allow the manufacturer to choose the appropriate carrier based upon the application for use.

For purpose of illustration, the images shown in Appendix B depict some of the most widely used AIDC carriers used in healthcare (medical devices and pharmaceuticals) today.

RFID may also be an acceptable AIDC technology. Examples of RFID are provided in Appendix C[5].

6.5 Considerations on bar code readers

Bar code readers are designed and manufactured in many configurations (e.g. fixed mount, handheld, tethered, cordless, wearable, mobile phone etc.) and, like many electronic devices, can be acquired with a wide range of factory and/or user selectable features and capabilities.

Bar code readers are available as “linear” scanners for “linear” symbologies only (e.g. Code 128) and as “image scanners” for linear and 2-dimensional (2D)-symbologies (e.g. Code 128 and Data Matrix).

Since image scanners can scan linear and 2D symbologies, it is recommended for users to utilize image scanners for UDI applications.

There is no additional technical knowledge needed to use (i.e. to scan with) a 2D/matrix versus 1D/linear scanner. In fact, both the omnidirectional reading capability of a 2D/matrix “camera” or “area imager” scanner, and the 2D/matrix scanner’s inherent ability to read both 2D/matrix and 1D/linear types of barcodes will make them easier and in the long run more economical to use in many instances. The only additional technical consideration is that every scanner (whether

[5] It should be noted that jurisdictions might choose to opt for certain AIDC systems only.

2D/matrix or 1D/linear) must be properly set up and/or configured for its intended use. This is generally easily done by ensuring that the firm the readers are purchased from sets them up (i.e. configures them) properly.

Readers for UDI applications need to support the Barcode symbologies in line with relevant international standard (including ISO/IEC 16022, ISO/IEC 18004, ISO/IEC 15417, ISO/IEC 15420).

Standard bar code symbology has a symbology identifier registered with ISO/IEC 15424. Scanners transmit the symbology identifier to differentiate between the data carriers of each issuing agency/entity.

Today, some RFID readers have the capability to read 1D/linear and 2D/matrix barcodes. However, bar code readers typically cannot read RFID tags without the addition of external / auxiliary RFID reading devices.

7.0 Application of UDI to packaging levels

7.1 Applying UDI to Medical Device Package Level Structures

One of the main principles of a UDI system is to apply a UDI to each packaging level of a medical device package structure. The DI of each package level requiring UDI must be unique to distinguish between package quantities at each package level.

The device package level structure is a key concept to understand in terms of UDI system. It is also important to note that, while most medical devices are contained within packages with labels, there are instances where the devices are no longer within the original packaging and therefore the label no longer exists.

Appendix D provides some examples of how packaging configurations are captured in the UDID.

7.2 UoU DI

The UoU DI is an unmarked 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 provide a DI to identify a device used on a patient when a DI does not appear on the label of the device.

The UoU DI should be assigned when the base package, i.e., the lowest packaging level with a UDI, has a Device Count greater than 1.

User education is key to assure proper assignment, entry and use of the unmarked UoU DI. The user education should include education of data submitters, data users and Electronic Health Record (EHR) system vendors.

Examples of packaging configurations (including UoU) are provided in Appendix D.

8.0 The Unique Device Identification Database (UDID)

Regulatory authorities are responsible for developing the UDID in their jurisdiction based upon local policy requirements and the principles developed in the IMDRF UDI Guidance (IMDRF/ UDI WG/N7Final:2013) and this document.

Providing public access to each UDID will further allow healthcare stakeholders to access essential information to identify devices.

8.1 Expectations for a good UDID design

The IMDRF UDI Guidance (IMDRF/UDI WG /N7Final:2013) indicates in its introductory section that: "The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices. Healthcare professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and its key attributes". The UDID is a designated source for device identification information.

To ensure that all stakeholders, in particular the healthcare sector, are able to obtain value from the UDI system and the UDID, regulators should consider the following principles when developing regional UDIDs.

Jurisdictions are recommended that their UDID is designed:

1. as a central medical device master database containing all essential information to identify devices in the regulatory jurisdiction
2. to include the entire package level hierarchy of a medical device (e.g. unit-of-use, base package, higher package levels). The hierarchy should be linked to a specific device and provide a parent–child relationship structure
3. to be freely and effectively accessible to all stakeholders, in particular the healthcare sector
4. in a way that relevant available UDI-DI related information can be integrated through downloads and/or Application Programming Interfaces (APIs) into:
    a. internal regulatory systems (such as adverse event reporting, recalls)
    b. device registries
    c. healthcare supply chain systems, clinical systems (e.g. electronic health records), and clinical engineering device maintenance systems
5. to ensure a high level of availability and reliability (e.g. multi-access automatic up- and downloads 24/7)
6. to ensure the integrity of data and data transmission processes using recognized data exchange standards, when possible
7. to connect the device UDI-DI information with codes and terms of a nomenclature[6] which would enable other stakeholders to: use the UDID data for activities like purchasing, stock

[6] According to Section 9.2 of the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013), nomenclature is listed as one of the core UDID data elements

handling, reimbursement or search; find UDID information related to similar devices or to enable regulatory authorities to effectively assess the safety and performance of product groups in the field

8. to have a set of transparent rules on UDI-DI related information updates
9. to keep history of UDID entries and make information on changes publicly available
10. to ensure via security protocols that information provided by the manufacturer (or an authorized third-party acting on behalf of a manufacturer) is successfully submitted
11. to provide clearly defined data validation rules specific to a single data field or a combination of data fields to ensure data integrity, that including, to the extent possible, reasonable automatic plausibility "checks" so that data format requirements for all data elements required for submission to an UDID shall remain stable over a long time
12. to have multiple options for submission (e.g. HL7 SPL, Excel or CSV files, Structured input via a Web-interface to allow for manual UDI data entry)
13. for web submissions, to be based upon user interface design principles so that data entries is intuitive for an average user
14. to accommodate the submission of data from authorized third parties
15. to notify manufacturers about data quality issues and track response to the notifications
16. to have validation procedures to ensure that data submitted is consistent across internal regulatory systems
17. in relation to kits, to capture the UDI-DI of the kit as well as of each medical device in the kit that is marked with a UDI.

During the design and development of the UDID, feedback from all the stakeholders that are expected to be using the UDID should be sought.

8.2 UDID Data Specifications

Regulators should ensure that UDID data specifications for UDID data elements[7] are available to relevant stakeholders as soon as practicable, in order to ensure that they have sufficient time for developing respective systems and procedures.

The following is a recommended data specification list at a data field level:

- field name
- field description
- field characteristics (numeric, alphanumeric)
- field length (number of digits, fixed length, variable length)
- indication whether field is a single value or multiple value field (maximum number of values allowed)

[7] Section 9.2 of the IMDRF UDI Guidance (IMDRF/UDI WG /N7Final:2013) provides a list of core UDID data elements

- list of predefined values (remark: value ‘blank’ or 'null' should be avoided)
- field edit rules (e.g., value changes allowed, deletion, only new values to be added, value locked after grace period)
- indication whether the field is mandatory, optional, or conditional (include rules for conditional)
- indication whether a value change triggers a new UDI-DI

Ideally, the UDID data specifications would be constructed in a data reference table. An example of data reference table is provided in the IMDRF information document (this document is under preparation).

Certain harmonized specifications for some UDID data elements are already included in the IMDRF Common Data Elements [8] document. They provide a controlled vocabulary, standardized nomenclature, structure and definition for those UDID data elements.

8.3 Submission of information to UDID by third-party submitter

As indicated in Section 10.2 of this guide, the manufacturer is ultimately held responsible for the information submitted to the UDID.

Regulators that allow a third-party submitter should establish a formal process to authorize those third-party solution providers to submit UDID data on behalf of a medical device manufacturer[9]. This process might include the following:

- the manufacturer provides third-party information, which is saved as part of the manufacturer’s account
- the third-party submitter completes the relevant testing on behalf of the manufacturer
- during submission processing, the UDID validates that third-party is authorized to submit data on behalf of the manufacturer
- the third-party submitter performs data validation before submitting data to the UDID

8.4 UDI-DI triggers

UDI-DI triggers are data elements within a device's UDID entry that, if changed, would require a device to obtain a new DI.

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) provides that, at a minimum, a new UDI-DI is required whenever there is a change that could lead to misidentification of the

[8] IMDRF/RPS WG/N19Final:2016

[9] Some jurisdictions might not have a specific process in place to authorize third-party solution providers

medical device and/or ambiguity in its traceability. Specifically, any change of one of the following UDID data elements[10] determines the need for a new UDI-DI:

a. Brand Name,

b. Device version or model,

c. Clinical Size (including Volume, Length, Gauge, Diameter),

d. Labeled as single use,

e. Packaged sterile,

f. Need for sterilization before use,

g. Quantity of devices provided in a package,

h. Critical warnings or contraindications: e.g. containing latex or Bis(2-ethylhexyl) phthalate (DEHP).

It shall be noted that new packaging configurations require a new UDI-DI.

