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Guidance on Medical Device Unique Device Identification (UDI) system



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33 **1 Introduction**

34 Currently, there is no standardised identification code or a system in Singapore to track and
35 identify the distribution and use of medical devices throughout the supply chain and in
36 healthcare system. Therefore, a harmonised identification system is necessary to improve the
37 traceability of medical devices to facilitate timely identification of specific medical devices and
38 patients treated with medical devices impacted by recalls, device failures or serious adverse
39 events.

40

41 **1.1 Scope**

42 This guidance document is intended to provide clarity on the regulatory requirements for
43 Unique Device Identification (UDI) implementation in Singapore and the details on the steps
44 to submit UDI information into the Singapore Medical Device Register (SMDR) and Class A
45 Medical Device Database. This guidance is to be used as a supplement to other guidance
46 documents published by HSA, including but not limited to GN-15, GN-21, and GN-23.

47

48 **1.2 References sources**

- 49 • UDI guidance in 2013 (IMDRF/UDI WG/N7 FINAL:2013)
- 50 • UDI Application Guide (IMDRF/UDI WG/N48 FINAL:2019)

51

52 **1.3 Definitions**

53 **AUTOMATIC IDENTIFICATION AND DATA CAPTURE (AIDC):** A technology used to
54 automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and
55 RFID.

56

57 **CLINICAL RESEARCH:** means any research involving human beings (whether or not a
58 regulated clinical trial)

59

60 **CUSTOM-MADE MEDICAL DEVICE (as set out in the Regulations):** means a medical device
61 that:-

- 62 a) is made at the request of a qualified practitioner and in accordance with the
63 specifications of the qualified practitioner regarding the design characteristics or
64 construction of the medical device;
- 65 b) is intended to be used only in relation to a particular individual; and
- 66 c) is not adapted from a mass-produced medical device.

67 **HUMAN READABLE INTERPRETATION (HRI):** is a legible interpretation of the data
68 characters encoded in the UDI Carrier.

69

70 **MANUFACTURE (as set out in the Act):** in relation to a health product, means to make,
71 fabricate, produce or process the health product and includes: -

- 72 • any process carried out in the course of so making, fabricating, producing or
73 processing the health product; and
- 74 • the packaging and labelling of the health product before it is supplied.

75

76 **PRODUCT OWNER (as set out in the Regulations):** in relation to a health product, means a
77 person who:

- 78 • supplies the health product under his own name, or under any trade mark, design,
79 trade name or other name or mark owned or controlled by him; and
- 80 • is responsible for designing, manufacturing, assembling, processing, labelling,
81 packaging, refurbishing or modifying the health product, or for assigning to it a purpose,
82 whether those tasks are performed by him or his behalf

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84 **REGISTRANT (as set out in the Act):** in relation to a registered health product, means the
85 person who applied for and obtained the registration of the health product under this Act.

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103 2 UDI System

104 Singapore will be adopting the UDI system which is an international system for tracking and
105 identification of medical devices. The fundamental elements of UDI system in Singapore is
106 aligned to the internationally harmonised principles published by the International Medical
107 Device Regulators Forum (IMDRF).

108 With UDI system in place, there will be greater efficiency and enhanced patient safety by
109 (*Figure 1*):

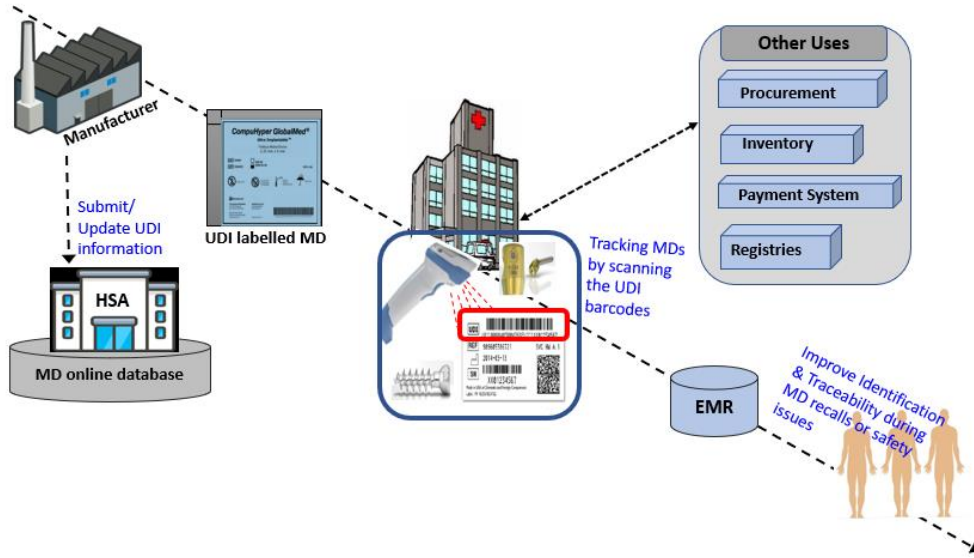
- 110 • Facilitating traceability of medical devices, especially for field safety corrective actions,
- 111 • Supporting identification of medical devices through distribution and use,
- 112 • Enabling timely identification of medical devices in adverse events,
- 113 • Reducing medical errors,
- 114 • Facilitating longitudinal capture of data on medical devices.

