DDC	WC	(DD1)	/N19R
KPS	WIT	(PDI)	MIYK.



# PROPOSED DOCUMENT

# **International Medical Device Regulators Forum**

Title: Common Data Elements for Medical Device Identification

**Authoring Group:** IMDRF RPS Working Group

**Date:** 8 July, 2015

32	Content	S	
33	1 Intro	duction	5
34	2 Scop	e	6
35	3 Refer	rences	6
36	4 Defin	nitions	6
37	5 Data	Elements Commonly Used thorough the Medical Device Life Cycle	6
38	5.1	Overview	6
39	5.2 S	Stakeholders	7
40	5.3 I	ife Cycle View of Common Data Elements	7
41	5.4 H	Harmonized Common Data Elements	9
42	5.4.1	Brand/Trade/Proprietary or Common Name - Type and Value	9
43	5.4.2	Business Entity Address	10
44	5.4.3	Business Entity Identifier	10
45	5.4.4	Business Entity Name	11
46	5.4.5	Business Entity Type	11
47	5.4.6	Component/Embedded Software Name and/or Version	12
48	5.4.7	Contains Cells or tissues	13
49	5.4.8	Control Number	13
50	5.4.9	Device Identifier (DI)	14
51	5.4.1	0 Device Image	14
52	5.4.1	1 Device Risk Classification	15
53	5.4.1	2 Device Type	15
54	5.4.1	3 Expiration Date	16
55	5.4.1	4 Kit	17
56	5.4.1	5 Lot or Batch Number	17
57	5.4.1	6 Manufacturing Date	18
58	5.4.1	7 Medical Device System	18
59	5.4.1	8 Method of sterilization	18
60	5.4.1	9 Model/ Version or Catalog/Reference Number – Type and Value	19
61	5.4.2	0 Modified Product/Catalog Number for reprocessed devices	20
62	5.4.2	1 Need for sterilization before use	20
63	5.4.2	2 Packaged sterile	20
64	5.4.2	3 Production Identifier (PI)	21

65	5.4.24	Regulatory Authorization Number	21
66	5.4.25	Regulatory Authorization Status	22
67	5.4.26	Reusable - Multi-Patient use device	22
68	5.4.27	Reusable - Single Patient use device	22
69	5.4.28	Serial Number	23
70	5.4.29	Single Use	23
71	5.4.30	Submission Number	24
72	5.4.31	Unique Device Identifier (UDI)	24
73			
74			
75			
76			
77			
78			
79			
80			

8 July 2015 Page 3 of 25

# 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. There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

**Preface** 

8 July 2015 Page 4 of 25

#### 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.

8 July 2015 Page 5 of 25

#### 133 **2 Scope**

- 134 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.

139

143

148149

150

169

#### 3 References

- 140 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)

#### 151 **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

- 155 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.

#### 158 **5.1 Overview**

- 159 For inclusion in this document, each data element had to meet some minimum criteria to be
- 160 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.

8 July 2015 Page 6 of 25

- 170 Although the RPS Common Data Elements Working Group discussed other device related terms
- 171 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).

187 188 189

175

178

179

180

181 182

183

184

185

186

Figure 1: Life Cycle Phases



190 191

192

193

194

195

196

#### 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.

197 198 199

200

201

202

#### 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

8 July 2015 Page 7 of 25

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 –	Premarket, Postmarket, Compliance
	Type and Value	
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	Premarket, Postmarket, Compliance
	Version	
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	Premarket, Postmarket, Compliance
	- Type and Value	
5.4.20	Modified Product/Catalog Number for	Postmarket, Compliance
	reprocessed devices	

8 July 2015 Page 8 of 25

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

#### 223 **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

229 *Type* 

228

230

231

232

234

235

236

237238

239

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

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

## 233 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

8 July 2015 Page 9 of 25

<b>^</b> 1 <b>^</b>	
. , /	

<b>Implementation Con</b>	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	None specified	
Set:		

241

242 Examples<sup>1</sup>:

Type: Brand NameValue: Brand X

#### 5.4.2 Business Entity Address

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

247248

245

Usage Notes: Premarket, Postmarket, Compliance

249

<b>Implementation Consi</b>	Implementation Considerations	
<b>Comments:</b>	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).	
<b>Data Format:</b>	Text	
<b>Preferred Value Set:</b>	None specified	