To date, those with experience implementing a UDI system into regulatory and healthcare systems have identified a significant challenge with the assignment of multiple DIs to products which share essential design and manufacturing characteristics. Inconsistent applications of UDI-DI triggers by manufacturers as well as a lack of agreement among different jurisdictions on the full list of UDI-DI triggers are among the key factors causing the multiple DI issue.

To minimize that risk, regulators that implement UDI systems and issuing agencies/entities would improve the value of the UDI system by ensuring that UDI-DI triggers other than the ones provided in the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) are kept to a minimum and that manufacturers implement those UDI-DI triggers consistently and in a way that promotes UDI as a global standard for device identification.

Jurisdictions that have started or plan to implement a UDI system should rely on learning UDI communities (on the issue of learning communities, see also Section 13) to look closely at the issue of multiple DIs.

9.0 UDI Format and Structure When Entered into Forms, Databases, Registries, etc.

While the data delimiters in the HRI are necessary to allow for a legible interpretation of the identifiers, the data delimiters themselves are not part of the parsed data set. Therefore, when the UDI is required to be reported in forms, or submitted in electronic data interchange (EDI) databases, the data delimiters should not be included or displayed as part of the data set itself.

[10] Definitions of UDI data elements have been provided by IMDRF in the document IMDRF/RPS WG/N19Final:2016

To take advantage of the structured data embedded in a UDI it is recommended that the UDI be parsed into discrete fields in database entries and forms in order to have the UDI data properly catalogued.

Using scanners, that enter the information in a parsed manner at the initial entry stage, is the most efficient method for capturing UDI, as it will alleviate the need to manually record the full UDI and to manipulate the data for future analysis. A suggested example to capture the UDI is as follows:

- **Device Identifier**: 10222222333334
- **Product identification:**
  - **Expiration Date:** 091231
  - **Lot:** A1345B
  - **Serial Number:** 1234

The IMDRF information document (the document is under preparation) provides further information and recommended best practices for recording UDI in electronic health sources.

10.0 Establishing Responsibility for Creating and Maintaining a UDI System

Establishing the fundamental elements of a UDI system requires that all relevant parties have a clear understanding of their role to achieve the system goals.

Regulatory authorities that intend to establish a UDI system are responsible for establishing the basic regulatory requirements and vision for the UDI as a global standard. Issuing agencies/entities, accredited or recognized by regulatory authorities, are responsible to define the general UDI specifications based on relevant international standards. Manufacturers are responsible for creating and maintaining globally unique UDIs for their medical devices by following the issuing agency/entity's specifications. Distributors, importers, healthcare providers and users significantly contribute to enhance the potential of the UDI as a key standard to facilitate adequate device identification through distribution and use on patients.

10.1 Regulatory Authority

To avoid each regulatory authority implementing and managing local UDI systems differently, the participating IMDRF jurisdictions have developed the details and specifications outlined in this document to harmonize their unique device identification system requirements, and increase global consistency of implementation.

The regulatory authorities that establish a UDI system are responsible for establishing a standardized UDI system to meet local regulatory requirements and to develop and maintain a local publicly available UDID that is capable of linking to other regulatory authority UDIDs. It is recognized that local specificities and regulations could impact certain aspects of UDI implementation.

Regulatory authorities have the following key oversight roles:

- accrediting issuing agencies/entities and overseeing their operations to an extent which may vary depending on each jurisdiction;
- issuing operational guidance and specifications;
- laying down and enforcing obligations for manufacturers in relation to the UDI system in a particular jurisdiction;
- when they deem appropriate, providing instructions for the importers, distributors and healthcare providers to facilitate uptake of the UDI system in the supply chain and clinical systems.

Additionally, the regulatory authorities have shared responsibility with accredited issuing agencies/entities, manufacturers, and standards development organizations to strengthen the UDI as a global standard by committing to ongoing harmonization of UDID data elements, and development of common vocabularies and exchange standards used in UDI implementation.

10.2 Manufacturer

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) states: "The medical device manufacturer should create and maintain globally unique UDIs on his medical devices."

To that purpose, manufacturers shall also keep any UDI related information in their device documentation.

Manufacturers are responsible for understanding both regulatory and issuing agency/entity requirements to accurately assign and place the UDI in human readable and AIDC format on the label or on the device itself and on all higher levels of device packaging. Based on a contract with a manufacturer, a third party may place the UDI carrier on the label or on the device itself and on all higher levels of device packaging on behalf of the manufacturer. However, under that scenario, the manufacturer is ultimately held responsible for the conformity of the UDI carrier[11].

Manufacturers are also responsible for the initial submission and updates to the information in the UDID. While manufacturers should also be allowed to engage with third parties who provide services to submit UDI data to the UDID (see Section 8.3 for additional information), the manufacturer is however ultimately held responsible for the information submitted[12].

10.2.1 Own brand or private labellers

Own-brand/private labelers shall be meant as companies/individuals, other than the original manufacturers of a device that make available on the market that device under their own brand name.

[11] It should be noted that certain jurisdictions might consider those third-parties as legally responsible for placing the UDI carrier on the label or on the device itself and on all higher levels of device packaging.

[12] It should be noted that certain jurisdictions might consider those third-parties as legally responsible for submission of data to the UDI database

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) indicates that own brand/private labelers assume all manufacturers' obligations, related to the UDI system, including obligations to place the UDI carrier on the label and to submit UDI information to the UDID.

However, when a company/individual that makes that make available on the market a device under its own brand name enters into an agreement with the original manufacturer of the device whereby that manufacturer is identified as such on the label, all relevant manufacturers 'responsibilities for that device remain with the original manufacturer including all UDI related responsibilities.

10.3 Issuing Agency/Entity

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) document states that "globally accepted ISO/IEC coding standards implemented by global organizations, such as GS1, HIBCC and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use. These organizations have responsibility for maintaining the global uniqueness of their coding systems."

The main task of these agencies/entities is to operate a system to be used by the manufacturers for assignment of the UDIs to their devices.

Issuing agencies/entities are responsible for defining the UDI as a trade item standard. Regulatory requirements take precedence over issuing agency/entity requirements.

If the issuing agency/entity intends to update their standards or specifications that have an impact on the UDI system, they are expected to submit a request for authorization to the relevant jurisdictions. Given the global nature of those standards or specifications, it is recommended that IMDRF regulatory authorities consult each other about the impact of those changes.

Issuing agencies/entities shall develop initiatives and tools to educate manufacturers on the appropriate use and implementation of the agencies'/entities' systems for the issuance of UDIs. This includes training and development of educational material.

Conditions for designation of agencies/entities shall include that:

- the agency/entity operates a system for the issuance of UDIs which conforms to the relevant international standards;
- the agency/entity undertakes to operate its system for the assignment of UDIs for a period which should be no less than 3 years;
- the agency/entity undertakes to make available to the relevant national authorities, upon request, any information concerning its system for the assignment of UDIs;

Jurisdictions may opt for setting additional agencies/entities' responsibilities. In this case, those jurisdictions might consider establishing agreements with the issuing agencies/entities, upon their designation, under which these entities would be required:

- to make available to regulators their tools that validate that the UDI-DI is meeting the issuing agency/entity's specification for a valid UDI-DI
- to work in cooperation with regulators and manufacturers to avoid problems listed below and correct, if needed:
    1. deficiencies in UDI creation (e.g. tests for validity, uniqueness, check digit)
    2. deficiencies in UDI placement and use (e.g. print quality, scannability, types of UDI carriers, surface and substrate impact)
- to have procedures in place to take necessary follow-up actions up to and including revoking the use of their system for the issuance of UDIs, whenever they become aware that manufacturers or labellers do not meet their requirements related to UDI
- to maintain a maximum level of stability regarding their requirements for data formats on UDI-DI and UDI-PI and their encoding in an AIDC
- to involve regulators when planning additions or changes to their specifications, particularly when those specifications have an impact on the construct of a UDI and the way it is captured
- to have the relevant global standards implemented consistently across their regional members
- to continuously supply to regulators educational materials, application forms, and access to other materials the issuing agency/entity provides for its members

It is recommended that regulatory authorities duly consider the impact of their agreements on global harmonization.

10.4 Expectations from stakeholders related to UDI

10.4.1 Distributors and importers

Distributors and importers are expected to control that, where applicable, a UDI carrier has been affixed to devices they receive, prior to further making available of the device.

Distributors and importers should assure that all device records they maintain include the UDI as an essential component to allow traceability of devices along the distribution chain. National regulators may consider legal or regulatory measures required for this purpose.

10.4.2 Healthcare providers

Jurisdictions might require that healthcare providers assure that all device records they maintain include the UDI as an essential component to allow traceability of devices along the distribution chain.

Healthcare providers can play a crucial role in signalling lack of compliance related to UDI requirements, as they receive and use most of the medical devices available on the market.

National regulators should consider legal or regulatory measures required for this purpose.

10.4.3 Other stakeholders

Providing specific fields for the UDI-DI and UDI-PI and key fields in UDIDs allows for the capture of structured standardized data.

