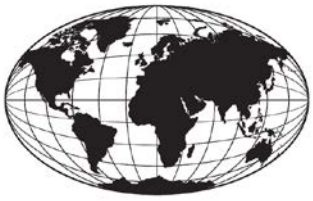

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Common Data Elements for Medical Device Identification

Authoring Group: IMDRF RPS Working Group

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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.

1 Introduction

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force (GHTF). The Forum will accelerate international medical device regulatory harmonization and convergence.

Regulators require submission of device identification information at different points in the regulatory lifecycle of a medical device. Structured device identification information is now or expected in the future to be included as part of pre-market submission, post-marketing distribution and use (disposal and discard), adverse event/vigilance reporting, and recall.

In future postmarket activities, a Unique Device Identification (UDI) system is expected to capture the device identification data elements at the level of a particular device. However, at the point of pre-market submission, specific device identification data elements are not always clearly specified. Therefore it would be useful to establish common data elements, for which values can be provided in the premarket processes and used throughout the lifecycle. Currently these data elements have not been identified resulting in the lack of a consistent nomenclature, definitions and structure for submission of this identifying information. Each type of submission may reference the product differently. For example, a pre-market submission may refer to a product trade name, the data attributes associated with UDI may contain brand name and a recall may refer to proprietary name – all referring to the same device. The identification information is also often submitted as part of unstructured device regulatory submission forms and other unstructured documents. The combination of different ways to identify a product and the unstructured way product information is submitted make it difficult over time to reconcile references to the same product (e.g., the same device may be described one way in a pre-market submission and another way in a post-marketing surveillance report).

Inconsistency in the format used to identify regulatory products as part of submissions and the lack of a harmonized nomenclature and structure for product identification information, currently result in multiple submissions of data, potential conflicts or inconsistencies in submitted information, and ultimately an inability to compile effective post-market surveillance information about a product. Lack of a common definition for regulatory product device identification information also increases the risk that, for regulatory purposes, a product may be referenced differently in different countries, which limits the ability to compile data or make comparisons across countries.

Consistent use of a standardized common set of structured data elements for submission of regulated product identification information will aid in long-term regulatory convergence by providing a common way for regulators to refer to what is regulated and as a result to track and report unambiguously on the national regulatory status of a product around the world.

2 Scope

This document outlines the common data elements for medical device identification that may be used through regulatory activities or process (pre-market, and post-market), including the future possibility of electronic regulatory submission of device identification information. This document will cover the harmonization of terms and their definitions– i.e., the focus is on definition.

3 References

The following references were used in the development of this document:

- IMDRF/UDI WG/N7 FINAL:2013, UDI Guidance - Unique Device Identification (UDI) of Medical Devices
- GHTF/SG1/N70:2011, Label and Instructions for Use for Medical Devices
- IMDRF/RPS WG/N13FINAL:2014, In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)
- IMDRF/RPS WG/N9FINAL:2014, Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)
- GHTF/SG2/N87, An XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities (Based on GHTF/SG2/N54: 2006)

4 Definitions

This document contains definitions as part of the contents of the document. Therefore, this section is not applicable.

5 Data Elements Commonly Used thorough the Medical Device Life Cycle

This document identifies preferable data elements that may be used to identify a medical device through its life span. The data elements resulted from consensus discussions and are still subject to specific regional considerations that are not included in this work item.

5.1 Overview

For inclusion in this document, each data element had to meet some minimum criteria to be considered harmonized and common across regions and regulatory life cycles. First the data element should be used in the identification of the medical device – i.e., the information should be recognizable and identify the medical device. Second, the data element exists during more than one of the product life cycle phases – and when possible exist in a majority of the life cycle phases. It is important to note that all data elements may be required or optional and that their use may vary based on the regulatory activity and/or regional requirements. In summary, all data elements listed as harmonized means that all of the participating Regulators agree that if the data element is relevant in *current or future regulatory activities* in each jurisdiction, that the term and definition will be considered for use.

Although the RPS Common Data Elements Working Group discussed other device related terms – i.e., device characteristics and regulatory tracking information that would be useful in the exchange of information between Regulators and Regulated Industry (and for future use by other stakeholders) there was a determination to only include data elements that aid in device identification at this time.