250

251 Examples<sup>2</sup>:

252 123 Main Street | Anywhere, TX 99999-0000 | USA

253 1-1, Yaesu 1-Chome | Chuo-ku, Tokyo 100-8994

254 Level 6 51 Jacobson St | BRISBANE QLD 4000

#### 255 **5.4.3** Business Entity Identifier

256 The alphanumeric value used to identify the business entity.

257

258 **Usage Notes:** Premarket, Postmarket, Compliance

259

<sup>1</sup> Note: the example is for illustration purposes only

8 July 2015 Page 10 of 25

<sup>&</sup>lt;sup>2</sup> Note: the example is for illustration purposes only

2	6Ω
_	UU

Implementation Considerations		
<b>Comments:</b>	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	
<b>Preferred Value Set:</b>	None specified	

261

262 Examples<sup>3</sup>:

- 263 USFDA: DUNS Number 123456789, FEI Number
   264 ANVISA: CNPJ number: 99.999.999/0001-99
- 265 **CHINA:** Organization Code: 123456-7; Business license registration number:
- 266 123456789012345
- 267 **JAPAN:**123456789 (business entity code), 12A3B45678 (MAH license number), AB12345678
- (Manufacturer registration number)Australia: Client ID, ARTG Number
- 270 **5.4.4 Business Entity Name**
- The text value used to identify the business entity.

272273

Usage Notes: Premarket, Postmarket, Compliance

274

Implementation Considerations	
<b>Comments:</b>	None
Data Format:	Text
Preferred Value Set: None specified	

275

- 276 Examples<sup>4</sup>:
- 277 Device Company A
- 278 ABC Devices

## 279 **5.4.5 Business Entity Type**

The value assigned to identify the type of business entity.

281

282 **Usage Notes:** Premarket, Postmarket, Compliance

283

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

<sup>&</sup>lt;sup>3</sup> Note: the example is for illustration purposes only

8 July 2015 Page 11 of 25

<sup>&</sup>lt;sup>4</sup> Note: the example is for illustration purposes only

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

284

# 285 Examples<sup>5</sup>:

286 See Preferred Value set.

# 5.4.6 Component/Embedded Software Name and/or Version

288 289

287

#### Гуре

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

290

Implementation Considerations	
<b>Comments:</b>	None
Data Format:	Code
Preferred Value	Name
Set:	Version

291

#### 292 Value

293 Provides the component software (i.e., embedded software) version name and/or version of the device.

295

Usage Notes: Premarket, Postmarket, Compliance

296

<b>Implementation Con</b>	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	None specified	
Set:		

297 298

8 July 2015 Page 12 of 25

<sup>&</sup>lt;sup>5</sup> Note: the example is for illustration purposes only

- 299 **Examples** $^6$ :
- 300 Version 1.1.17
- 301 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

306 Usage Notes: Premarket, Postmarket, Compliance

307

305

302

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

- 308 Examples<sup>7</sup>:
- 309 Not applicable.

#### **310 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.

313314

Usage Notes: Postmarket and Compliance

315

<b>Implementation Con</b>	<b>Implementation Considerations</b>	
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	None specified	
Set:		

#### 316

# 317 Examples<sup>8</sup>:

318 55516551555Q

8 July 2015 Page 13 of 25

<sup>&</sup>lt;sup>6</sup> Note: the example is for illustration purposes only

<sup>&</sup>lt;sup>7</sup> Note: the example is for illustration purposes only <sup>8</sup> 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

322323

319

**Usage Notes:** Postmarket and Compliance

324

<b>Implementation Con</b>	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	None specified	
Set:		

325 Examples<sup>9</sup>:

- 326 (01)10199912345678(10)A12345(21)XYZ123456789
- 327 (01)10199912345678
- 328 10199912345678
- 329 Australia: ARTG 123456

# **5.4.10 Device Image**

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

332

333 Usage Notes: Premarket, Postmarket, Compliance

334

<b>Implementation Con</b>	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	None specified (Note: in this case, no file format has been specified)	
Set:		

335336

# Examples 10:

337 None available.

8 July 2015 Page 14 of 25

<sup>&</sup>lt;sup>9</sup> Note: the example is for illustration purposes only

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).

341342

338

Usage Notes: Premarket, Postmarket, Compliance

343

<b>Implementation Consid</b>	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	
<b>Preferred Value Set:</b>		
	I, II, III, IV	

344

345 Examples  $^{11}$ :

346 See Preferred Value set.

## **5.4.12 Device Type**

348 *Type* 

349 The code system used for device type.

350

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

351 352

Code

The code used to represent the device type.

