



## **Global Harmonization Working Party**

Towards Medical Device Harmonization

### **PROPOSED FINAL DOCUMENT**

**Title:** Creation and Placement of Unique Device Identifier

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17 **Introduction**

18 The implementation of the UDI System will help to establish a single, globally  
19 harmonized system, so that medical device stakeholders will no longer have to access  
20 multiple, inconsistent, and incomplete sources in an attempt to identify a medical device  
21 and, its key attributes. It is critical to note that the benefits of UDI can only accrue if all  
22 stakeholders integrate and utilize UDI throughout their respective systems and  
23 processes, avoiding the distribution or dispensing of counterfeit, expired, prohibited or  
24 withdrawn medical devices. Therefore, strengthening training and guidance in  
25 production, distribution, and use is of great significance in the implementation of the  
26 UDI System.

27 A UDI System comprises three parts: the unique device identifier, the UDI data carrier  
28 and the UDI database, corresponding to UDI creation, placement and data upload  
29 respectively. To address UDI creation and placement, this document stipulates the  
30 requirements for implementation and application by stakeholders, and is a useful  
31 supplement to the relevant regulations. Given the diverse nature of medical devices,  
32 discrepancies may exist in UDI implementation for different device types. This  
33 document also specifies the requirements for UDI creation and placement for specific  
34 device types, with the intent to provide references for UDI implementation and  
35 application by medical device stakeholders.

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# Creation and Placement of Unique Device Identifier

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## 1 Scope

This document specifies the requirements for UDI creation and placement.  
This document applies to UDI implementation and application by all stakeholders.

## 2 Terms, Definitions and Abbreviations

### 2.1 Terms and Definitions

#### 1) General Terms

##### **Unique Device Identification system**

The identification system for medical devices composed of a device identifier, a production identifier, a unique device identifier data carrier, and unique device identification database.

##### **Label**

The literal instructions, graphic information appearing on the medical device itself or on its packaging, which are used to identify the product features and indicate the safety warnings and other information.

##### **Labelling**

The label, instructions for use and any other information related to the identification, technical description, intended use and proper use of the medical device, not including shipping document.

##### **Direct Marking**

The process of applying the unique device identifier permanently to the device itself.

##### **Shipping Container**

A container where the traceability is controlled by a logistics system process whose contents may vary from one shipment to another.

##### **Packaging Level**

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87 The various levels of device packages that contain a fixed quantity of medical devices.

88 Note: This does not include shipping containers.

89

90 **Minimum sales unit**

91 For the purpose of product sales, the minimum sales package of the product assigned by  
92 the manufacturer.

93 Note1: The minimum sales unit is usually the lowest level of packaging with UDI.

94 Note2: When the minimum sales unit contains multiple medical devices, healthcare  
95 facilities should have access to the minimum sales unit packaging to ensure the traceability  
96 of the medical device.

97

98 2) Unique Device Identifier

99 **Unique Device Identifier(UDI)**

100 A series of codes composed of numbers, letters and/or symbols and created based on a  
101 standard. It is comprised of device identifier and production identifier and used for the  
102 uniqueness identification of a medical device.

103 Note 1: The word “unique” does not imply serialization management of individual  
104 products.

105 Note 2: It can be used for the management and tracing of medical device products.

106

107 **Device Identifier (UDI-DI)**

108 A unique code specific to a specification, model or packaging of medical device.

109 Note: Device identifier can be used as the “access key” to information stored in a unique  
110 device identification database to associate the product information, manufacturer  
111 information and registration information of the medical device.

112

113 **Production Identifier (UDI-PI)**

114 A code that identifies the data related to the production process of the medical device.

115 Note: According to the actual application requirements, a production identifier may  
116 include the serial number, batch/lot number, software version, manufacturing date, and  
117 expiration date of the medical device.

118

119 **Data Delimiter**

120 A character or character set that defines a specific data element in a unique device

---

121 identifier.

122 Note1: It should conform to the coding standard of the issuing agency.

123 Note2: Some examples of data delimiters include application identifier (AI) and object  
124 identifier (OID).

125

### 126 **Unit of Use Device Identifier (UoU UDI-DI)**

127 An identifier assigned to an individual medical device when a UDI is not labeled on the  
128 individual device at the level of its unit of use. Its purpose is to associate the use of a  
129 device to/on a patient.

130 Note: For example, for one pack of N ( $N > 1$ ) blood collection tubes, an identifier assigned  
131 to an individual blood collection tube when a UDI is not labeled on the individual blood  
132 collection tube.