115 In line with the internationally harmonised principles published by the International Medical
116 Device Regulators Forum (IMDRF), the UDI system will comprise of:

- 117 • Development of unique device identifiers (UDIs) based on globally harmonised
118 standards.
- 119 • Placement of UDIs in human readable interpretation (HRI) and Automated
120 Identification for Data Capture (AIDC) formats on device package labels of the smallest
121 unit of supply and on all higher levels of packaging or in some cases directly marked
122 on the devices.

123 **NOTE:** UDIs applied on the medical device labels for EU or the USA markets will
124 be accepted as is for Singapore.

- 125 • Submission of minimum additional necessary UDI data elements such as UDI-DI to
126 UDI Databases (UDID) by registrants, local manufacturers and importers. In the case
127 of Singapore, the UDIDs will be the Singapore Medical Device Register (SMDR) for
128 medical devices with risk Class B or higher and Class A Medical Devices database for
129 Class A medical devices.



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Figure 1: Applicability of UDI

149 2.1 Unique Device Identifier (UDI) Format

150 The UDI is a numeric or alphanumeric code that comprises of two parts: UDI-Device Identifier
 151 (UDI-DI) and UDI-Production Identifier (UDI-PI) (*Figure 2*).



152
 153 *Figure 2: UDI Format*

- 154 • Device Identifier (UDI- DI)
 - 155 ○ A unique numeric or alphanumeric code specific to a model of medical device
 - 156 ○ Mandatory, fixed portion of the UDI identifies a manufacturer's specific product and package configuration
 - 157 ○ Used as the "access key" to information stored in UDI database (UDID)
- 158 • Production Identifier (UDI- PI)
 - 159 ○ A numeric or alphanumeric code that identifies the unit of device production
 - 160 ○ Includes serial number, lot/batch number, software version and manufacturing and/or expiration date
- 161 • Data Delimiters
 - 162 ○ Included in the human readable information of the UDI to allow for legible interpretation of the coded information
 - 163 ○ Different pre-determined Data Delimiters are used by different issuing agencies (e.g. GS1 – (01), (11) etc.; HIBCC - \$, \$\$7 etc.; ICCBBA - =/, => etc.)

164 2.2 AIDC and HRI Form of UDI

165 The UDI on the label or on the device itself and on all higher levels of device packaging must
 166 be presented in human readable interpretation (HRI) format and Automated Identification for
 167 Data Capture (AIDC) technology forms (*Figure 3*). Examples of AIDC technologies include bar
 168 codes, QR codes, RFID.

169 When the AIDC form of UDI is scanned using a AIDC reader, data can be automatically
 170 captured and the UDI or the device identifier of a device is transmitted and entered into an
 171 electronic patient record or other computer systems via an automated process. If the AIDC
 172 form of UDI cannot be scanned or used, the HRI format may be used instead. HRI is a legible
 173 interpretation of the data characters encoded in the UDI Carrier, typically presented adjacent
 174 to or below the AIDC carrier.



180

181

Figure 3: AIDC and HRI form of UDI

182 There are some carriers that are only approved for specific applications (e.g. retail point of
183 sale). Therefore, it is important for manufacturer to understand the appropriate application of
184 each carrier and thus choose the appropriate carrier based upon the application for use.

