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HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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Guidance on Medical Device Unique Device Identification (UDI) system

HSA Health Sciences Authority

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1 Introduction

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

1.1 Scope

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

1.2 References sources

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

1.3 Definitions

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

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

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

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

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

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

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

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

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

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

2 UDI System

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

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

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

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

- Development of unique device identifiers (UDIs) based on globally harmonised standards.
- Placement of UDIs in human readable interpretation (HRI) and Automated Identification for Data Capture (AIDC) formats 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.

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

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

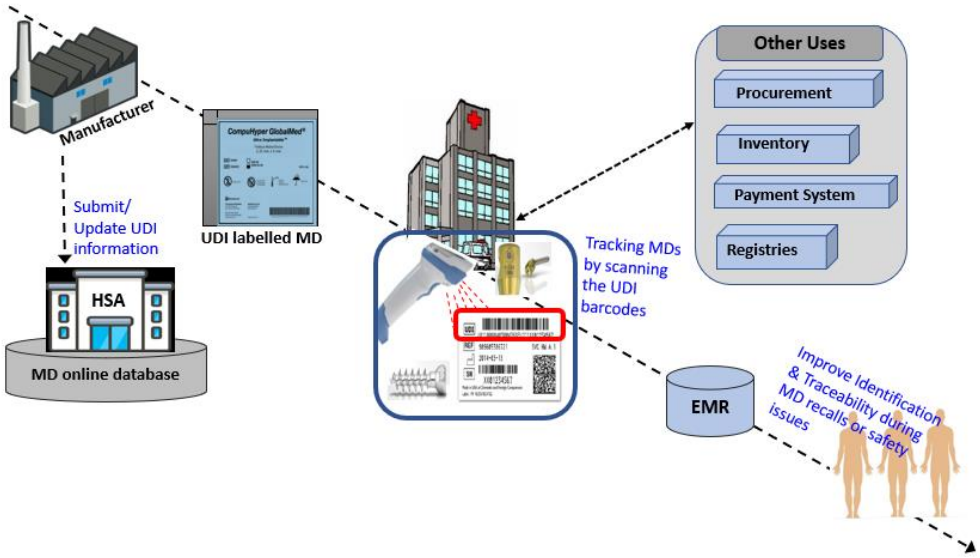


Figure 1: Applicability of UDI

2.1 Unique Device Identifier (UDI) Format

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

Figure 2: UDI Format

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

2.2 AIDC and HRI Form of UDI

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

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

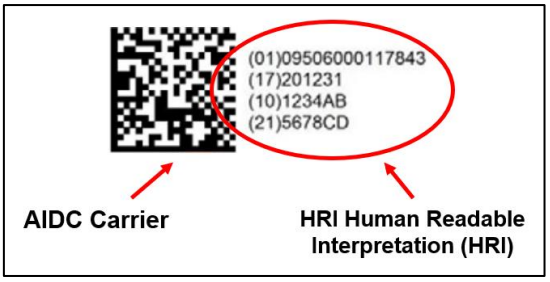


Figure 3: AIDC and HRI form of UDI

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

2.3 Labelling Requirements for UDI in Singapore

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

- The placement of UDIs will be in HRI and AIDC formats 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.

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

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

2.4 Data Elements for UDI Databases (UDIDs)

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

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

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

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

Table 1: UDI data elements for SMDR

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)

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

3 Process of implementing UDI

3.1 Developing and placement of UDI for medical devices

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

Medical Devices marketed in the USA and/or EU:

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

Medical Devices not marketed in the USA or EU:

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

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

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

3.1.1 Issuing Agency (IA)

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

Conditions for Designation of IA in Singapore

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

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

Organisations interested to be designated as an issuing agency for UDI in Singapore may contact HSA via our online form.

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

3.1.2 UDI-DI Triggers

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

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

Medical devices undergo changes as part of their product life cycle. If there are significant changes to the registered medical device that requires the device's UDI-DI to be changed, a 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.

3.1.3 Direct Marking

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

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

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

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

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

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

3.2 Submission of UDI Data Elements to UDI Databases

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

UDI related data elements for all risk classes of medical devices can be updated on a voluntary 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