133

### 134 3) Unique Device Identifier Data Carrier

#### 135 **Unique Device Identifier Data Carrier**

136 The data medium that stores or transfers the UDI. The UDI Carrier is the means to convey  
137 the UDI by using AIDC and, if applicable, its HRI.

138

#### 139 **One-dimensional bar code (1D bar code)**

140 A bar code symbol that represents information only in one-dimensional direction. Usually  
141 referred to as a linear bar code.

142

#### 143 **Two-dimensional bar code (2D bar code)**

144 A bar code symbol that represents information in two-dimensional directions. Contains  
145 information within its horizontal and vertical structure.

146

#### 147 **Radio frequency identification (RFID)**

148 A technology that uses the electromagnetic or inductive coupling in the RF section of the  
149 spectrum to intercommunicate with an RF tag for the purpose of the unique reading of its  
150 identity through various modulation and coding schemes.

151

#### 152 **RF Tags**

153 A data carrier that is used for the identification of an object or article and has the ability to

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154 store information, receive electromagnetic modulation signals from a reader-writer and  
155 send back corresponding signals.

156

157 4) Unique Device Identification Database

158 **Unique Device Identification Database (UDID)**

159 The database that stores the device identifier and other relevant information about specific  
160 devices.

161

162 **2.2 Abbreviations**

163 The following abbreviations are applicable to this document.

164 AIDC: automatic identification and data capture

165 HRI: human readable information/interpretation

166 UDI: unique device identifier

167 UDID: unique device identification database UDI-DI: device identifier

168 UDI-PI: production identifier

169 UoU UDI-DI: unit of use device identifier

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171

172 **3 General principles for UDI creation**

173 UDI creation should follow the general principles listed below.

174 1) The UDI should contain two parts: an UDI-DI and an UDI-PI.


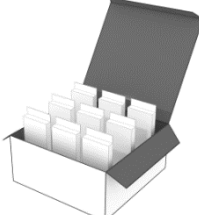
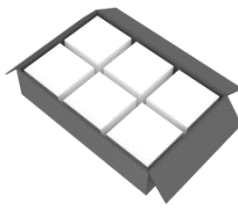
175 2) The UDI should be created according to the coding rules of the issuing agency  
176 selected; if the national regulations and standards provide otherwise, such provisions  
177 should be followed.

178 3) A UDI should be assigned to the device itself, its package, or the minimum sales unit  
179 of the medical device, and higher levels of packaging (not including shipping  
180 containers) should have their own UDI.

181 4) Different UDI-DIs should be assigned to each level of device packaging, see Table 1,  
182 and the linkage in the UDID should be maintained.

183

184 Table 1 Device Identification and Packaging Diagram of Medical Devices

|   |   |   |
|---|---|---|
|  |  |  |
| Single device or minimum package  | Box   | Carton  |
| Quantity=1  | Quantity in each box=9  | Quantity in each carton=54  |
| Device identifier A   | Device identifier B   | Device identifier C   |

185

186 5) When the minimum sales unit contains more than one identical unit of use, a UoU UDI-  
 187 DI should be assigned and stored in the UDID to associate the use of a device with a  
 188 patient.

189 6) The UDI-DI should be stable. If there is no change in the essential characteristics of  
 190 the medical device, the UDI-DI should remain the same, but whenever there is a change  
 191 that could lead to misidentification of the medical device and/or ambiguity in its  
 192 traceability, a new UDI-DI is required, for example, change in the quantity of products  
 193 in the package, packaging sterility status and/or labeling for single use, etc.

194 Note: Essential characteristics of UDI-DI can be further outlined in national regulations.  
 195 Whether this is the responsibility of an individual or an institution can depend on  
 196 national regulations. It is recommended to minimize differences between regulatory  
 197 agencies.

198 7) The composition of the UDI-PI should be consistent with the label. For example, when  
 199 the label of the medical device contains one or more of the production batch number,  
 200 serial number, manufacturing date and expiration date of the medical device, it is  
 201 recommended that they should be part of the UDI-PI, and the content should be  
 202 identical to the corresponding information on the label; if the representation format of  
 203 the date is involved, it should conform to the coding standard of the issuing agency  
 204 selected.

205 Note1: If some regulatory agencies allow other traceability information in the label, the  
 206 manufacturing date may not be placed in the PI.

207 Note2: Software as a Medical Device (SaMD) version.

208 8) The UDI-PI characteristics (e.g. lot or serial number) shall be defined by the  
 209 manufacturer according to the manufacturer's quality management. For medical devices



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210 controlled by batch production, considering the application scenario, if marking on a  
211 single product is required, a serial number should be included in addition to the  
212 combination of UDI-DI and production batch number, or other data delimiters should  
213 be included according to the coding standard of the issuing agency selected.