Regulatory reviewers, epidemiologists, clinical researchers and members of professional societies rely on clinical trial and real world data sources (Electronic health records, registries, reimbursement data, and medical device registries) to evaluate the patient and device safety.

Currently, the device identification information collected in clinical care and device registries is not structured or standardized. Often, it is captured in text fields and narrative that cannot easily be used for device evaluation.

Integrating UDI into device evaluation methodologies likewise improves the accuracy of clinical and research data. Researchers will easily see the value of the UDI to improve the quality of research data.

Both device industry and jurisdictions should encourage interdisciplinary participation within their own organizations between those who design and maintain UDIDs and their own internal users of this data in order to provide value to their internal customers and support UDI adoption within their own organizations.

10.4.4 International standards and terminology development organizations

Standards and terminology development organisations (such as ISO/IEC, AIM, SNOMED, and HL7) are crucial to global harmonization in the UDI field, as they set detailed technical specifications on aspects such as UDI allocation rules, structure and placement of UDI carrier, and relevant data exchange.

Regulators, manufacturers and healthcare providers, who plan to adopt and implement a UDI system, are recommended to actively engage with those organizations.

11.0 General Considerations to Facilitate an effective UDI Implementation

11.1 Transitional period

The considerations listed in the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) include a risk-based approach to UDI implementation and the “need for all supply chain stakeholders to have sufficient time to prepare their systems, process and staff, for the proper use of the UDI systems.”

The following is an example of an effective implementation schedule of a UDI system that jurisdictions could consider:

- Initial implementation period in jurisdictions should begin no less than two years from the publishing of the National UDI system requirements for the highest risk devices,

followed by 2 year incremental implementations for each risk category of medical devices.

- Direct Marking timelines should provide an additional two years for implementation at each risk level.

Regulators shall ensure that relevant technical specifications are adopted and published. In particular, technical specification for UDI data elements and for data exchange protocols should be available well ahead of the date of application of the relevant National UDI requirements.

When setting the timelines for adoption of those specifications, regulators shall consult the relevant stakeholders.

11.2 UDI implementation arrangements

The following implementation arrangements should be considered by regulators for a successful UDI implementation:

- Public forums for UDI system education and public comment on the UDI system
- Engagement with national medical device trade associations
- UDI system conferences to allow industry stakeholders to learn and help educate on UDI implementation
- Help Desk service to assist industry with implementation questions
- Guidance documents to address issues or challenges that arise
- Process for manufacturers to apply for exceptions and/or alternative methods for marking a UDI
- UDID data submission training and education webinars
- UDID user group sessions to obtain feedback from both UDID submitters and UDID users
- Promoting a better understanding of UDI user requirements by forming regional UDI expert clinical and supply chain groups or learning communities to identify and specify best practices for UDI implementation that can be shared globally

12.0 Special cases

This Section intends to complement or, where necessary, clarify some of the requirements set in Section 10 of the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013), based on learning experience with certain specific device types in the course of the last few years.

12.1 Implantable devices

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

"Implantable devices should follow the rules listed below:

1. All unit packs of implantable devices (lowest level of packaging) need to be identified/AIDC marked with an UDI (UDI-DI + UDI-PI);

2. PI should have the following characteristics:
   a. serial number for active implantable devices,
   b. serial number for other implantable devices or lot number according to the manufacturer's quality management system;

3. The UDI of the implantable device must be identifiable prior to implantation."

In relation to those requirements, it must be noted that:

- Implantable devices are not always required to have a UDI carrier on the device itself (direct marking)
- The rationale of requirements in 3. ("The UDI of the implantable device must be identifiable prior to implantation") is to minimise the risks of misidentification of the implanted device
- It shall be ensured that the UDI can be scanned prior to implantation and linked to any electronic system, this implying that an AIDC is present.

12.2 Reusable devices requiring reprocessing between uses

The IMDRF UDI Guidance (IMDRF/WG/N7Final:2013) states: "Medical devices that are reusable should have a UDI Carrier on the device itself. The UDI Carrier of reusable medical devices that require reprocessing between patient uses should be permanent and readable after reprocessing cycles for the intended life of the device. Manufacturers may determine that this may not be possible or warranted on some devices due to size, design, materials, processing, or performance issues."

The determination of whether a device is reusable or not is to be made by the manufacturer. That determination should be reflected in the instructions of use, together with any relevant appropriate information on appropriate processes for allowing reuse.

Direct marking is the preferred solution for placing the UDI Carrier on the device itself. There are a variety of methods for applying direct marking, including both intrusive methods (e.g., dot pin; etching; direct laser marking; etc.) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; permanent adhesive label; etc.).

The standard ISO/IEC TR 24720 provides guidelines for direct marking, namely in relation to selection of methods of marking based on material. Other useful standards in this context include ISO 28219, ISO/IEC TR 29158. Issuing agencies/entities (see References in Section 2) might have recommendations on key aspects of direct marking, including substrate requirements, symbol dimensions, symbol quality, and symbol placement.

Direct marking supports accurate identification and capture of a UDI (and when marked with an AIDC carrier, allows auto-capture) when the device is no longer accompanied by its label or package containing the UDI. The figure below shows examples of direct marking on surgical instruments.

Figure 3: Example of direct marking

An exemption to the direct marking obligation shall be foreseen under the following circumstances:

a. any type of direct marking would interfere with the safety or performance of the device;

b. the device cannot be directly marked because it is not technologically feasible.

The applicability of those exemptions shall be based on evaluations of the size, design, materials, processing, or performance issues related to the device in question.

Examples of usability issues linked to direct marking are provided in Appendix F.

12.3 Non-IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that "The manufacturer of the Kit is responsible for identifying the Kit with a UDI including both UDI-DI and UDI-PI."

12.3.1 Placement of UDI carrier on the medical device contents of kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that

"Medical device contents of Kits should have a UDI Carrier on their packaging or on the device itself".

Where applicable and practicable, the UDI of the medical device contents of kits should be readable and scannable from the outside of the kit. In this context, it should be noted that there

are situations where the presence of multiple bar code could lead to confusion scanning and the ability to read and scan the UDI of the contents of the kit from the outside of the kit does not provide any value or benefit to users.

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates the following exemption to the requirement whereby medical device contents of Kits should have a UDI Carrier on their packaging or on the device itself:

a. Individual single-use disposable medical devices within a Kit, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual use outside the context of the Kit do not require their own UDI Carrier.

   Example: An unpackaged sterile syringe within a sterile Kit cannot be used for another procedure, due to the lack of a sterile barrier once removed from the Kit;

b. Medical devices that are normally exempted from having a UDI Carrier on the relevant level of packaging do not need to have a UDI Carrier when placed within a Kit."

For the example provided under b), it must be noted that this does not apply to devices that are being broken down from bulk packaging for use in a kit when the bulk package manufacturer intends them to remain in the box until the point of use.

Appendix G provides useful example of UDI assignment for non-IVD kits in relation to issues explored under Sections 12.3.1 and 12.3.2.

12.3.2 Exemption for non-IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that

"Orthopedic procedure trays whose contents are configured for a specific order are exempted from this UDI requirement"[13]

Figure 4 represents an example of this kind of orthopedic procedure tray. These trays are often delivered to a hospital in a stainless-steel box, then stored and sterilized by the hospital for use in a procedure. After the procedure, the hospital will normally replace used parts and re-sterilize the box with its original and replaced contents.

[13] Jurisdictions may differ in relation to the qualification of these trays as medical devices.

Figure 4: Example of orthopedic trays used in trauma and spine surgeries

It is important to note that these trays are made up of registered and approved medical devices, including instruments and/or implants, in their own right, and are distributed together in non-sterile metal containers strictly for healthcare provider convenience, the convenience of sterilization processing and to accommodate set replenishment in the field or the hospital. The medical devices included in the trays shall be identified individually and are subject to UDI rules at the individual level.

The original exemption provided by the IMDRF Guidance (IMDRF/UDI WG/N7Final:2013) does not address the needs of clinical users and patients for identifying the devices in those trays.

12.4 IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

"The manufacturer of the IVD Kit is responsible for identifying it with a UDI including both UDI-DI and UDI-PI"

12.4.1 Medical device contents of IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

1. "Medical device contents of IVD Kits should have a UDI Carrier on their packaging or on the device itself,
    a. The IVD Kit is a device and all aspects of this guidance that is relevant apply to it. If an IVD Kit does not include any components which on their own are considered medical devices the only UDI is the UDI of the kit itself;
    b. Reagents used in automated systems bear bar codes necessary for their handling and identification by the automated systems. This does not constitute a UDI;
    c. Individual single-use medical devices packaged within an IVD Kit, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual use outside the context of the IVD Kit do not require their own UDI Carrier;

d. Medical devices that are normally exempted from having a UDI Carrier on the relevant level of packaging do not need to have a UDI Carrier when placed within an IVD Kit."

In relation to those requirements, some additional considerations can be made:

- IVD kits contain at least one item which on its own can be considered a medical device.
- It must be highlighted that, for individual single-use medical devices packaged within an IVD Kit, whose uses are generally known to the persons by whom they are intended to be used, they do need a UDI when distributed as replacement parts for the kit.