5.2 Stakeholders

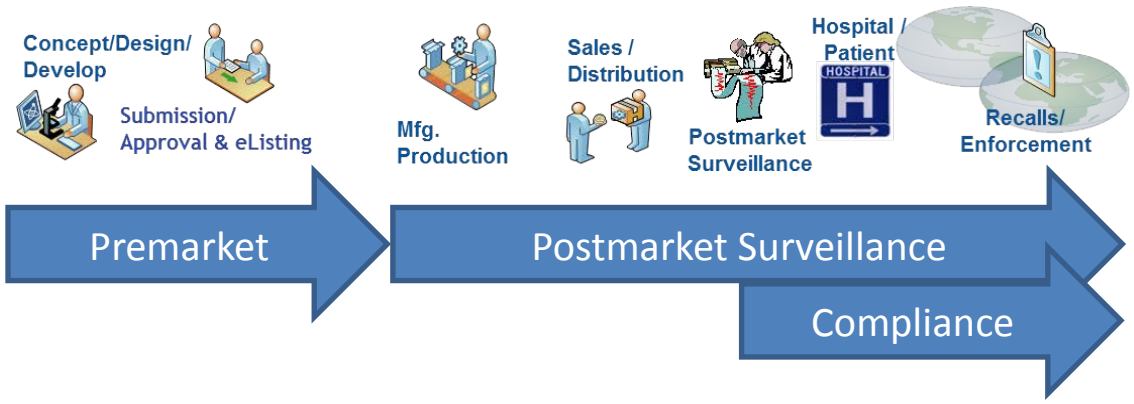
The stakeholders involved in the exchange and/or use of data elements to identify a medical device include, but are not limited to the following:

- Regulators
- Regulated Industry (e.g., Sponsors, Applicants, Manufacturers, Labelers, Suppliers and Distributors, Maintenance/Servicing)
- Users of Medical Devices (e.g., Hospitals, Physicians, Patients, Consumers)

5.3 Life Cycle View of Common Data Elements

The regulatory activities that are involved in the medical device life cycle span the premarket, postmarket and compliance life cycle phases. These life cycles are important in the evolution of data elements used to identify a medical device throughout its distribution and use (disposal and discard).

Figure 1: Life Cycle Phases



Premarket Life Cycle

The premarket life cycle includes regulatory activities associated with preparation or authorization to market a medical device, including but not limited to: submission of a request for regulatory feedback, submission of a request to perform clinical studies, submission of regulatory product information to support an application or notification of marketing a device (e.g., submissions of data to ensure safety and effectiveness), labeling information, and any relevant registration or listing information.

Postmarket Life Cycle

The post market life cycle includes activities that follow certain requirements and regulations to ensure safety and effectiveness once devices are on the market. Medical device manufacturers as well as other firms involved in the distribution of devices are responsible for maintaining

tracking systems (e.g., unique device identification and supply chain tracking), reporting of device malfunctions, and reporting serious injuries and adverse events. Regulators are responsible for postmarket surveillance signal detection, signal assessment, authorizing risk management activities and review of post market commitments.

Compliance Life Cycle

The compliance life cycle includes activities to ensure that medical device manufacturers are complying with medical device regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, and includes monitoring and auditing activities. When a medical device manufacturer fails to comply with these requirements they may either take voluntary actions to correct the violation (e.g., product withdrawal), or regulatory action may be taken that may include removal of marketing authorization, risk communications, warning letters and recalls.

The data elements provided in this document appear in alphabetical order. In addition, the data elements presented do not imply a "requirement" for the exchange and/or use of the data, but only the potential data to identify a medical device at each life cycle phase based on the regulatory requirements in each of the jurisdictions.