214  
215

#### 216 **4 General Principles for UDI Placement**


217 UDI placement should follow the general principles listed below.

- 218 1) The UDI placement requirements should not replace the requirements of existing  
219 marking or labelling regulations.
- 220 2) UDI placement should be done according to the criteria or specifications of the issuing  
221 agency, and the issuing agency should provide the data carrier rules for its criteria,  
222 including but not limited to the requirements for carrier type, size, placement and  
223 carrier quality, and the recommendation for the corresponding HRI representation  
224 form.
- 225 3) UDI data carriers include AIDC and HRI, and the HRI portion should include data  
226 delimiter. In case of space constraints or restrictions of use, the AIDC carrier form  
227 should be favored.
- 228 4) To facilitate all stakeholders throughout distribution and use to quickly search and  
229 locate UDI data carriers, the UDI graphic symbols (see Table 2) specified in 5.7.10 of  
230 ISO 15223-1:2021 should be used to identify data carriers containing UDI  
231 information. If used, it shall comply with the requirements of ISO 15223-1:2021. For  
232 the one-dimensional code and/or two-dimensional code data carrier identification  
233 using this symbol, see Figure 1.

234  
235

**Table 2 Symbols to convey medical device information**

| Reference number and graphic | Title | Description | Requirements | Notes | Restrictions of use | ISO/IEC symbol number and registration date |
|------------------------------|-------|-------------|--------------|-------|---------------------|---|
|------------------------------|-------|-------------|--------------|-------|---------------------|---|

|  |                                 |  |   |  |          |            |
|--|---------------------------------|--|---|--|----------|------------|
| <p>5.7.10 (ISO 15223-1:2021)</p>  | <p>Unique Device Identifier</p> | <p>Indicates a data carrier that contains Unique Device Identifier information</p> | <p>This symbol may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the Unique Device Identifier carrier.</p> | <p>This symbol identifies the UDI carrier, including the AIDC and HRI.</p> | <p>—</p> | <p>N/A</p> |
|--|---------------------------------|--|---|--|----------|------------|

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**Figure 1 Schematic representation of 1D and/or 2D bar code using UDI graphic symbol**

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Note: This figure is for the purpose of illustration only to provide a reference for the use of UDI graphic symbols.

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242

243

5) UDI data carriers should be placed in an easily visible position. If other types of AIDC representation other than UDI are placed on the relevant packaging, label or device, the placement of these other internal or proprietary AIDC markings should be done in such a way as to avoid causing confusing with UDI data carriers.

246

247

6) UDI data carriers should be readily readable throughout distribution and use of medical devices. Currently, the common forms of data carriers include: marking on the package, marking on the label and direct marking on the device itself, as shown in Figures 2 to 4.

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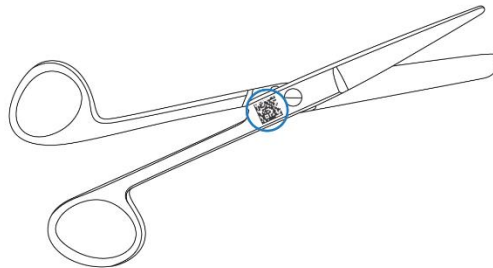
251  
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**Figure 2 Marking on the medical device package**



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**Figure 3 Marking on the medical device label**



257  
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**Figure 4 Direct marking**

Note: The above figures are only the UDI representation.

260  
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7) Direct Marking

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- i. For reusable medical devices, which intended to be used more than once and intended to be reprocessed before each use, direct marking should be assigned with UDI data carriers. If direct marking is used, the UDI data carrier should be readable after each reprocessing cycle for the intended life of the product.
- ii. Direct marking should not compromise the safety and effectiveness of the medical device.

- 
- 269           iii.   Some jurisdictions may place direct marking mandatory for certain kind of  
270                    device. While the definition of reprocessing can be further outlined in national  
271                    regulations.
- 272           iv.   If the medical device is packaged, the direct marking may be accepted different  
273                    than UDI-DI on the device label.
- 274           8)   The influence of transportation, storage and handling environment on the readability  
275                    of UDI data carriers should be taken into consideration. The placement of UDI data  
276                    carriers may refer to the relevant requirements of the national regulations and  
277                    standards.
- 278           9)   Avoiding scanning obstacles
- 279                    Anything that will obscure or damage a barcode will reduce scanning performance  
280                    and shall be avoided. For example:
- 281                    i.   Never position the barcode on the item in an area with inadequate space. Do  
282                    not let the other graphics encroach on the space for the barcode.
- 283                    ii.   Never place barcodes, including Quiet Zones, on perforations, die-cuts, seams,  
284                    ridges, edges, tight curves, folds, flaps, overlaps and rough textures.
- 285                    iii.   Never put staples through a barcode or its Quiet Zones.
- 286                    iv.   Never fold a barcode around a corner.
- 287                    v.   Never place a barcode under a package flap.
- 288                    vi.   Barcodes used for production control purposes SHOULD be obstructed  
289                    wherever possible before entering general distribution.
- 290           Obscuring the barcodes on individual units inside the multipack is necessary so they are  
291           not confused with the outer multipack barcode, which shall have different DIs. If the  
292           space permits, considering the management and use needs of medical devices, it is  
293           encouraged to assign UDI data carriers at the level of device unit of use.
- 294
- 295