185

186 2.3 Labelling Requirements for UDI in Singapore

187 The inclusion of UDI on the device labels will be an additional requirement. It is not meant to
188 replace any other existing marking or labelling requirements as set out in [GN-23 Guidance on
189 Labelling for Medical Devices](#).

- 190 • The placement of UDIs will be in HRI and AIDC formats on device package labels of
191 the smallest unit of supply and on all higher levels of packaging or in some cases
192 directly marked on the devices.

Note: UDIs applied on the medical device labels for EU or the USA markets can
be used for Singapore

- 193 • Medical devices that require product registration and/or authorised for supply via
194 Special Access Route (SAR) in Singapore are required to comply with UDI requirement
195 and the devices should be labelled with UDI prior to supply.
- 196 • Medical devices intended for export only from Singapore and strictly not for supply in
197 Singapore are not required to comply with the UDI requirement.
- 198 • Shipping containers are not required to be labelled with UDI.
- 199 • Medical devices exclusively for retail Point of Sale (POS) directly to consumers do not
200 need to encode **Production Identifiers (PI)** in AIDC on the point of sale package.

201

202 2.4 Data Elements for UDI Databases (UDIDs)

203 The UDIDs in Singapore are the existing Singapore Medical Device Register (SMDR) for class
204 B or higher medical devices and the Class A medical device database for Class A medical
205 devices.

206 The SMDR and Class A medical device database captures most of the essential information
207 on the medical devices being supplied in Singapore, such as brand name, model identifier,
208 intended use, name of product owner. Therefore, only certain minimum necessary UDI data
209 elements will be required to be included to supplement the existing information (*Table 1 & 2*).
210 It is crucial to note that UDI-PI information shall not be included in SMDR or Class A MD
211 database.

212 Both SMDR and Class A Medical device Database can be viewed by the general public at
213 <http://www.hsa.gov.sg/e-services/infosearch>

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235 **2.4.1 UDI Data Elements - SMDR**

Data Entry site	Data element	Data format	Description
Manual input via MEDICS eService Form	Issuing agency	Checkbox	Selection options consisting of GS1, HIBCC, ICCBBA
	Sterile medical device	Radio Button	Yes or No
	Description of sterile medical device: (e.g. sterilization methods)	Textarea [string]	E.g. EO sterilization, Radiation sterilization, etc
	Device containing latex	Radio button	Yes or No
	Device containing DEHP	Radio button	Yes or No
	Device with measuring function	Radio Button	Yes or No
Excel upload file	UDI-DI	String	UDI- Device Identifier
	DM DI Number (only if different from UDI-DI)	String	Direct mark- Device Identifier (applicable only if is different from the UDI-DI)
	Clinical Size (including Volume, Length, Gauge, Diameter)	String	To include the specifications for the MD model in the "Brief description" column of Annex 2 list of configurations
	SAMD Version	String	Applicable if software is available. To include the version number for the device model in the "Brief description" column of Annex 2 list of configurations

236 *Table 1: UDI data elements for SMDR*

237

238 **2.4.2 UDI Data Elements - Class A Medical Device Database**

Data Entry site	Data element	Data format	Description
Excel upload file	UDI-DI	String	UDI- Device Identifier
	DM DI Number (only if different from UDI-DI)	String	Direct mark- Device Identifier (applicable only if is different from the UDI-DI)
	Issuing agency	String	To indicate the IA (e.g. GS1, HIBCC, ICCBBA)

239 *Table 2: UDI data elements for Class A medical device database*

240

241 **3 Process of implementing UDI**

242 **3.1 Developing and placement of UDI for medical devices**

243 Manufacturers or Product owners are responsible for accurately assigning and placing the
244 UDI in HRI and AIDC formats on the device label or on the device itself and on all higher levels
245 of device package level hierarchy following the issuing agency's specifications.

246 Medical Devices marketed in the USA and/or EU:

247 i. Manufacturer or Product owners whose medical devices are marketed in the USA
248 and/or EU and have been labelled with UDI based on the US or EU requirements can
249 use these UDI as is for Singapore. Registrants of these Class B, C or D medical
250 devices or the importer of these Class A medical devices can submit the UDI
251 information as is to the SMDR and/ or Class A Medical Device Database. (Proceed to
252 section 3.2.1).