Table 1: Summary of Data Elements by Life Cycle

Section	Data Element	Applicable Life Cycle Phase
5.4.1	Brand/Trade/Proprietary or Common Name – Type and Value	Premarket, Postmarket, Compliance
5.4.2	Business Entity Address	Premarket, Postmarket, Compliance
5.4.3	Business Entity Identifier	Premarket, Postmarket, Compliance
5.4.4	Business Entity Name	Premarket, Postmarket, Compliance
5.4.5	Business Entity Type	Premarket, Postmarket, Compliance
5.4.6	Component/Embedded Software Name and/or Version	Premarket, Postmarket, Compliance
5.4.7	Contains Cells or tissues	Premarket, Postmarket, Compliance
5.4.8	Control Number	Postmarket, Compliance
5.4.9	Device Identifier (DI)	Postmarket, Compliance
5.4.10	Device Image	Premarket, Postmarket, Compliance
5.4.11	Device Risk Classification	Premarket, Postmarket, Compliance
5.4.12	Device Type	Premarket, Postmarket, Compliance
5.4.13	Expiration Date	Postmarket, Compliance
5.4.14	Kit	Premarket, Postmarket, Compliance
5.4.15	Lot or Batch Number	Postmarket, Compliance
5.4.16	Manufacturing Date	Postmarket, Compliance
5.4.17	Medical Device System	Premarket, Postmarket, Compliance
5.4.18	Method of sterilization	Premarket, Postmarket, Compliance
5.4.19	Model/ Version or Catalog/Reference Number – Type and Value	Premarket, Postmarket, Compliance
5.4.20	Modified Product/Catalog Number for reprocessed devices	Postmarket, Compliance

Section	Data Element	Applicable Life Cycle Phase
5.4.21	Need for sterilization before use	Premarket, Postmarket, Compliance
5.4.22	Packaged sterile	Premarket, Postmarket, Compliance
5.4.23	Production Identifier (PI)	Postmarket
5.4.24	Regulatory Authorization Number	Premarket, Postmarket, Compliance
5.4.25	Regulatory Authorization Status	Premarket, Postmarket, Compliance
5.4.26	Reusable - Multi-Patient use device	Premarket, Postmarket, Compliance
5.4.27	Reusable - Single Patient use device	Premarket, Postmarket, Compliance
5.4.28	Serial Number	Postmarket, Compliance
5.4.29	Single Use	Premarket, Postmarket, Compliance
5.4.30	Submission Number	Premarket
5.4.31	Unique Device Identifier (UDI)	Postmarket, Compliance

5.4 Harmonized Common Data Elements

The following sections are organized by individual common data elements, and provide the harmonized description of each data element, the life cycle (i.e., usage) and implementation information (e.g., data format and any relevant value sets – i.e., structured, controlled vocabulary).

5.4.1 Brand/Trade/Proprietary or Common Name – Type and Value

Type

Type of value that identifies the name of the device marketed.

Implementation Considerations	
Comments:	None
Data Format:	Code
Preferred Value Set:	Brand Trade/Proprietary Common

Value

The name under which the device is marketed. If there is a Brand name, a Brand Name must be provided. If not, a Trade or Proprietary Name and finally if there is no Brand/Trade/Proprietary, a Common name would be acceptable.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The brand/trade/proprietary name of a medical device may not be the same in all regions -- i.e., the medical device is branded differently across regions and may vary due to regulatory or marketing decisions. The common name may also be duplicative of the device type in some situations; and device type may be preferred as it is a controlled vocabulary.
Data Format:	Text
Preferred Value Set:	None specified

Examples[1]:
Type: Brand Name
Value: Brand X

5.4.2 Business Entity Address

The physical and/or mailing/postal location of the business entity.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The type of address information will need to be clear and consistently provided, especially with international addresses (i.e., address parts need to be defined for each region).
Data Format:	Text
Preferred Value Set:	None specified

Examples[2]:
123 Main Street | Anywhere, TX 99999-0000 | USA
1-1, Yaesu 1-Chome | Chuo-ku, Tokyo 100-8994
Level 6 51 Jacobson St | BRISBANE QLD 4000

5.4.3 Business Entity Identifier

The alphanumeric value used to identify the business entity.

Usage Notes: Premarket, Postmarket, Compliance

[1] Note: the example is for illustration purposes only
[2] Note: the example is for illustration purposes only

Implementation Considerations	
Comments:	An identifier is preferred to unstructured data (i.e., the name and physical address) as the identifier may be updated in one location and persisted across many different uses for the business entity. However, the identifier may not be available in all situations. See Business Entity Name and Business Entity Address.
Data Format:	Numeric or alphanumeric
Preferred Value Set:	None specified

Examples[3]:
USFDA: DUNS Number 123456789, FEI Number
ANVISA: CNPJ number: 99.999.999/0001-99
CHINA: Organization Code: 123456-7; Business license registration number: 123456789012345
JAPAN:123456789 (business entity code), 12A3B45678 (MAH license number), AB12345678 (Manufacturer registration number)
Australia: Client ID, ARTG Number

5.4.4 Business Entity Name

The text value used to identify the business entity.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Text
Preferred Value Set:	None specified

Examples[4]:
Device Company A
ABC Devices

5.4.5 Business Entity Type

The value assigned to identify the type of business entity.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The type depending on the regulatory activity undertaken in the exchange or use of the medical device identification data.