## 296 **5 UDI Creation and Placement General Principles for Specific Device Types**

### 297 **5.1 Medical Device Kits**

298           UDI creation and placement for medical device kits should follow the general  
299           principles listed below:

- 300           1)   Individually sold and used medical device kits should have their own UDI;
- 301           2)   Individually sold and used medical devices within a medical device kit should have  
302           their own UDI;

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303 3) Single-use disposable medical devices within a medical device kit which are not  
304 intended for use outside the context of the kit do not require their own UDI.

305

## 306 **5.2 Software as a Medical Device (SaMD)**

307 UDI creation and placement for SaMD should follow the general principles listed below.

- 308 1) The UDI should be assigned at the level of the device.
- 309 2) The full version of the software is considered an important tool to achieve SaMD  
310 traceability and should be displayed in the UDI-PI.
- 311 3) A major software update for SaMD would require a new UDI-DI, and only a minor  
312 software update would require a new UDI-PI (not a new UDI-DI).

313 Major software update whenever there is a modification that changes:

- 314 (i) the original performance;
- 315 (ii) the safety or the intended use of the software;
- 316 (iii) interpretation of data.

317 Minor software update are generally associated with bug fixes, usability enhancements that  
318 are not for safety purposes, security patches or operating efficiency.

319 Minor software update shall be identified by a manufacturer-specific form of identification.

- 320 4) Typically, the software version can be represented by the data delimiter of the  
321 production batch number. If the issuing agency assigns a specific data delimiter for the  
322 software version, such specification can also be followed.
- 323 5) When the SaMD is delivered on a physical medium, e.g. CD or DVD, each package  
324 level shall bear the human readable and AIDC representation of the complete UDI. The  
325 UDI that is applied to the physical medium containing the SaMD and its packaging must  
326 be identical to the UDI assigned to the system level SaMD.
- 327 6) UDI should be provided on a readily accessible screen by the user in an easily-readable  
328 plain-text format (e.g. an “about” file or included on the startup screen).
- 329 7) The SaMD lacking a user interface must be capable of transmitting the UDI through an  
330 Application Programming Interface (API).

331 Note: The cybersecurity of the UDI data transfer requires integrity of all incoming data,  
332 ensuring that it is not modified in transit or at rest. Also, it requires all data originating from  
333 external sources is well-formed and compliant with the expected protocol or specification.

- 334 8) Only the human readable portion of the UDI is required in electronic displays of the  
335 SaMD. (including data delimiter).

336 The UDI AIDC marking needs not be used in the electronic displays, e.g. about menu, splash

337 screen, etc...; i.e. SaMD not being distributed by the use of physical data carriers (CDs,  
338 DVDs or similar) will not carry an AIDC.

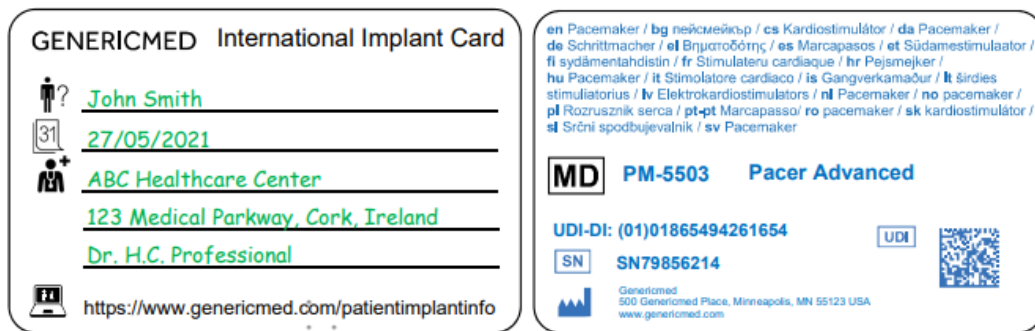
339

### 340 5.3 Implantable Devices

341 UDI creation and placement for implantable devices should follow the general principles  
342 listed below:

- 343 1) The lowest level of device packaging of implantable devices shall be identified with  
344 an UDI;
- 345 2) The UDI-PI of active implantable devices shall contain at least the serial number, and  
346 the UDI-PI of other implantable devices shall contain at least the production batch  
347 number and/or serial number;
- 348 3) The UDI of the implantable device must be identifiable prior to implantation;
- 349 4) If the implantable device is affixed with an identification used to record medical  
350 device-related information in the medical record, UDI information should be included.