253 Medical Devices not marketed in the USA or EU:

254 ii. Manufacturers or product owners whose medical devices are not marketed in the USA
255 or EU, are required to develop and implement UDI for Singapore. They should choose
256 an issuing agency designated by HSA (refer section 3.1.1) for implementing the UDI
257 system and assign UDI to their medical devices based on the requirements specified
258 in this guidance document.

259

260 The following sections describe specific information applicable to manufacturers
261 considering to implement UDI system for Singapore.

- 262 • Designated issuing agency in Singapore (refer to section 3.1.1)
- 263 • Implementing of UDI-DI triggers should be in a consistent manner that
264 promotes UDI as a global standard for device identification (refer to section
265 3.1.2)
- 266 • Direct marking on medical devices (refer to section 3.1.3)

267

268 **3.1.1 Issuing Agency (IA)**

269 An issuing agency is an organization designated by HSA to operate a system for the issuance
270 of UDIs for regulatory purposes. Examples of Issuing Agencies/Entities recognised by IMDRF
271 are GS1, the Health Industry Business Communications Council (HIBCC) and the
272 International Council for Commonality in Blood Banking Automation (ICCBBA).

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274

275 Conditions for Designation of IA in Singapore

276 The organisation designated as an Issuing agency shall fulfil the following criteria.

- 277 • Has a presence in Singapore;
- 278 • Operates a system for the issuance of UDIs which conforms to the relevant
279 international standards;
- 280 • Issue UDIs that is adequate to identify a device throughout its distribution and use;
- 281 • Makes its system for the issuance of UDIs available to all users in accordance with a
282 set of predetermined and transparent terms and conditions;
- 283 • Undertakes to make available to HSA, upon request, any information concerning its
284 system for the assignment of UDIs.

285 Organisations interested to be designated as an issuing agency for UDI in Singapore may
286 contact HSA via our [online form](#).

Note: The designated issuing agencies in Singapore will be listed in this document once finalised.

287

288 **3.1.2 UDI-DI Triggers**

289 If the same DI is used for newer versions of a medical device after changes are made to the
290 devices, may result in misidentification of the medical device and/or ambiguity in its
291 traceability. A new UDI-DI should be considered for changes to the any of the following
292 device's UDID data elements:

- 293 a) Brand Name;
- 294 b) Device version or model;
- 295 c) Clinical Size (including Volume, Length, Gauge, Diameter);
- 296 d) Labelled as single use;
- 297 e) Packaged sterile;
- 298 f) Need for sterilization before use;
- 299 g) Quantity of devices provided in a package;
- 300 h) Critical warnings or contraindications: e.g. containing latex or Bis (2-ethylhexyl)
301 phthalate (DEHP);
- 302 i) New packaging configurations.

303 Medical devices undergo changes as part of their product life cycle. If there are significant
304 changes to the registered medical device that requires the device's UDI-DI to be changed, a
305 Change Notification or a new premarket application may be required.

Note: For determination of whether a change notification is required, please refer to [GN-21](#)
[Guidance on Change Notification for Registered Medical Devices](#).

306

307 **3.1.3 Direct Marking**

308 Direct marking, for purposes of UDI requirements, is placing the UDI and, potentially the full
309 UDI carrier, permanently on the device itself.

310 It is useful for medical devices that are reusable to have the UDI on the device itself. The UDI
311 of reusable medical devices that require reprocessing between patient uses should be
312 permanent and readable after reprocessing cycles for the intended life of the device.

313 When considering direct marking for devices, manufacturers or product owners should
314 carefully consider the following:

- 315 a) Potential interference arising from any type of direct marking on the safety or
316 performance/effectiveness of the device;
- 317 b) Technological feasibility of direct marking on the specific device in question.

318 In considering the above, manufacturers should evaluate the characteristics of the selected
319 direct mark technology as well as size, design, materials, processing, or performance issues
320 related to the device.

321 Where direct marking-Device identifier (DM-DI) for the device is available, companies may
322 submit the direct marking- device identifier (DM-DI) number to the SMDR and/or Class A
323 Medical Device Database (refer to section 3.2).

324

325 **3.2 Submission of UDI Data Elements to UDI Databases**

326 To ensure smooth transition during the phased UDI implementation in Singapore, HSA has
327 enhanced our online submission system, MEDICS Medical Device Information and
328 Communication System (MEDICS) and introduced a new eService (refer to section 3.2.1) to
329 allow the upload of UDI information.