[3] Note: the example is for illustration purposes only
[4] Note: the example is for illustration purposes only

Data Format:	Code
Preferred Value Set:	Manufacturer Applicant Marketing Authorization Holder (MAH) Fabricator Original Equipment Manufacturer (OEM) Reprocessor Importer Distributor Supplier Contract Manufacturer Authorized Agent/Representative/Correspondent Labeler Service Agent

Examples[5]:
See Preferred Value set.

5.4.6 Component/Embedded Software Name and/or Version

Type
The type of data being sent for the component/embedded software.

Implementation Considerations	
Comments:	None
Data Format:	Code
Preferred Value Set:	Name Version

Value
Provides the component software (i.e., embedded software) version name and/or version of the device.
Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The values for this data element will not be structured – i.e, the major, minor and patch numbering may be different across devices. The name may be provided in addition to the version to distinctly identify the device's component/embedded software.
Data Format:	Text
Preferred Value Set:	None specified

[5] Note: the example is for illustration purposes only

Examples[6]:
Version 1.1.17
Version 2.0

5.4.7 Contains Cells or tissues

An value that indicates if the device contains cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient; Note - this does not include IVDs

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[7]:
Not applicable.

5.4.8 Control Number

A production identifier indicating the Unit lot or batch for the unit of medical devices; may be synonymous with serial number as well.

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	The control number may be a combination of the serial and lot number for the medical device – and is therefore a distinct production identifier. A control number is a production identifier and may be included in the UDI by its application identifier*. *The identifier indicates the type of production identifier that follows. Note that this may be specific to the issuing agency algorithm. Note : The control number is not applicable in all jurisdictions.
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[8]:
55516551555Q

[6] Note: the example is for illustration purposes only
[7] Note: the example is for illustration purposes only
[8] Note: the example is for illustration purposes only

5.4.9 Device Identifier (DI)

A unique numeric or alphanumeric value specific to a model of a medical device. The value provided for this data element must be following ISO/IEC standards

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	Depending on the risk classification of the device, this information may be available prior to commercial distribution. The DI may be parsed from the UDI because the value is concatenated; or may be a separate value (non-concatenated). If the value is concatenated, the algorithm may be used to parse only the DI value.
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[9]:
(01)10199912345678(10)A12345(21)XYZ123456789
(01)10199912345678
10199912345678
Australia: ARTG 123456

5.4.10 Device Image

An image of the medical device to aid in the identification and visualization of the device.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The device image may be more useful with certain classes or types of devices. As the device image is meant to provide additional visual aid to the individual – other device data may also be available. The image may be a photo, illustration or schematic drawing to be used for the purpose of aiding in the identification of the device.
Data Format:	Image
Preferred Value Set:	None specified (Note: in this case, no file format has been specified)

Examples[10]:
None available.

[9] Note: the example is for illustration purposes only
[10] Note: the example is for illustration purposes only

5.4.11 Device Risk Classification

A classification based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e., the hazard it presents).

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The device risk classifications may vary in regions that have not adopted the GHTF (IMDRF) Risk Classifications. The device risk classification may vary in regions that have not adopted the preferred value set.
Data Format:	Code
Preferred Value Set:	I, II, III, IV

Examples[11]**:**
See Preferred Value set.

5.4.12 Device Type

Type
The code system used for device type.

Implementation Considerations	
Comments:	The nomenclature system may vary in each jurisdiction – e.g., GMDN, JMDN.
Data Format:	Identifier (text or numeric)
Preferred Value Set:	GMDN Code System

Code
The code used to represent the device type.

Implementation Considerations	
Comments:	The preferred nomenclature system would be GMDN at the time of this publication. As this is a code system, the code will allow any system to resolve a display value (e.g., GMDN Preferred Term Name) The device type may be preferred over the common name as it is a controlled vocabulary. The device type may vary in regions that have not adopted the

[11] Note: the example is for illustration purposes only

	preferred value set.
Data Format:	Code
Preferred Value Set:	GMDN

Value

Name of the common device type associated with a nomenclature system.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	The name value would be determined by the code value submitted – i.e., this value is the display name of the code.
Data Format:	Text
Preferred Value Set:	GMDN

Examples[12]**:**
Type: GMDN
Code: 99999
Value: Sample GMDN Name

Type: JMDN
Code: 12345678
Value: Sample JMDN Name

5.4.13 Expiration Date

The expiry date of the device.