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

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

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

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

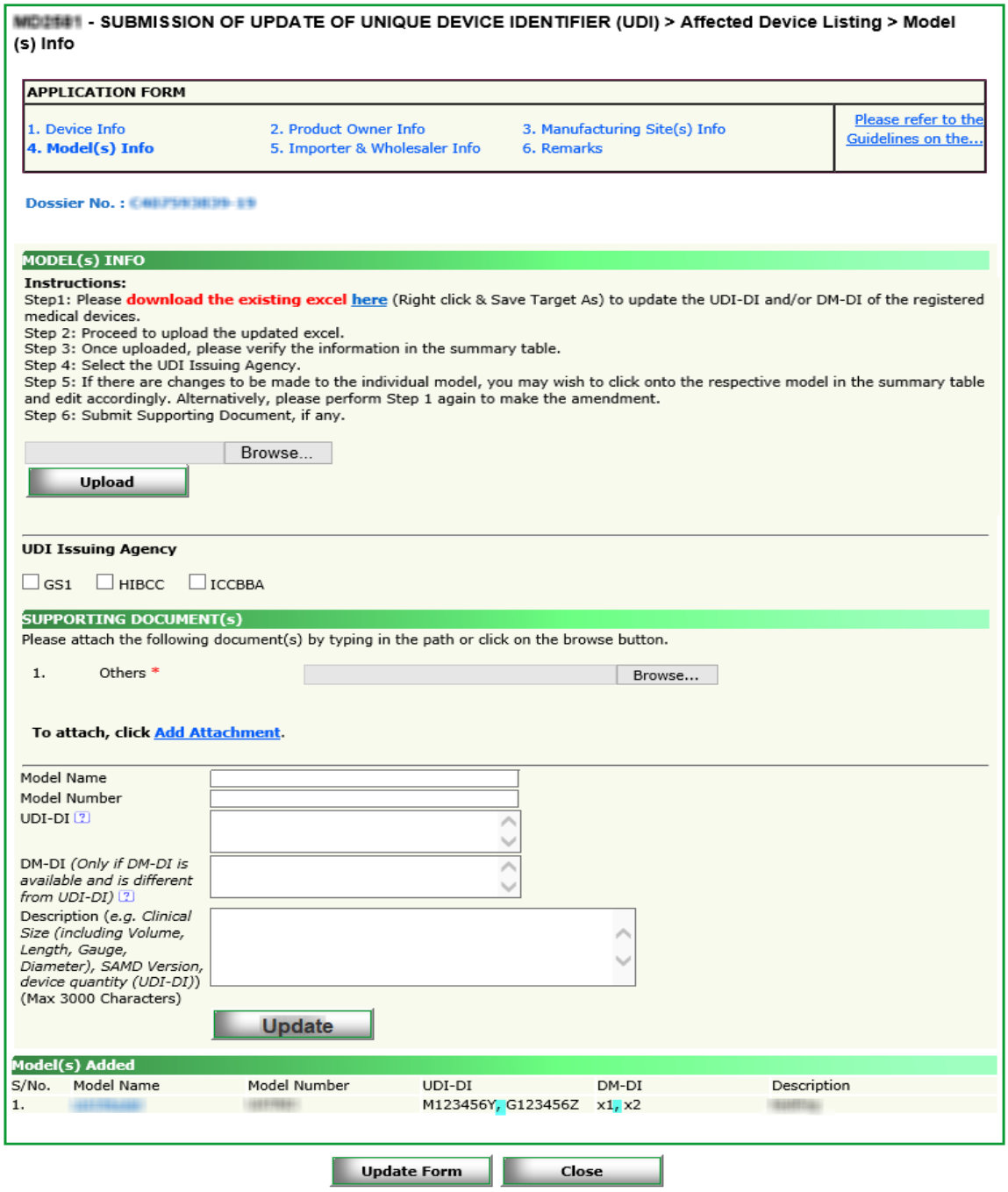


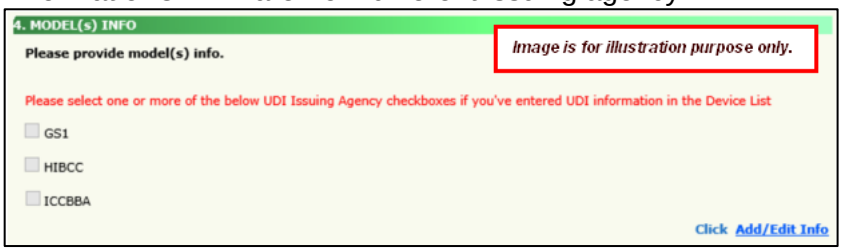
Figure 4: New eService

3.2.2 Submitting UDI Information to UDIDs

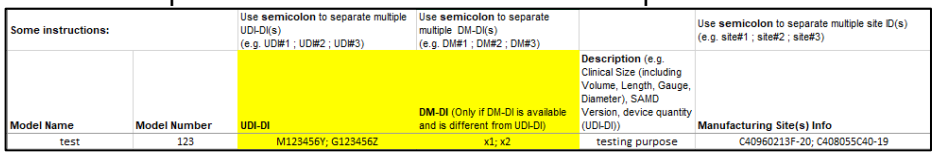
- **Singapore Medical Device Register (SMDR)**

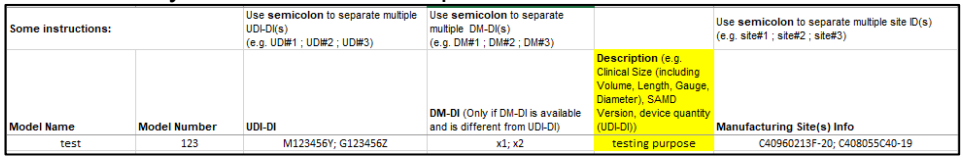
Registrants are responsible for the submission and update of UDI data elements for device registration (i.e. risk class B or higher) listed on SMDR under the authorisation of the product owner. They are also required to ensure that the UDI data is verified to be accurate before submitting the data to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

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

<table>
<tr><th>Data element</th><th>Data Input guideline</th></tr>
<tr><td>Issuing agency (i.e. GS1, HIBCC, ICCBBA)</td><td>
Able to check more than one issuing agency if there are more format of UDI-DI are from different issuing agency.