330 UDI related data elements for all risk classes of medical devices can be updated on a voluntary
331 basis even before the compliance date for each implementation phase comes into effect.

Note: From the compliance date, UDI will be mandatory for the respective categories of medical devices

332

333 **3.2.1 Adding UDI-DI and Issuing agency for registered medical devices on SMDR**

334 The new eService is developed to allow registrants to add UDI-Device Identifier (UDI-DI) and
335 the issuing agency for the registered medical devices listed under Model Info section. (*Figure*
336 *4*). It allows a maximum of 30 device registrations to be submitted in a single application and
337 can be performed without a change notification application.

338 Registrants are also required to provide a declaration to confirm that the addition of UDI-DI
339 and IA for the models listed in the device registration do not change any of the device listing
340 information. Upon approval of the application, the UDI-DI and issuing agency information of
341 the applicable device registration will be updated in Singapore Medical Device Register
342 (SMDR).

343 For update of the other UDI data elements (i.e. other than UDI-DI and IA), a change notification
344 application will be required. Therefore, registrants may update the remaining UDI data
345 elements when submitting a Change Notification application.

Note: Refer to [GN-21 Guidance on Change Notification for Registered Medical Devices](#) for information on fees applicable and to identify the category of Change Notification applicable for each proposed type of change.

346

MD2141 - SUBMISSION OF UPDATE OF UNIQUE DEVICE IDENTIFIER (UDI) > Affected Device Listing > Model(s) Info

APPLICATION FORM

1. Device Info	2. Product Owner Info	3. Manufacturing Site(s) Info	Please refer to the Guidelines on the...
4. Model(s) Info	5. Importer & Wholesaler Info	6. Remarks	

Dossier No. : **CANP538239-13**

MODEL(S) INFO

Instructions:
 Step 1: Please **download the existing excel** [here](#) (Right click & Save Target As) to update the UDI-DI and/or DM-DI of the registered medical devices.
 Step 2: Proceed to upload the updated excel.
 Step 3: Once uploaded, please verify the information in the summary table.
 Step 4: Select the UDI Issuing Agency.
 Step 5: If there are changes to be made to the individual model, you may wish to click onto the respective model in the summary table and edit accordingly. Alternatively, please perform Step 1 again to make the amendment.
 Step 6: Submit Supporting Document, if any.

Browse...

Upload

UDI Issuing Agency

GS1 HIBCC ICCBBA

SUPPORTING DOCUMENT(S)

Please attach the following document(s) by typing in the path or click on the browse button.

1. Others * Browse...

To attach, click [Add Attachment](#).

Model Name

Model Number

UDI-DI ^(?)

DM-DI (Only if DM-DI is available and is different from UDI-DI) ^(?)

Description (e.g. Clinical Size (including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UDI-DI)) (Max 3000 Characters)

Update

Model(s) Added

S/No.	Model Name	Model Number	UDI-DI	DM-DI	Description
1.	123456789	123456789	M123456Y,G123456Z	x1,x2	123456789

Update Form **Close**

347

348 *Figure 4: New eService*

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350

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352

353

354 **3.2.2 Submitting UDI Information to UDIDs**

355 **• Singapore Medical Device Register (SMDR)**

356 Registrants are responsible for the submission and update of UDI data elements for device
357 registration (i.e. risk class B or higher) listed on SMDR under the authorisation of the
358 product owner. They are also required to ensure that the UDI data is verified to be accurate
359 before submitting the data to the database.

360 For submission of data to SMDR via MEDICS, Registrants currently upload a completed
361 excel file to input the list of medical device models included under each SMDR listing. To
362 update the UDI information applicable to each of the models within this excel file,
363 Registrants are required to follow the below guideline (*Table 3*) and input the necessary
364 information for each data element accordingly. After completing the information, the excel
365 file is then uploaded on to their online application as per current process. Upon approval
366 of the application, information will be reflected in the respective UDIDs (*Figure 5*).