353 354

<b>Implementation C</b>	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	

\_

8 July 2015 Page 15 of 25

<sup>&</sup>lt;sup>11</sup> Note: the example is for illustration purposes only

	preferred value set.
Data Format:	Code
<b>Preferred Value Set:</b>	GMDN

355 356

Value

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

357 358

Usage Notes: Premarket, Postmarket, Compliance

359 360

Implementation Considerations	
<b>Comments:</b>	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
<b>Preferred Value Set:</b>	GMDN

361

Examples<sup>12</sup>: 362 Type: GMDN 363 **Code:** 99999 364

365 Value: Sample GMDN Name

366

367 **Type:** JMDN 368 **Code:** 12345678

369 Value: Sample JMDN Name

370

### **5.4.13 Expiration Date**

372

371 The expiry date of the device.

373 **Usage Notes:** Postmarket and Compliance

374

Implementation Considerations	
<b>Comments:</b>	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	None specified
Set:	

375

Examples 13: 376 2020-01-01 377

8 July 2015 Page 16 of 25

Note: the example is for illustration purposes onlyNote: the example is for illustration purposes only

- 378 (01)10199912345678(17)200101(21)XYZ123456789
- 379 (17)200101
- 380 200101
- 381 **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.
- 385

Usage Notes: Premarket, Postmarket, Compliance

386 387

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

388

- 389 Examples  $^{14}$ :
- 390 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.

396397

**Usage Notes:** Postmarket and Compliance

398

Implementation Considerations	
<b>Comments:</b>	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)
<b>Preferred Value Set:</b>	None specified

399

- 400 Examples  $^{15}$ :
- 401 (01)10199912345678(10)A12345 (21)XYZ123456789
- 402 (10)A12345
- 403 A12345

<sup>14</sup> Note: the example is for illustration purposes only

8 July 2015 Page 17 of 25

<sup>&</sup>lt;sup>15</sup> Note: the example is for illustration purposes only

#### **5.4.16** Manufacturing Date

The date the device was manufactured.

405 406 407

404

**Usage Notes:** Postmarket and Compliance

408

Implementation Considerations	
<b>Comments:</b>	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
<b>Preferred Value Set:</b>	None specified

409

- Examples 16: 410
- 411 2015-01-01
- (01)10199912345678(11)150101(21)XYZ123456789 412
- 413 (11)150101
- 414 150101

#### 415 **5.4.17 Medical Device System**

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

419

420 Usage Notes: Premarket, Postmarket, Compliance

421

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

422 423

- Examples<sup>17</sup>:
- Not applicable. 424

#### 425 **5.4.18** Method of sterilization

- If yes is answered to "requires sterilization before use", then the method of sterilization should 426
- be indicated. 427

428

429 **Usage Notes:** Premarket, Postmarket, Compliance

8 July 2015 Page 18 of 25

<sup>&</sup>lt;sup>16</sup> Note: the example is for illustration purposes only

<sup>&</sup>lt;sup>17</sup> Note: the example is for illustration purposes only

430

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

431

- 432 Examples  $^{18}$ :
- 433 Dry Heat, Ethylene Oxide, Steam, H<sub>2</sub>O<sub>2</sub>

## 434 **5.4.19** Model/ Version or Catalog/Reference Number – Type and Value

435 *Type* 

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

438

Implementation Considerations	
<b>Comments:</b>	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	Model
Set:	Version
	Catalog/Reference

439 440

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

443

444 **Usage Notes:** Premarket, Postmarket, Compliance

445

Implementation Considerations	
<b>Comments:</b>	None
Data Format:	Text
Preferred Value	None specified
Set:	

446

- 447 Examples 19:
- 448 **Type:** Model
- 449 **Value:** X1000

<sup>18</sup> Note: the example is for illustration purposes only

8 July 2015 Page 19 of 25

<sup>&</sup>lt;sup>19</sup> Note: the example is for illustration purposes only

#### 450 **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
- 452 their handling of device. The new device identification from the reprocessor is important for the
- 453 tracking purpose.