12.4.2 Placement of UDI on IVD kits

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

“Placement of UDI on IVD Kits:

a. The IVD Kit UDI is generally affixed to the outside of the packaging;
b. The UDI must be readable or in the case of AIDC scan able, whether placed on the outside of the IVD Kit package or inside a transparent package"

Appendix G provides a useful example of a UDI assignment for IVD kits in relation to issues explored under Sections 12.4.1 and 12.4.2.

12.5 Configurable medical devices

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

"For configurable medical device systems the rules listed below should be followed:

1. A UDI is allocated to the entire, configurable medical device system and is called the System UDI.
2. A system UDI-DI is allocated to defined groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given product line as described in a regulatory file.
3. A system UDI-PI is allocated to each individual system. A later change of a component, sub-systems or accessory of the system does not change the UDI-PI of the system.
4. The carrier of the System UDI should be put on the assembly that most likely does not get exchanged in its lifetime and should be identified as the System UDI.
5. Each component, sub-system or accessory that is considered a medical device and a distributed or supplied unit needs a separate UDI.

6. A new UDI-DI is required when the activities performed results in modifications to a previously marketed device intended for resale leads to a new medical device.

7. A new UDI-DI is not required when the activities performed do not result in a change/modification in performance, safety and/or intended use, of a previously marketed device intended for resale. The activities shall be performed in accordance with the manufacturer's instructions."

In relation to 3, if a later change of component results in a new model/version of the configurable device, then that would trigger a new system UDI-DI (as well as new system UDI-PI). If that change did not result in a new version/model, there would be no change in system UDI-DI (or system UDI-PI). Appendix H provides useful examples on this specific issue.

12.6 Software as a medical device

12.6.1 UDI Assignment Criteria

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) indicates that:

"The UDI should be assigned at the system level of the Software as a Medical Device (SaMD).

The version number of the SaMD is considered the manufacturing control mechanism and should be displayed in the UDI-PI.

The following change of a SaMD would require a new UDI-DI:

- Major SaMD revisions shall be identified with a new UDI-DI;

Major SaMD revisions are meant as complex or significant changes affecting:

1) the original performance and effectiveness,
2) the safety or the intended use of the SaMD,

These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

The following change of a SaMD would require a new UDI-PI (not a new UDI-DI),

- Minor SaMD revisions shall be identified with a new UDI-PI;

Minor SaMD revisions are generally associated with bug fixes, usability enhancements (not for safety purpose), security patches or operating efficiency.

Minor revisions shall be identified by manufacturer-specific identification methods (e.g. version, revision number, serial number, etc.)"

12.6.2 UDI Placement Criteria

The IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013) states that:

“

a. When the SaMD is delivered on a physical medium, e.g. CD or DVD, each package level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the SaMD and its packaging must be identical to the UDI assigned to the system level SaMD.

b. UDI should be provided on a readily accessible screen by the user in an easily readable plain-text format (e.g. an “about” file or included on the startup screen).

c. The SaMD lacking a user interface (e.g. middleware for image conversion) must be capable of transmitting the UDI through an API.

d. Only the human readable portion of the UDI is required in electronic displays of the SaMD. The UDI AIDC marking needs not be used in the electronic displays, e.g. about menu, splash screen, etc…; i.e. SaMD not being distributed by the use of physical carriers (CDs, DVDs or similar) will not carry an AIDC.

e. The human readable format of the UDI for the SaMD should include the Application Identifiers (AI) for GS1, and Flag Characters for HIBC, to assist the end user in identifying the UDI and determining which standard is being used to create the UDI."

In relation to those requirements, it shall be noted that:

- When the SaMD is delivered on a physical medium, e.g. CD or DVD, each package level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the first packaging level of the physical medium should be identical to the UDI assigned to the system level SaMD. This UDI information – HRI and AIDC - can be placed in a booklet or inlay that accompanies the physical medium. The physical medium itself is not a medical device and therefore does not require a separate UDI. The physical medium may be controlled by its own lot, batch or serial number or by another means of production control".

- In relation to point d), "will not carry" shall be read as "will not be required to", as manufacturers will always be in a position to opt for those SaMD to carry an AIDC.

Appendix I provides useful example of UDI assignment for software in relation to issues explored under Sections 12.6.1 and 12.6.2.

12.7 Contact lenses

UDI -DIs are assigned by manufacturers for a given version or model of a device.

However, contact lenses are currently assigned UDI-DIs for a given version or model, prescription level, and (for gas permeable lenses) material resulting in the assignment of multiple UDI-DIs for each model/version of contacts lens.

There are three types of contact lenses addressed in this guide: rigid gas permeable, intraocular lenses and soft contact lenses. For soft contact lenses, entering these data might constitute a burden to manufacturers and could affect the IT infrastructure of authorities.

The following is the current thinking for addressing this issue by lens type:

- **Rigid Gas Permeable Lenses**

These are made-to-order lenses and conventional type contact lenses.[14] Assignment rules for UDI-DI for these specific devices are to be based upon the material/color, so that only a change of material would trigger a new UDI-DI.[15] [16]

- **Intraocular Contact Lens**

This type of contact lens is high risk implantable (Class III in US) and the overall number of device records for this category is relatively low compared to other contact lens types. These devices have multiple DIs.

- **Soft Contact Lenses**

For this type of lenses, the following options can be considered:

  - Allow entry of submissions based on current industry practice and under the same rules as intraocular lenses
  - Capture key soft contact lens attributes as part of the device record to help users distinguish multiple device records for a given version or model. For example – Base Curve, Diameter, Thickness, Power, Cyl, Axis etc.
  - If necessary, allow ability to capture range for prescription, i.e., -6 to +6

However, regulatory authorities should cooperate to find a consistent, effective way to deal with those products.

[14] Conventional type contact lenses are those lenses which are usually intended to be worn from six months to a year.

[15] Please note that in some jurisdictions, in the case of Rigid Gas Permeable Lenses, the specification holder might me held responsible for UDI regulatory compliance.

[16] It should be noted that certain jurisdictions might require Rigid Gas Permeable Lenses to be subject to the same requirements as soft contact lenses.

13.0 Update of application guide and issues for future consideration

The IMDRF Management Committee might consider ways to systematically review this application guide, in order to incorporate learning from implementation of UDI in different jurisdictions as well as to ensure that the document is accurate and complete with respect to ISO versions, UDI formats, data standards, vocabulary, and relevant guidance and user community activities.

IMDRF jurisdictions will explore ways of mobilizing local learning UDI Communities with global governance to allow for Global Community of Practice that, based on the framework provided by this guide, share best practices on emerging issues including (but not limited to):

- contact lens attributes
- assignment of other multiple UDI-DI use cases
- software versioning
- identification of kits
- tools and device categorization nomenclature for grouping similar devices
- clinically relevant size dimensions by device type
- low unit of measures.

Those issues might also be considered under future IMDRF work items.

Appendices

Appendix A: UDI HRI formats to be used for each of the issuing agencies/entities

1. **GS1 Standards**

Issuing Agency/Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	Numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22 (max)	20 (max)
GS1	(21)	Serial Number	alphanumeric	22 (max)	20 (max)
GS1		***Maximum Base UDI***	***alphanumeric***	***76***	***66***
ex: 01)09506000117843(11)141231(17)201231(10)1234AB(21)5678CD					

GS1 Sample UDI labels:
http://www.gs1.org/sites/default/files/docs/healthcare/udi_label_samples_-_20150317.pdf

2. **HIBCC Standards**

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	+	DI	Alphanumeric	7 to 24	6 to 23
HIBCC	$	Lot Number Only	Alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	$$	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:	18	18

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
			alphanumeric		
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	$$6	Expiration Date followed by Lot Number	Exp. Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	Alphanumeric	20	18
HIBCC	$$+7	Serial Number only (alternative option)	Alphanumeric	22	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:	18	18

Issuing Agency /Entity	Data Delimiter	Identifier	Data type	Human Readable Field Size	Database Field size
			alphanumeric		
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	Alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC	/14D	Expiration Date (supplemental to secondary barcode as optional format)	numeric [YYYYMMDD]	12	8
HIBCC		***Maximum Base UDI***	***Alphanumeric***	***70 to 87***	***58 to 75***
Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

HIBCC Sample UDI labels:
http://www.hibcc.org/wp-content/uploads/2016/02/HIBCC-UDI-Label-Examples.pdf

3. ICCBBA Standards

Issuing Agency/Entity	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Donation Identification Number	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		***Maximum Base UDI for***	***Alphanumeric***	**79**	**67**

		HCT/Ps			
Ex of Human Readable Barcode:=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

Blood Bags Only	**Identifying Symbol**	**Identifier**	**Data type**	**Eye Readable Barcode Field Size**	**Database Field Size**
ICCBBA	=)	DI for blood containers (bags)	Alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	Alphanumeric	12	10
ICCBBA		***Maximum Base UDI for Blood Bags***	***Alphanumeric***	***24***	***20***
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					

ICCBBA Sample UDI labels:
https://www.iccbba.org/subject-area/medical-devices/label-examples