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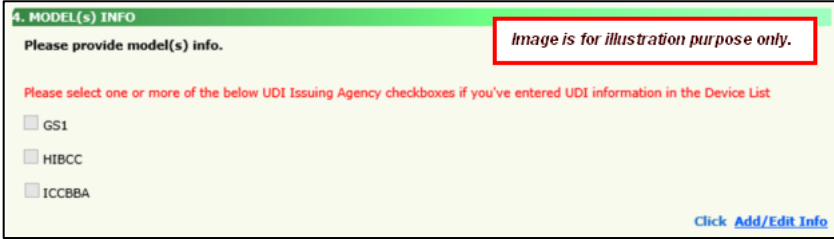
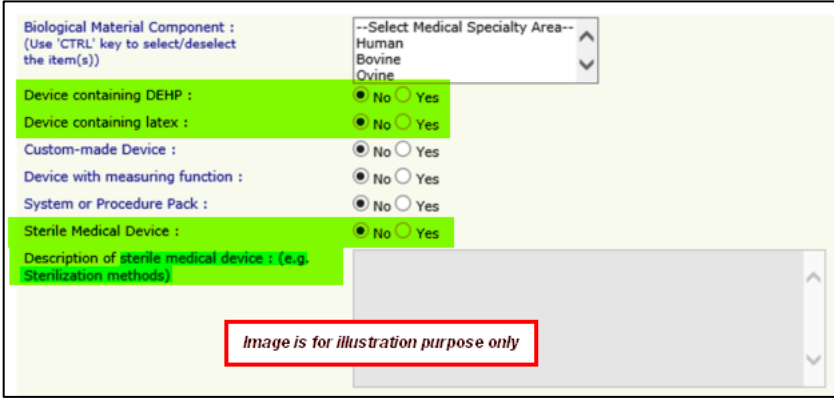
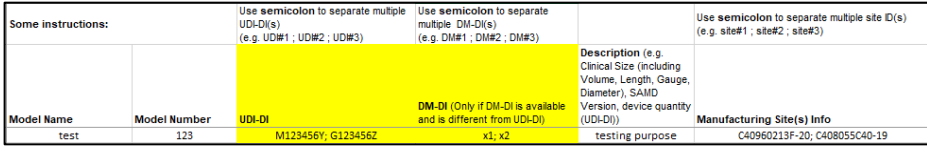
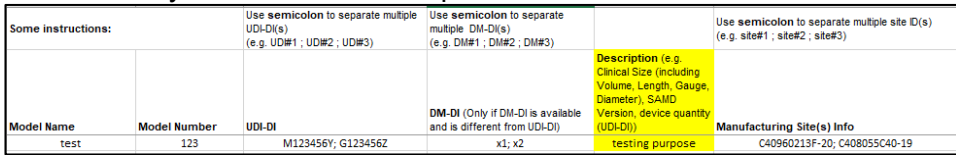
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Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	<ul style="list-style-type: none"> Able to check more than one issuing agency if there are more format of UDI-DI are from different issuing agency. 
Sterile medical device Description of sterile medical device: (e.g. sterilization methods) Device containing latex Device containing DEHP Device with measuring function	<ul style="list-style-type: none"> Highlighted fields are UDI data element fields added to the product registration e-service. If <u>any one</u> of the medical devices models listed in model info (s) section fulfil the conditions, registrant is required to indicate a "YES". 
UDI-DI DM DI Number (only if different from UDI-DI)	<ul style="list-style-type: none"> The UDIs applied on the medical device labels for EU or the USA markets can be used in Singapore. If there are multiple UDI-DI or DM-DI for each model, use semicolon (;) to separate each UDI-DI. The UDI carrier shall be placed on device package labels of the smallest unit of supply and on all higher levels of packaging or in some cases directly marked on the devices (i.e: DM-DI). If each higher level of packaging has a different UDI-DI and are available for supply in Singapore, a new row shall be added in the excel file to capture that UDI-DI information and appropriate description shall be indicated in the "description" column. 
Clinical Size (including Volume, Length, Gauge, Diameter) SAMD Version	<ul style="list-style-type: none"> Additional information for each model of medical device should be clearly indicated in "Description" column. 