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	An expiration date is a production identifier and may be included in the UDI by its application identifier* or provided as a separate value. *The identifier indicates the type of production identifier that follows. Note that this may be specific to the issuing agency algorithm.
Data Format:	yyyy-mm-dd (ISO standard) or yymmdd
Preferred Value Set:	None specified

Examples[13]**:**
2020-01-01

[12] Note: the example is for illustration purposes only
[13] Note: the example is for illustration purposes only

(01)10199912345678(17)200101(21)XYZ123456789
(17)200101
200101

5.4.14 Kit

Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device**.**

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[14]**:**
Not applicable.

5.4.15 Lot or Batch Number

A value that represents one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and are intended to have uniform characteristics and quality within specified limits.

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	A lot or batch number is a production identifier and may be included in the UDI by its application identifier*or provided as a separate value. *The identifier indicates the type of production identifier that follows. Note that this may be specific to the issuing agency algorithm.
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[15]**:**
(01)10199912345678(10)A12345(21)XYZ123456789
(10)A12345
A12345

[14] Note: the example is for illustration purposes only
[15] Note: the example is for illustration purposes only

5.4.16 Manufacturing Date

The date the device was manufactured.

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	A manufacturing date is a production identifier and may be included in the UDI by its application identifier* or provided as a separate value. *The identifier indicates the type of production identifier that follows. Note that this may be specific to the issuing agency algorithm.
Data Format:	yyyy-mm-dd (ISO standard) or yymmdd
Preferred Value Set:	None specified

Examples[16]**:**
2015-01-01
(01)10199912345678(11)150101(21)XYZ123456789
(11)150101
150101

5.4.17 Medical Device System

A medical device comprising a number of components or parts intended to be used together to fulfill some or all of the device's intended functions, and is sold as specified by its manufacturer (e.g., under a single name, or sold as one item).

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[17]**:**
Not applicable.

5.4.18 Method of sterilization

If yes is answered to "requires sterilization before use", then the method of sterilization should be indicated.

Usage Notes: Premarket, Postmarket, Compliance

[16] Note: the example is for illustration purposes only
[17] Note: the example is for illustration purposes only

Implementation Considerations	
Comments:	Source: IMDRF UDI Guidance. In some regions, the values are specified in regulations.
Data Format:	Code
Preferred Value Set:	Regional

Examples[18]**:**
Dry Heat, Ethylene Oxide, Steam, H_2O_2

5.4.19 Model/ Version or Catalog/Reference Number – Type and Value

Type

Type of value that identifies the medical device's configuration, features, specifications, performance, size and/or composition.

Implementation Considerations	
Comments:	The Model/Version numbers are preferred, but in cases where only a Catalog/Reference number exists it may be used.
Data Format:	Code
Preferred Value Set:	Model Version Catalog/Reference

Value

Alphanumeric that identifies each device according to its configuration, features, specifications, performance, size and/or composition.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Text
Preferred Value Set:	None specified

Examples[19]**:**
Type: Model
Value: X1000

[18] Note: the example is for illustration purposes only
[19] Note: the example is for illustration purposes only

5.4.20 Modified Product/Catalog Number for reprocessed devices

The reprocessor should be assigning a new or modified product or catalog number to reference their handling of device. The new device identification from the reprocessor is important for the tracking purpose.

Usage Notes: Postmarket, Compliance

Implementation Considerations	
Comments:	This value is not known until the device has been reprocessed.
Data Format:	Alphanumeric
Preferred Value Set:	Not applicable

Examples[20]:
X1000-A123

5.4.21 Need for sterilization before use

Need for sterilization before use? (Yes/No) – If yes, then the method of sterilization should be indicated

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	Source: IMDRF UDI Guidance
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[21]:
Not applicable

5.4.22 Packaged sterile

Indicates whether or not the device is packaged sterile. E.g., Packaged sterile? (Yes/No)

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	Source: IMDRF UDI Guidance
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[22]:
Not applicable

[20] Note: the example is for illustration purposes only
[21] Note: the example is for illustration purposes only
[22] Note: the example is for illustration purposes only

5.4.23 Production Identifier (PI)

A numeric or alphanumeric code that identifies the unit of device production including serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date.