Appendix B: AIDC carriers most widely used in healthcare

1. **GS1 Standards**

- GS1 Data Matrix with DI and PI's (Expiration Date + Lot/Batch Number)

(01)09506000117843
(17)201231
(10)1234AB

- GS1 Data Matrix with DI and PI's (Expiration Date + Lot/Batch Number + Serial Number)

(01)09506000117843
(17)201231
(10)1234AB
(21)5678CD

- GS1-128 concatenated with DI and PI's (Expiration Date + Lot/Batch Number)

- GS1-128 non-concatenated (shared in 2 parts)

a) DI only

b) PI's (Expiration Date + Lot/Batch Number)

- EAN13 with DI only

2. **HIBCC Standards**

- Data Matrix with DI and PI (Expiration Date + Lot/Batch Number)

+A999ABC123DE1/$$3221231LOT876S

- Code128 non-concatenated with DI and PIs (Expiration Date + Lot/Batch Number)

- QR-Code with DI and PI (Expiration Date + Lot/Batch Number)

+A999ABC123DE1/$$3221231LOT876S

3. **ICCBBA Standards**

- ISBT128 with DI and PI's (Donation Identification Number, Serial Number, and Expiration Date)

Data Matrix with DI and PI’s (Serial Number + Donation Identification Number + Expiration Date)

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

Appendix C: Examples of RFID carriers

1. GS1 Standards

The data encoded in a GS1 barcode can also be encoded in a RFID tag, provided that a serial number is part of the data elements.

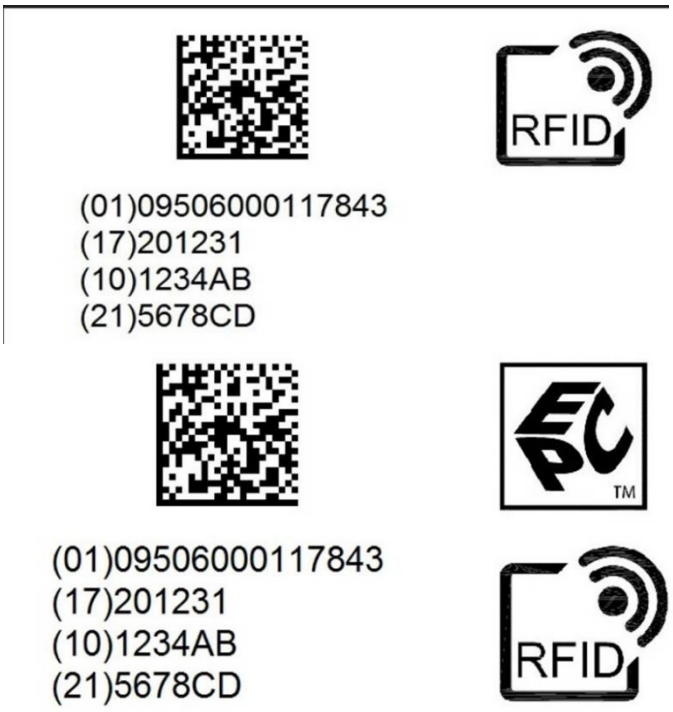
The use of an RFID tag requires that a specific RFID emblem is applied on the label/packaging/device to indicate the presence of radio frequency identification (RFID). The ISO/IEC standard 29160 specifies the design and use of the RFID Emblem.

In Europe, the standard EN 16656 on RFID Emblem is similar to ISO/IEC 29160 except that it requires that only the generic RFID Emblem shall be used as the RFID notification sign.

Both standards allow using optionally other signs, such as the EPC (Electronic Product Code) seal, in addition to the required generic RFID Emblem.

The EPC seal is the sign used to notify when unique EPCs are encoded onto RFID tags. GS1's EPC Tag Data Standard (TDS) specifies the data format of the EPC, and provides encodings for numbering schemes -- including the GS1 keys -- within an EPC/RFID.

Note: today, the relevant GS1 application standards on RFID do not yet address specific location/placement of the RFID Emblem on a label. Relevant CEN standards do state that in the absence of an appropriate application standard, the RFID Emblem shall be placed such that it is easily visible to those trying to read the RFID tag or label. To improve readability, the RFID Emblem should be located near the actual transponder. The visuals below are for example only.



2. HIBCC Standards

A HIBC UDI data string for the Barcode will be encoded with an RFID tag in a 1:1 relation; therefore scanning a Data Matrix with HIBC will yield the same result as scanning a RFID tag.

For RFID applications for UDI the appropriate standards for the product and packaging levels are

- ISO ISO 17367, Supply chain applications of RFID – Product tagging
- ISO ISO 17366, Supply chain applications of RFID – Product packaging

The AIDC and HRI formats are required under the UDI regulation. Therefore, the HRI is not required to be repeated for RFID again, if already present for another type of AIDC format. The ISO/IEC 29160 RFID Emblem is required to be shown as a visible indicator that an RFID is

present by a generic RFID Emblem or optional by a RFID Emblem showing frequency and application by a two character code. This optical visible indicator for frequency and application is helpful in areas where different RFID systems are in use and for diagnostic if a RFID Tag is not read.

The generic RFID Emblem according to ISO/IEC 29160 figure 2:

Fig. Generic RFID Emblem 

telling “RFID inside”

Table A.1 (below) of ISO/IEC 29160 shows the appropriate RFID emblems for UDI, using a two character code assignement.

Table A.1 — Two-character code assignments for the RFID Emblem (excerpt)

Emblem “B5”: 860-960 MHz (UHF) ISO/IEC 18000-63 ISO 17366 Product packaging

Fig. 1b) RFID Emblem “B5” 

Emblem “B7”: 860-960 MHz (UHF) ISO/IEC 18000-63 ISO 17367 Product tagging

Fig. 2) RFID Emblem “B7” 

Examples of serialized UDI HIBC to be encoded in Barcode and optional RFID
a) on a product +A999ABC123DE0/$+1234567Y

b) on a package +A999ABC123DE1/$+1234567Y

Fig. 3) UDI applied on a product package with Data Matrix and RFID

Fig. 4) UDI applied on a product with Data Matrix and RFID

Note to Fig. 3 and 4: Human Readable Interpretation (HRI) contains the UDI data within an envelope of two Stars (*)

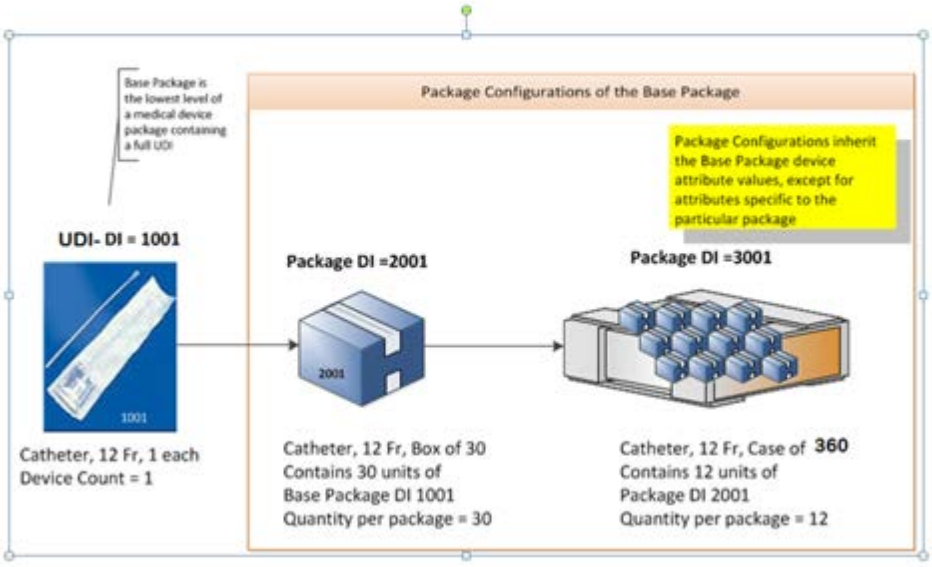
3. ICCBBA Standards

RFID tags are not currently used to carry identification information for medical products of human origin (MPHO), although some organizations are starting to add an RFID tag as a ‘license

plate' based on the unique tag identifier. This is in addition to the barcoded information and would not carry UDI information.