384 Table 3: Data input guideline for SMDR

385

PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device Device Category Registrant Product Owner Importer Wholesaler Local Manufacturer Advanced Search

Advanced Search (Multiple criteria search is always AND condition)

Search Criteria	Search Entry	Search Mode
Device Proprietary/Brand Name :	<input type="text"/>	Starts With ▼
Registrant :	<input type="text"/>	Starts With ▼
Product Owner :	<input type="text"/>	Starts With ▼
Importer & Wholesaler :	<input type="text"/>	Starts With ▼
Local Manufacturer :	<input type="text"/>	Starts With ▼
Registration No. :	<input type="text"/>	Starts With ▼
Model Name :	<input type="text"/>	Starts With ▼
Model Identifier :	<input type="text"/>	Starts With ▼
UDI-DI :	<input type="text"/>	Starts With ▼
DM-DI :	<input type="text"/>	Starts With ▼
Device Class/IVD Category :	--Select Medical Device Class-- ▼	
Specialty Category :	--Select Medical Specialty Area-- ▼	
Biological Material Component :	--Select Biological Material Component-- ▼	
Product Owner Country :	--Select Country-- ▼	
Professional Use Only :	<input type="checkbox"/>	

386

387 *Figure 5: Public SMDR*

388

389 **• Class A Medical Device Database (Voluntary Basis)**

390 Local manufacturers and/or Importers are responsible for the submission and update of UDI
 391 data elements for class A medical devices listed on Class A Medical Device Database. They
 392 are also required to ensure that the data is verified to be accurate before submitting the data
 393 to the database.

394 For submission of data to Class A Medical Device Database via MEDICS, local manufacturers
 395 and/ or importers are required to download the previously submitted excel file from MEDICS
 396 to input the UDI related information according to the below guideline (*Table 4*) for the medical
 397 devices included in the Class A list. After completing the information, the excel file is then
 398 uploaded on to their online application as per current process. Upon approval of the
 399 application, information will be reflected in the respective [UDIDs](#) (*Figure 6*).

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Data element	Data Input guideline																		
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	<ul style="list-style-type: none"> A drop-down list to select the issuing agency of the UDI-DI and DM-DI. 																		
UDI-DI	<ul style="list-style-type: none"> The UDIs applied on the medical device labels for EU or the USA markets can be used in Singapore. If there are multiple UDI-DI or DM-DI for each model, a new row is to be added. 																		
DM DI Number (only if different from UDI-DI)	<ul style="list-style-type: none"> The UDI carrier shall be placed on device package labels of the smallest unit of supply and on all higher levels of packaging or in some cases directly marked on the devices (i.e: DM-DI). 																		
SAMD Version	<ul style="list-style-type: none"> If each higher level of packaging has a different UDI-DI and are available for supply in Singapore, a new row shall be added in the excel file to capture that UDI-DI information and appropriate description shall be indicated in the “description” column. <div data-bbox="539 719 1326 947" style="border: 1px solid black; padding: 5px;"> <p>HSA [Dealer Licence] - Class A Exemption list</p> <table border="1"> <thead> <tr> <th>Record ID (To be generated by HSA System)</th> <th>Product Owner</th> <th>Name as per Device label</th> <th>Intended purpose</th> <th>Device Identifier (Model No.)</th> <th>UDI-DI (For multiple UDI-DI, please input them in a new row)</th> <th>DM-DI (Only if DM-DI is available and is different from UDI-DI. For multiple DM-DI, please input them in a new row)</th> <th>UDI Issuing Agency</th> <th>Name of Manufa</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div>	Record ID (To be generated by HSA System)	Product Owner	Name as per Device label	Intended purpose	Device Identifier (Model No.)	UDI-DI (For multiple UDI-DI, please input them in a new row)	DM-DI (Only if DM-DI is available and is different from UDI-DI. For multiple DM-DI, please input them in a new row)	UDI Issuing Agency	Name of Manufa									
Record ID (To be generated by HSA System)	Product Owner	Name as per Device label	Intended purpose	Device Identifier (Model No.)	UDI-DI (For multiple UDI-DI, please input them in a new row)	DM-DI (Only if DM-DI is available and is different from UDI-DI. For multiple DM-DI, please input them in a new row)	UDI Issuing Agency	Name of Manufa											

404 Table 4: Data input guideline for Class A Medical Device database

405

PUBLIC ENQUIRY - CLASS A MEDICAL DEVICE DATABASE

Class A Medical Device Search (Multiple criteria search is always AND condition)