351



352

353

353 **Figure 5 Patient Implant Card Representation**

354

### 355 5.4 Configurable Medical Device

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

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

361

#### 362 **Configuration**

363 Configuration is a combination of items of equipment, as specified by the manufacturer,  
364 that operate together to provide an intended use or purpose as a medical device. The

---

365 combination of items may be modified, adjusted or customized to meet a customer need.  
366 The configuration may take place before a device is purchased or after the device has been  
367 placed on the market.

368 Examples:

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

373

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

- 375 1. A UDI-DI is allocated to the entire, configurable medical device system and may be  
376 referred to as a “Configurable Device UDI” or “System UDI”. The Configurable  
377 Device UDI or System UDI is used on device labels, device registrations, UDI  
378 databases, and for various processes where UDI is utilized.  
379
- 380 2. A Configurable Device UDI-DI is allocated to defined groups of configurations, not  
381 per configuration within the group. While generally UDI-DI assignments are applied  
382 to medical devices models with entirely homogeneous features, a Configurable device  
383 by definition has different variations, and the UDI-DI is therefore defined by the  
384 collection of possible configurations for a given product model as described in a  
385 regulatory file.  
386
- 387 3. The UDI-PI for a Configurable device is generally a serial number and is allocated to  
388 each individual system. Since there is expected to be known variability for the possible  
389 variations of configurations for this model, the UDI-PI is essential to distinguishing  
390 between specific variations of the device. Note that a given Configurable Device or  
391 System UDI may have additional UDI-PI indicators including manufacturing date, etc.  
392 Additionally, a later change or addition of a component, sub-systems, or accessory of  
393 the system that has already been placed on the market does not change the original UDI-  
394 DI or UDI-PI of the system. It is necessary to be able to uniquely identify the changed  
395 device configurations in the field and the applicable records may now include more than  
396 one UDI for the device.  
397
- 398 4. The carrier of the System UDI should be placed on the assembly or portion of the device

---

399 that most likely does not get exchanged in its lifetime.

- 400
- 401 5. Each component, sub-system or accessory that is considered a medical device and is
- 402 distributed or supplied independently from the original device needs a separate UDI.
- 403 Some Configurable Devices may have multiple UDI assignments.
- 404
- 405 6. A new UDI-DI is required when the activities performed results in modifications to a
- 406 previously marketed device intended for resale leads to a new medical device.

407

408 Note1: If a change of a device in the field would significantly change the safety,

409 performance or the intended purpose (and these changes are not within the limits of the

410 original configuration), those changed devices should be identifiable. To make the

411 changed device identifiable a manufacturer should provide an upgrade kit (which, itself,

412 is considered a medical device) with a correspondent UDI which meets all UDI

413 requirement (e.g. labelling, publication to UDI database(s), etc.). The UDI of the

414 upgrade kit together with the original System UDI will be used to identify the changed

415 device. A UDI label should accompany the upgrade kit and be permanently attached to

416 the System UDI and captured in the record of the specific device.

417

418 Note2: An “upgrade kit” (to be distinguished from the term “kit” defined in this

419 document) is a term commonly used in industry to denote a packaged medical device

420 used to upgrade an installed medical device (after this latter has been sold and first use

421 or installation is completed). The “upgrade kit” includes all of the components or

422 constituents required for the medical device upgrade and may also include installation

423 instructions, service manuals and user manuals.

424

425 **Alternate Process**

426 An alternate process would be that a manufacturer might perform this change as new

427 installation (comparable with a resale of a modified device as described in point 6) the

428 new installed device would need to be marked with a corresponding new System UDI.

429 If this alternate process is utilized, the device manufacturer is responsible for updating

430 the UDI labeling for devices that have been placed on the market and making the

431 associated change in the applicable regulatory databases.

432



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433 **6 References**

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437 Devices.

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439 Guide.

440 [4] BS EN 1556:1998 Bar coding. Terminology

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455 repealing Council Directives 90/385/EEC and 93/42/EEC

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457 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and  
458 Commission Decision 2010/227/EU

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-----End of the Document-----