454 455

**Usage Notes:** Postmarket, Compliance

456

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

457

- 458 Examples  $^{20}$ :
- 459 X1000-A123
- 460 5.4.21 Need for sterilization before use
- Need for sterilization before use? (Yes/No) If yes, then the method of sterilization should be
- 462 indicated

463 464

**Usage Notes:** Premarket, Postmarket, Compliance

465

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

466

- 467 **Examples**  $^{21}$ :
- 468 Not applicable
- 469 **5.4.22 Packaged sterile**
- 470 Indicates whether or not the device is packaged sterile. E.g., Packaged sterile? (Yes/No)

471

472 **Usage Notes:** Premarket, Postmarket, Compliance

473

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

474 Examples <sup>22</sup>:

475 Not applicable

.\_\_\_\_

8 July 2015 Page 20 of 25

<sup>&</sup>lt;sup>20</sup> Note: the example is for illustration purposes only <sup>21</sup> Note: the example is for illustration purposes only

<sup>&</sup>lt;sup>22</sup> 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.

480 481

476

**Usage Notes:** Postmarket

482

Implementation Considerations	
<b>Comments:</b>	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	None specified
Set:	

483

- 484 Examples  $^{23}$ :
- 485 (01)10199912345678(10)A12345(21)XYZ123456789
- 486 (10)A12345(21)XYZ123456789

#### 487 **5.4.24 Regulatory Authorization Number**

- 488 A number which is issued when the medical device is authorized for marketing.
- 489 490

90 **Usage Notes:** Premarket, Postmarket and Compliance

491

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	None specified
Set:	

492

493 Examples  $^{24}$ :

494 **USFDA:** P009999, P010001/S001, K010001

495 **ANVISA:** 80009999991, 10009999991

496 Health Canada: 65390
 497 Japan: 22700BZX0000000
 498 Australia: ARTG 123456

499

8 July 2015 Page 21 of 25

<sup>&</sup>lt;sup>23</sup> Note: the example is for illustration purposes only

<sup>&</sup>lt;sup>24</sup> Note: the example is for illustration purposes only

#### 500 **5.4.25 Regulatory Authorization Status**

The decision or action of the regulatory activity.

501 502 503

Usage Notes: Premarket, Postmarket, Compliance

504

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

505

506 Examples  $^{25}$ :

507 Approved, Approvable

#### 508 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.

511

512 **Usage Notes:** Premarket, Postmarket, Compliance

513

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

514

- 515 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.

520

521 **Usage Notes:** Premarket, Postmarket, Compliance

522

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

523

8 July 2015 Page 22 of 25

<sup>&</sup>lt;sup>25</sup> Note: the example is for illustration purposes only

<sup>&</sup>lt;sup>26</sup> Note: the example is for illustration purposes only

- 524 Examples<sup>27</sup>:
- 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.

529530

**Usage Notes:** Postmarket and Compliance

531

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.
<b>Data Format:</b>	Numeric or Alphanumeric (depending on issuing agency algorithm)
<b>Preferred Value</b>	None specified
Set:	

532

- 533 Examples  $^{28}$ :
- 534 (01)10199912345678(10)A12345 (21)XYZ123456789
- 535 (21)XYZ123456789
- 536 XYZ123456789
- **537 5.4.29 Single** Use
- A single-use device, also referred to as a disposable device, intended for use on one patient
- 539 during a single procedure.

540

541 **Usage Notes:** Premarket, Postmarket, Compliance

542

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

543

- 544 Examples<sup>29</sup>:
- Not applicable

<sup>27</sup> Note: the example is for illustration purposes only

8 July 2015 Page 23 of 25

<sup>&</sup>lt;sup>28</sup> Note: the example is for illustration purposes only <sup>29</sup> 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.

549 **Usage Notes:** Premarket

550

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
<b>Preferred Value</b>	None specified
Set:	

551

546

547

548

552 Examples  $^{30}$ :

553 **USFDA:** P009999/S001/A001, K010001/S001

554 **ANVISA**: 3590009/15-9 555 **Health Canada**: 201235 556 **Japan**:1234567890123

557

558

#### **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.

562

563 **Usage Notes:** Postmarket, Compliance

564

Implementation Considerations	
<b>Comments:</b>	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)
<b>Preferred Value Set:</b>	None specified

 $\overline{\text{Examples}^{31}}$ :

566 (01)10199912345678(10)A12345(21)XYZ123456789

<sup>30</sup> Note: the example is for illustration purposes only

8 July 2015 Page 24 of 25

<sup>31</sup> Note: the example is for illustration purposes only

567
568
569
570
571
572
573
574
575
576
577
578
579
No Appendices available in this document

8 July 2015 Page 25 of 25