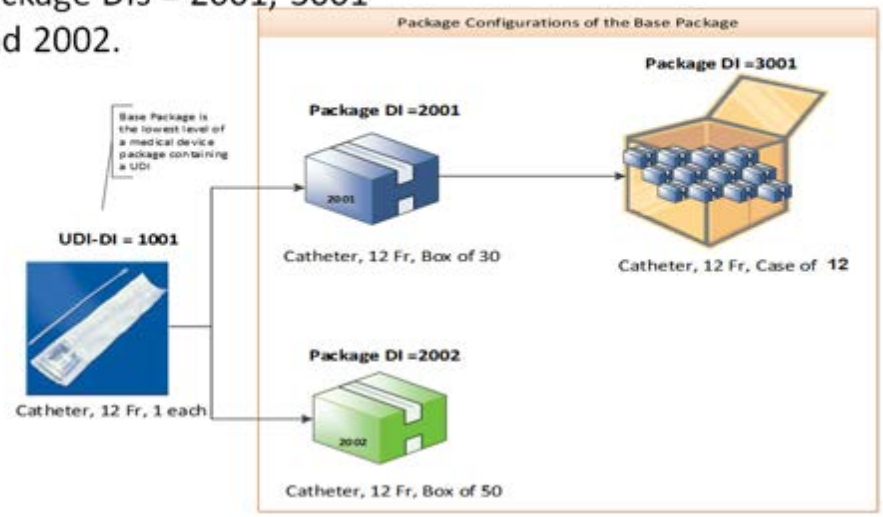
Appendix D: Examples of registration of packaging configurations

Package Configuration Example 1



Package Configuration Example 2

UDID Entry: UDI-DI = 1001
Package DIs = 2001, 3001 and 2002.



NB: Package configurations of a device are part of the same DI record.

Appendix E: Examples of UoU and packaging configurations

UOU Package Example

Single Item
(Unmarked)

Tray of 25
(Full UDI Marked)

Case of 1000
(Full UDI Marked)

Unit of Measure (Package Level)	ANSI UOM	Device Identifier (DI)	Qty	Units at Next pkg level	Contains DI Package
Single Item	-	UOU DI (Unmarked)	1	-	-
Tray (Lowest Pkg Level with DI)	TY	Lowest Pkg Level DI (Full UDI Marked)	25	-	No
Case	CA	Case Level DI (Full UDI Marked)	1000	40	Tray

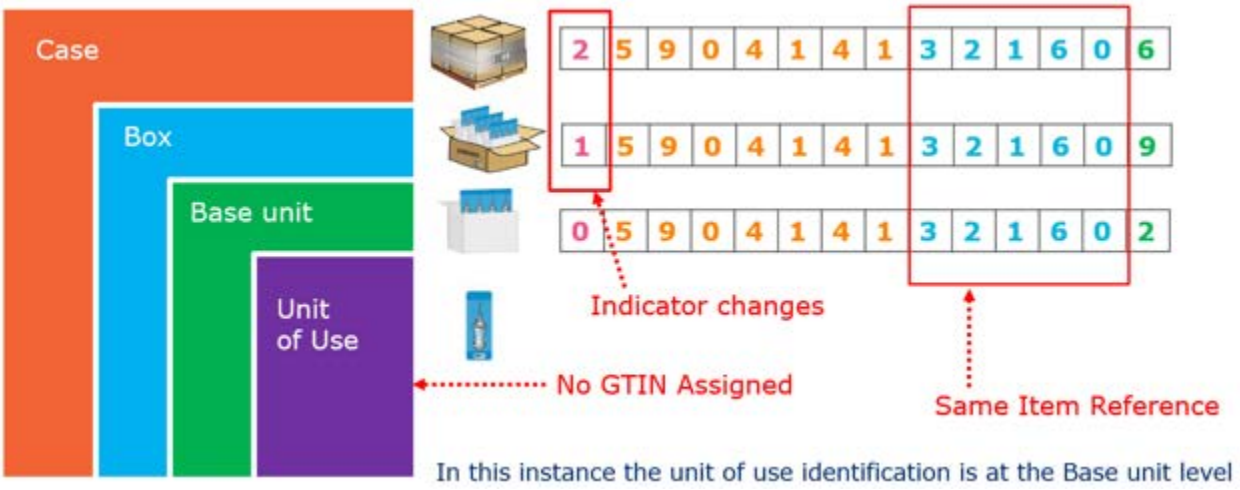
Lowest packaged level ≠ UOU

- Many products used on patients have multiple items in the lowest packaging level
- This concept is not generally used in industries outside healthcare
- There may be **clinical** reasons why we would like to track individual items within these specific packages
- From a **supply chain** perspective, the item cannot be replenished at any level lower than the lowest packaged level

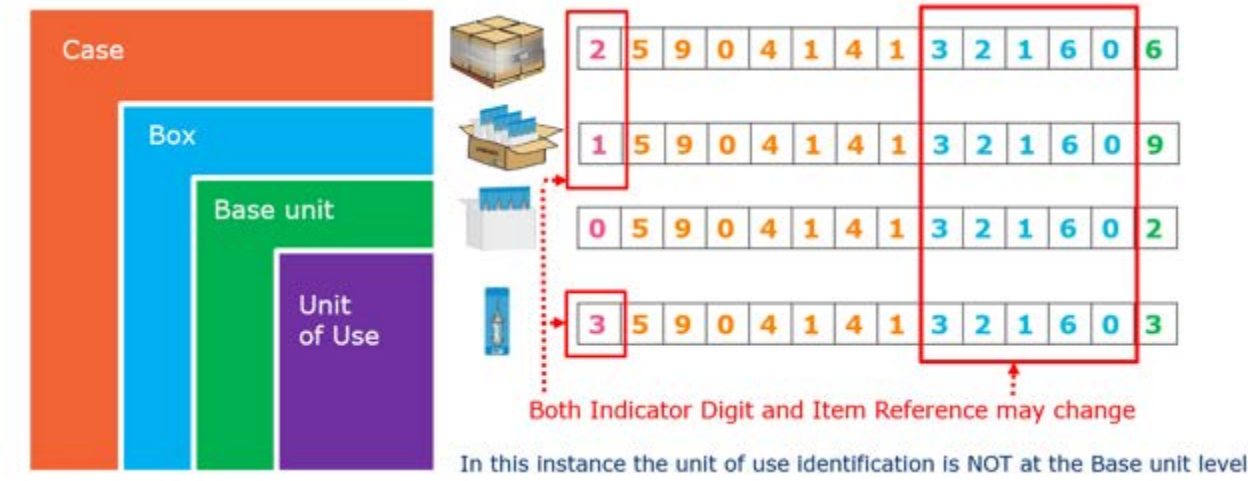
1. GS1 Standards

The examples below are using GTIN-13 and GTIN-14.

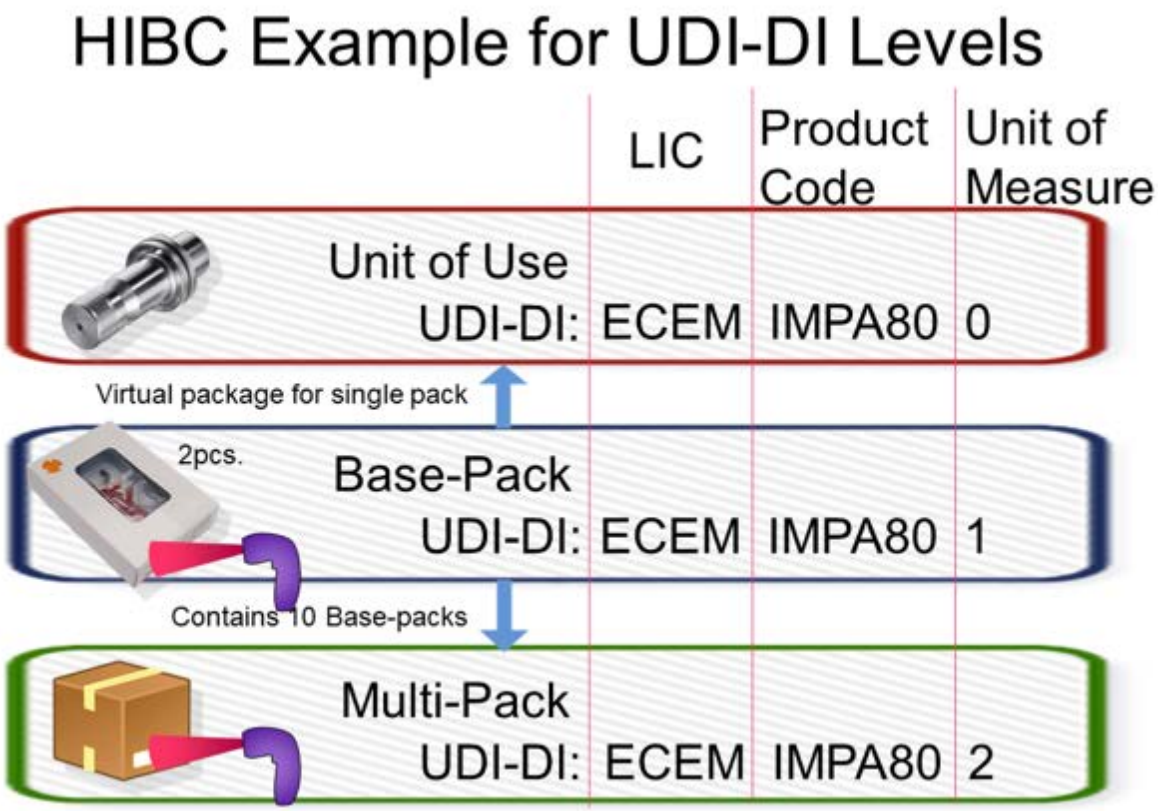
- GTIN (i.e. UDI-DI) Assignment Methods where the GTIN (i.e. UDI-DI) has a Device Count = 1.