Search Criteria	Search Entry	Search Mode
Dealer's Licence No :	<input type="text"/>	Contains ▼
Dealer's Name :	<input type="text"/>	Contains ▼
Product Owner Name :	<input type="text"/>	Contains ▼
Name as per Device Label :	<input type="text"/>	Contains ▼
Device Identifier :	<input type="text"/>	Contains ▼
UDI-DI :	<input type="text"/>	Contains ▼
DM-DI :	<input type="text"/>	Contains ▼
Intended Purpose :	<input type="text"/>	Contains ▼
Country of Manufacturer :	<input type="text"/>	Contains ▼
Sterility of Devices :	<input type="checkbox"/> Sterile <input type="checkbox"/> Non-sterile	
Dealer's Type :	<input type="checkbox"/> Importer <input type="checkbox"/> Manufacturer	

406

407 Figure 6: Class A Medical Device Database

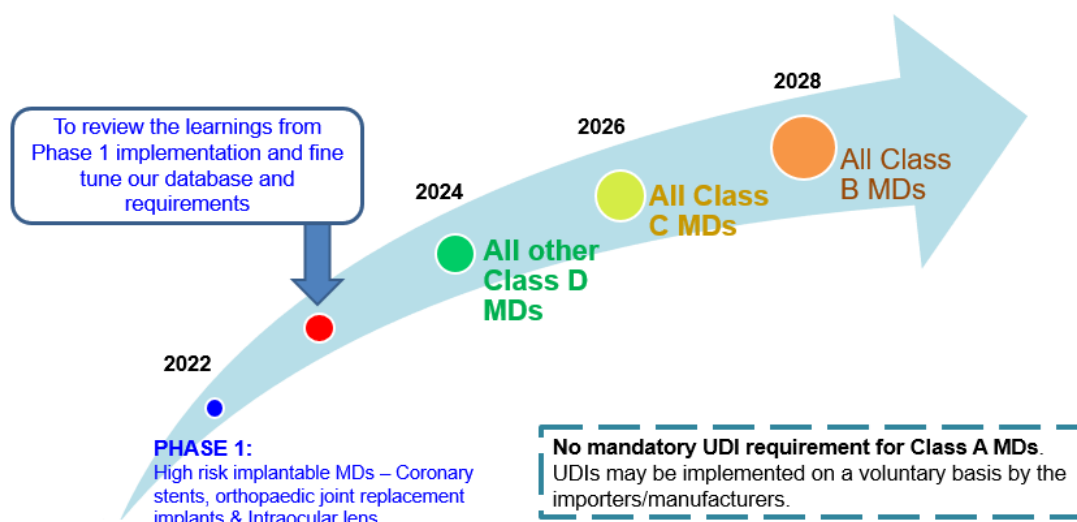
408

409 **4 UDI Implementation Timeline**

410 All class B, C or D medical devices including *in vitro* diagnostics (IVDs) are required to be
 411 registered with HSA on the SMDR, prior to their placement on the Singapore market. Class A
 412 medical devices are required to be listed on the Class A medical device database.

413 To allow for adequate preparation time for all stakeholders, the requirement for medical
 414 devices to be labelled with UDI prior to their placement on Singapore market (i.e. including
 415 those supplied via Special Access Routes) will be implemented in phases based on a risk-
 416 calibrated approach (*Table 5*).

417 Medical devices that are supplied in Singapore **after** the respective compliance date based
 418 on the risk class, are required to comply with UDI requirement unless otherwise specified.



419

420 *Figure 7: Overview of UDI Implementation timeline in Singapore*

Note: For an understanding of the product registration process and requirements, you can download the Quick Guide at: <http://www.hsa.gov.sg/medical-devices/regulatory-overview>

421

422 **Proposed Compliance Date for each Implementation Phase:**

Phase	Category of devices	Compliance Date
1	All Coronary stents, orthopaedic joint replacement implants and Intraocular lens	1 Nov 2022
2	All Class D General medical devices and IVDs	1 Nov 2024
3	All Class C General medical devices and IVDs	1 Nov 2026
4	All Class B General medical devices and IVDs	1 Nov 2028
--	<ul style="list-style-type: none"> UDIs for Class A General medical devices and IVDs may be implemented on a voluntary basis. UDIs will not be required for medical devices for clinical research, investigational testing or clinical trial and custom-made medical devices 	

423 *Table 5: Proposed Compliance date*

Note: The proposed compliance date for the various phases is tentative and is subject to adjustments based on the progress of the earlier phases of implementation.

424



www.hsa.gov.sg

Contact Information:

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg



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