Usage Notes: Postmarket

Implementation Considerations	
Comments:	The PI may be parsed from the UDI because the value is concatenated; or may be a separate value (non-concatenated). If the value is concatenated, the algorithm may be used to parse only the PI value.
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[23]**:**
(01)10199912345678(10)A12345(21)XYZ123456789
(10)A12345(21)XYZ123456789

5.4.24 Regulatory Authorization Number

A number which is issued when the medical device is authorized for marketing.

Usage Notes: Premarket, Postmarket and Compliance

Implementation Considerations	
Comments:	Authorization numbers are assigned by each regulatory authority. A medical device may have many authorization numbers. Note: In some regions, the authorization number is the same as the submission number.
Data Format:	Numeric or Alphanumeric
Preferred Value Set:	None specified

Examples[24]**:**
USFDA: P009999, P010001/S001, K010001
ANVISA: 80009999991, 10009999991
Health Canada: 65390
Japan: 22700BZX00000000
Australia: ARTG 123456

[23] Note: the example is for illustration purposes only
[24] Note: the example is for illustration purposes only

5.4.25 Regulatory Authorization Status

The decision or action of the regulatory activity.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	Notes: Regulatory activities and decisions are based on regional requirements.
Data Format:	Code
Preferred Value Set:	Regional

Examples[25]:
Approved, Approvable

5.4.26 Reusable - Multi-Patient use device

The repeated use or multiple use of any medical device including devices intended for reuse on multiple patients, with reprocessing (cleaning, disinfection or sterilization) between uses.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[26]:
Not applicable.

5.4.27 Reusable - Single Patient use device

The repeated use or multiple use of any medical device including devices intended for reuse on one patient, with reprocessing (cleaning, disinfection or sterilization) between uses.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

[25] Note: the example is for illustration purposes only
[26] Note: the example is for illustration purposes only

Examples[27]:
Not applicable.

5.4.28 Serial Number

A unique sequence of numbers or letter in a series used to identify an individual unit of a medical device.

Usage Notes: Postmarket and Compliance

Implementation Considerations	
Comments:	A serial number is a production identifier may be included in the UDI by its application identifier*or provided as a separate value. *The application identifier indicates the type of production identifier that follows. Note that this may be specific to the issuing agency algorithm.
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[28]:
(01)10199912345678(10)A12345(21)XYZ123456789
(21)XYZ123456789
XYZ123456789

5.4.29 Single Use

A single-use device, also referred to as a disposable device, intended for use on one patient during a single procedure.

Usage Notes: Premarket, Postmarket, Compliance

Implementation Considerations	
Comments:	None
Data Format:	Boolean (Y/N)
Preferred Value Set:	Yes/No

Examples[29]:
Not applicable

[27] Note: the example is for illustration purposes only
[28] Note: the example is for illustration purposes only
[29] Note: the example is for illustration purposes only

5.4.30 Submission Number

A tracking number which is issued to the regulatory activity when submitted by the applicant.

Usage Notes: Premarket

Implementation Considerations	
Comments:	Submission numbers are assigned by each regulatory authority. A medical device may have many submission numbers, e.g., initial submission, amendments and renewals. Note: In some regions, the submission number is the same as the authorization number.
Data Format:	Numeric or Alphanumeric
Preferred Value Set:	None specified

Examples[30]**:**
USFDA: P009999/S001/A001, K010001/S001
ANVISA: 3590009/15-9
Health Canada: 201235
Japan:1234567890123

5.4.31 Unique Device Identifier (UDI)

A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. The UDI is comprised of the device identifier (DI) and production identifier (PI). It allows the unambiguous identification of a specific medical device.

Usage Notes: Postmarket, Compliance

Implementation Considerations	
Comments:	The UDI may be available as one string value (concatenated) or may be parsed into its parts (see DI and PI).
Data Format:	Numeric or Alphanumeric (depending on issuing agency algorithm)
Preferred Value Set:	None specified

Examples[31]**:**
(01)10199912345678(10)A12345(21)XYZ123456789

[30] Note: the example is for illustration purposes only
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No Appendices available in this document