- GTIN (i.e. UDI-DI) Assignment Methods where the GTIN (i.e. UDI-DI) has a Device Count >1.



2. **HIBCC Standards**



The last field of the HIBC UDI-DI is the "Unit of Measure". The Unit of Measure is a number (0-9) assigned by the manufacturer to indicate package level. The Unit of Measure is always located directly after the Product Code. Units of Measure 1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest.

A "Unit of Use UDI-DI" can be created from the UDI-DI of the base pack by using the Unit of Measure “0”.

2. **ICCBBA Standards**

Medical devices containing Medical Products of Human Origin are distributed as single units due the unique nature of each item and its associated donation identification number. Thus, the Unit of Use will be the base pack DI for products labelled with ISBT 128.

Appendix F: Usability issues linked to direct marking

Surface wear / treatment

Due to mechanical influences during use and preparation, surface abrasion occurs. Directly marked products can thereby lose readability. When reprocessing instruments, regionally different re-processing cycles and in particular cleaners are used (North America - neutral cleaners, Europe - alkaline cleaners). With highly alkaline cleaners, marking fades faster over the entire life cycle.

Scratches **Abrasion on tempering inscription** **Abrasion**

Damage to the DM due to scratches or inclusions limits the readability of the carrier.

Corrosion

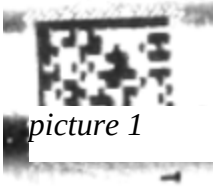
Thermal and deforming influences changes material properties, which lead to corrosion in CoCr alloys. Corrosion causes the code to become unreadable. Corrosion holes can be interpreted by the scanner as marked modules.

Material

Thermal melting influences on plastics

Reflection / Contrast

Picture 1 - The surface is disturbed by inappropriate lighting (e.g. reflection, resolution, contrast).



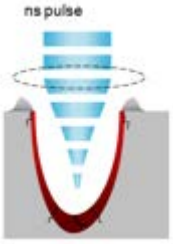
picture 1

Picture 2 - With dark materials, there is a lower contrast ratio to the marking, which affects the readability.

picture 2

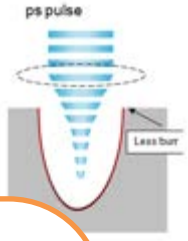
Laser Marking

Stainless steel or titanium alloys are marked with conventional systems based on an ns-laser (nanosecond laser) via the engraving effect. Too little engraving (tempering inscription) leads to faster fading.



Passivation of stainless steel with this technique is a mandatory step to avoid corrosion. Passivation is usually done before and/or after the marking.

When marking with a ps-laser (picosecond laser), the material does not get warm due to a very short pulse duration. The surface is slightly roughened, the mark appears jet black and this regardless of the viewing direction. The passivation layer on reusable instruments is not attacked which limits the possibility to corrosion.

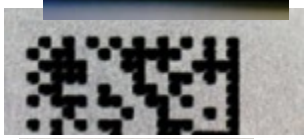


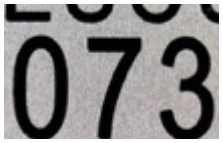
Marking with ns-Laser

The

On curved / cylindric devices with a diameter of 7mm a marking is possible.

Marking with ps-Laser





On curved / cylindric devices with a diameter of 3mm a marking is possible.

Marking 1,25 x 4mm
Marking 1,75 x 5,5mm

The readability of the plain text is independent of the marking method. Because of space reasons a marking of that, the plain text from of the UDI might not be always possible.

1:1

1:1

When used properly, the readability of a validated laser marking with a data-matrix is still given after at least 500 cycles.

(based on experiences made by

individual device manufacturers)[17]

[17] Users should discard using a reusable instrument, if damage (e.g. corrosion, chipping, discoloration, etc.) is seen.

Appendix G: Kit Examples

- **Non-IVD kit examples**

Example 1: A sterile, disposable laparotomy kit contains a Mayo stand drape, 4 standard drapes, a laparotomy drape, table cover, 2 hand towels, 2 gowns, and a paper suture bag in a single package.

This kit contains two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user.

This kit should be identified with one UDI.

Example 2: It follows the same principles of Example 1 except the kit is customizable to meet health provider preferences.

Best practice recommendation: While it is the manufacturer that determines when a change to a device constitutes a new model/version of the device, unless there is a relatively small number of potential customizations, using DIs to differentiate between customized variations is not recommended because it can produce a very large number of DI records. Instead, differences in customized variation can be accounted for using UDI-PIs.

This kit should be identified with one UDI.

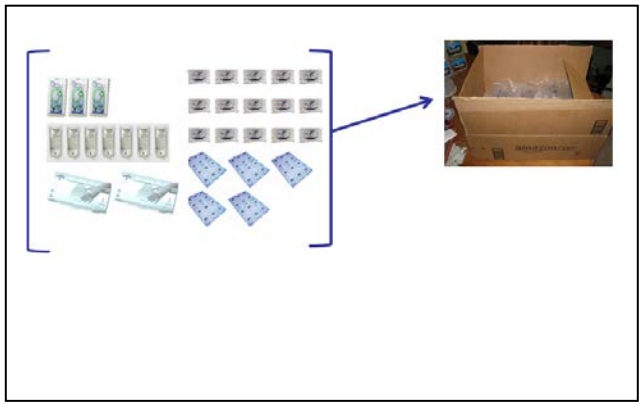
Example 3: Several implant components (including inflatable band, access port and tubing) and multiple sterile accessories (calibration assembly, end plug, closure tool, needles) are together in one package under one label. All the contents of the package are used or disposed of in a single procedure.

None of the devices in the kit are replaced, substituted, repackaged, sterilized, processed or modified before the devices are used by an end user.

This kit should be identified with one UDI.

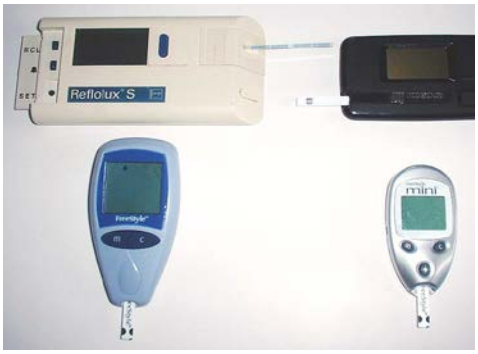
- **Collection of items not defined as kits examples**

Example 1: A collection of finished and labeled devices that are not necessarily intended to be used together and placed in a box for delivery to the hospital. The content of the box changes from day to day depending on what the hospital orders. In the case, the box contains 3 stethoscopes, 6 saline bags, 10 packages of IV tubing, 2 boxes of gloves and 4 cartons of EKG electrodes.



This is an example of a shipping container and no UDI is required on the shipping container. The collection is not itself a medical device (a "kit") because the collection is not based on an intended use, but includes a continually varying collection based on what a customer ordered today. Note that each individual item should bear a UDI.

Example 2: A manufacturer manufactures two versions/models of a device. Model A is more popular than Model B. To sell more of Model B, the two models, when sent to retailers and distributors, are packaged in an assorted case that always includes 5 of Model A and 3 of Model B, i.e. a standard configuration.



Although both devices may have similar indications for use, Model A and Model B were not combined in a device package with the intent they are used together to achieve a common intended use. Rather, these two or more different models/versions of devices were packaged together for business reasons.

This package configuration itself is not a device (not a kit). However, to adequately identify this fixed configuration through distribution and use, packages require UDI.

Recommended best practice: place a UDI on each device in the packaging configuration and place a UDI on the package that contains the devices.

- **Example of an IVD kit (Microbial identification tests)**

Contents of kit includes various items (e.g. swabs, reagents, control materials) intended to be used together to detect specific organisms per the device indication.

The kit is a medical device and requires a UDI. Any items distributed separately require a UDI.

Recommended best practice: if items in this IVD kit are also in other IVD kits, then those individual items should also be identified by a UDI.

- **Examples from issuing entities**[18]

1. **GS1 Kit Examples**

Example 1:

This is self-adherent wrap (class I medical device) that comes in multiple colors.

The "each" is a pouched roll of self-adherent wrap.

Six (6) rolls of each color (6 colors) are packaged together in a 36-roll hospital kit.

Each color has a different Catalog code/REF, internal SKU, and GTIN.

[18] Please note these examples represent current thinking and are open to feedback

The multi-color kit has a different Catalog code/REF, internal SKU and DI than would a case composed of a single color product.

The kit has a UDI and each item in the kit has a UDI.

Example 2:

This is a 2-jar impression material. One jar contains a catalyst and the other jar a base, when combined the material cures and captures a dental impression. Products like this are a single medical device, the two components share the same conformity assessment, technical file and registration in every country of the world. Depending on the product, sometimes refills of a single component are sold, sometimes not.

The kit should be identified with one UDI.

2. HIBCC Example

	HIBC CODE DATA							
	Flag	LIC	REF	UoM	De-limiter	LOT	Check	HIBC
KIT UDI	+	A999	KIT1X	1	/$	LOT1X	N	*+A999KIT1X1/$LOT1XN*
UDI Comp.1	+	A999	COMPO1	1	/$	LOT1	/	*+A999COMPO11/$LOT1/*
UDI Comp.2	+	A999	COMPO2	1	/$	LOT2	%	*+A999COMPO21/$LOT2%*

The kit should be identified with a UDI and each item in the kit should be identified with one UDI.

Appendix H: Examples of changes to configurable medical devices

- **Changes where UDI-DI and UDI- PI remain unchanged**

Example 1:
An installed CT system has an x-ray tube which has reached the end of its life and is replaced with a newer model tube by the original manufacturer without other changes to the device or its labeling. The manufacturer has determined that this does not constitute a new version/model of the system, according to their documented procedures for assessing device changes (e.g. the safety profile, the performance of the system and the intended use are unchanged). Because the change in the component does not result in a new model/version of the system, the system UDI-DI and UDI-PI remain unchanged.

Example 2:
For an x-ray system that is a configurable device where both the 50 kV generator and the 100 kV generator is an option (covered by what is specified for the defined groups of configurations), the 50 kV generator is replaced by 100kV generator or vice versa. The manufacturer has determined that this does not constitute a new version/model, according to their documented procedures for assessing device changes, and therefore the system UDI-DI and UDI-PI remain unchanged. Because the change in the voltage of the generator does not result in a new model/version, the system UDI-DI and UDI-PI remain unchanged.

Example 3:
The addition of an accessory, (e.g. adding a coil to an installed MRI system where coils are part of the configurable system) that is covered by what is specified for the defined groups of configurations does not result in a new model/version of the system. Because the addition of the accessory does not result in a new model/version, the system UDI-DI and UDI-PI remain unchanged. Because the accessory is being distributed separately from the system, the coil should have its own UDI.

- **Changes that induce a change of both UDI-DI and UDI-PI**

Example 1:
An installed MRI System 'Model A' is upgraded in a way that it becomes 'Model B' which is not covered by the defined groups of configurations for Model A, as the safety profile, the performance of the system or the intended use are changed. The manufacturer has determined that this upgrade/model change does result in a new model according to their documented procedures for assessing device changes. Because the upgrade results in a new model/version, a new UDI-DI and UDI-PI is required for the system.

Example 2:
A X-Ray system with a 50 kV generator is changed to a 100 kV generator. These generator options are not specified for the defined groups of configurations, and the performance of the system is changed. The manufacturer has determined that this constitutes a new version/model of the system because the change in the generator of the X-ray system results in a new model/version of the system, a new UDI-DI and UDI-PI is required for the system. .

Example 3:
An interventional x-ray system introduces a new stabilizing mechanism designed to prevent patient head movement during operating and imaging procedures. Although the imaging capabilities are unchanged, this represents a new safety profile for the patient and changes the specifications of the system, and therefore the manufacturer has determined that this upgrade/model change does result in a new model/version according to their documented procedures for assessing device changes. Because this design change to the system results in a new version/model of the system, a new UDI-DI and UDI-PI is required for the system.

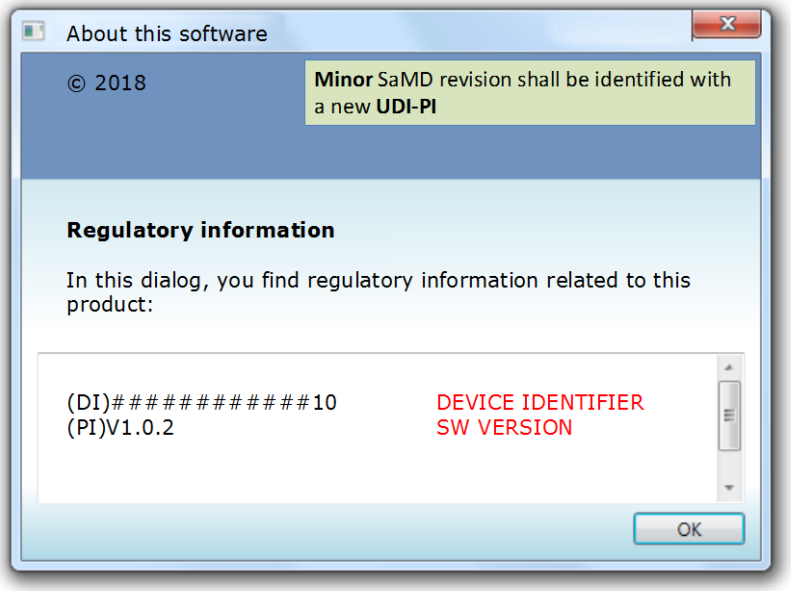
NB: If the stabilizing mechanism is an accessory, and not considered part of the defined configurable system, then no new UDI is required for the x-ray system. A UDI is required, however, for the stabilizing accessory.

Example 4:
A new diagnostic algorithm is introduced on a cardiac ultrasound system allowing new data calculations and imaging options. The algorithm introduces new indications for use and changes the performance of the system, and therefore the manufacturer has determined that this upgrade/model change does result in a new model/version of the cardiac ultrasound system according to their documented procedures for assessing device changes. Because the change results in a new version/model of the system, a new UDI-DI and UDI-PI is required for the system.

Appendix I: Example of UDI assignment for software

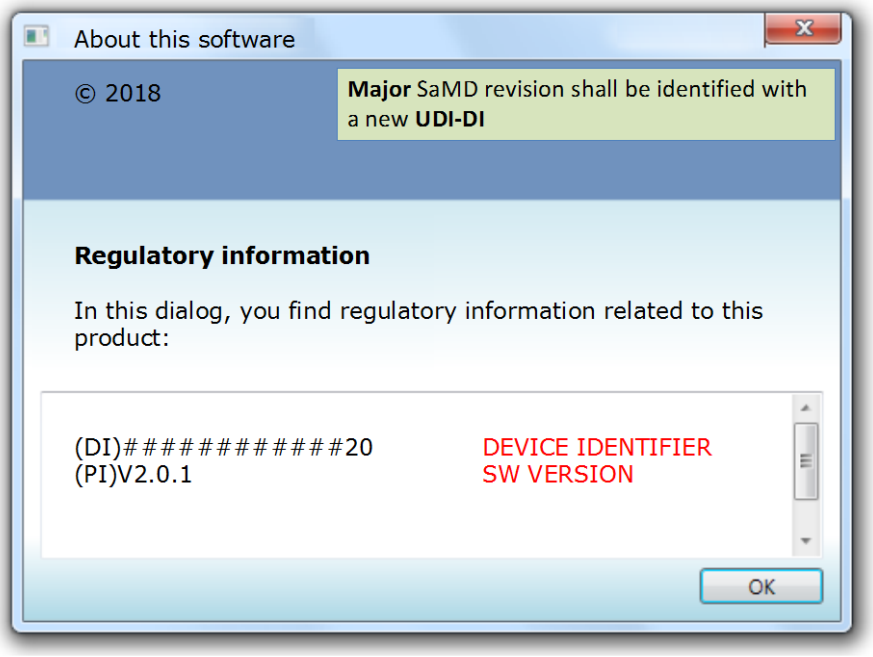
Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013

Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013

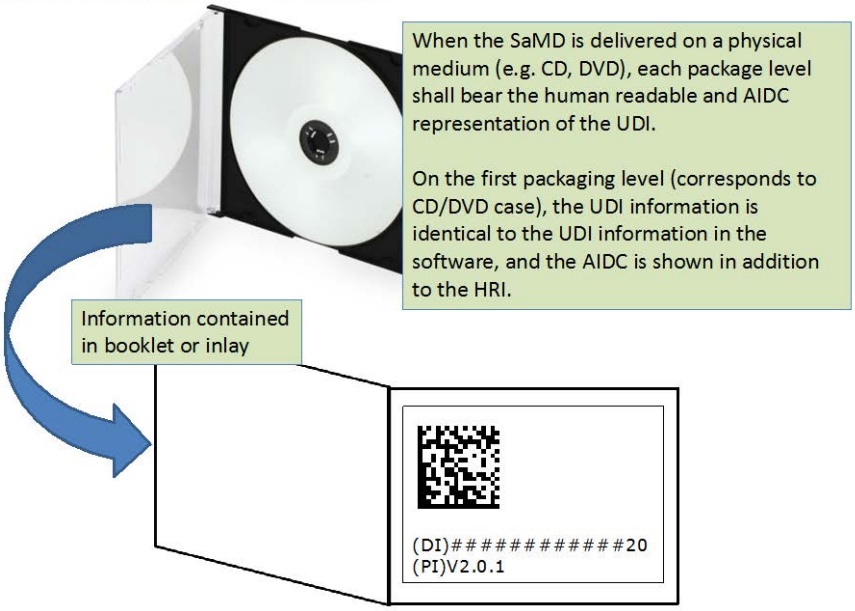


NB: SaMD version might be captured in the lot UDI-PI in certain national regulations.

Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013



Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013



NB: SaMD version might be captured in the lot UDI-PI in certain national regulations.