</td></tr>
<tr><td>Sterile medical device
Description of sterile medical device: (e.g. sterilization methods)
Device containing latex
Device containing DEHP
Device with measuring function</td><td>
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”.


</td></tr>
<tr><td>UDI-DI
DM DI Number (only if different from UDI-DI)</td><td>
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.


</td></tr>
<tr><td>Clinical Size (including Volume, Length, Gauge, Diameter)
SAMD Version</td><td>
Additional information for each model of medical device should be clearly indicated in “Description” column.


</td></tr>
</table>

384 *Table 3: Data input guideline for SMDR*

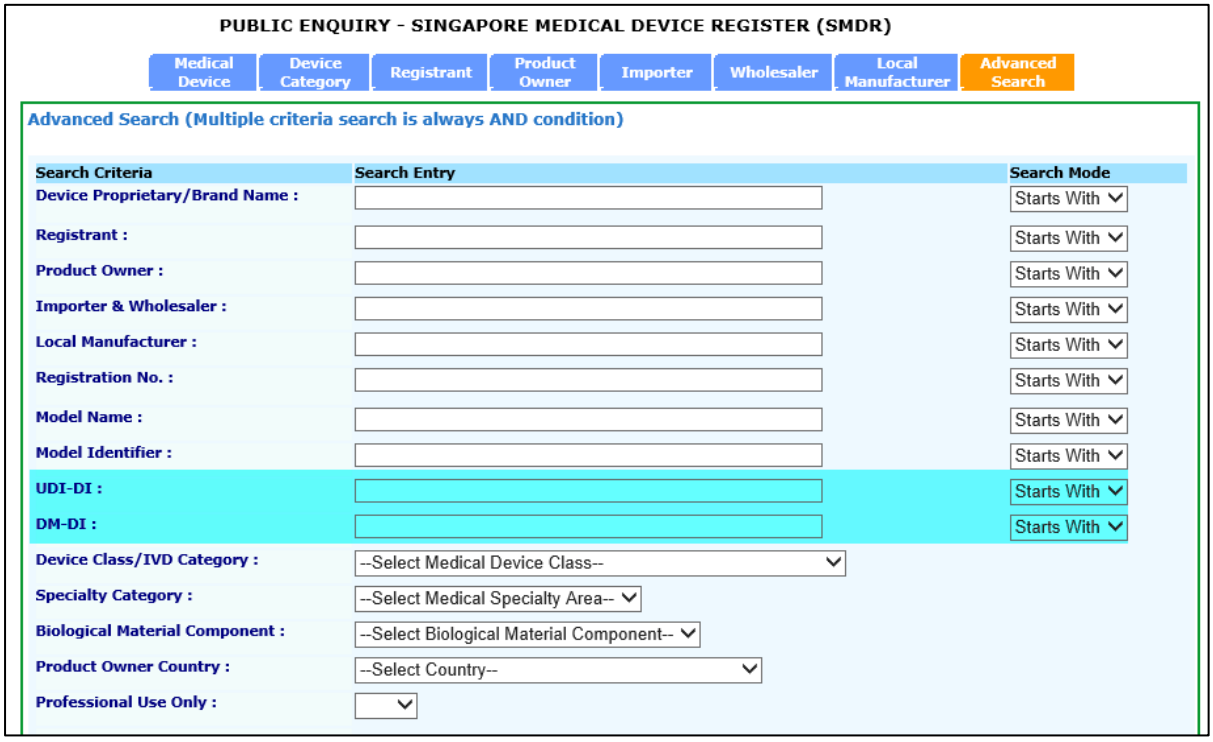


Figure 5: Public SMDR

- **Class A Medical Device Database (Voluntary Basis)**

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

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

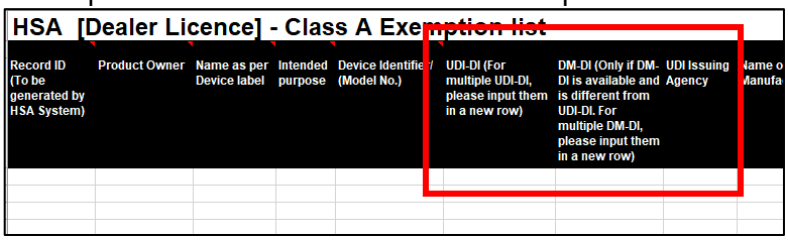
Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	• A drop-down list to select the issuing agency of the UDI-DI and DM-DI.
UDI-DI DM DI Number (only if different from UDI-DI) SAMD Version	• The UDIs applied on the medical device labels for EU or the USA markets can be used in Singapore. If there are multiple UDI-DI or DM-DI for each model, a **new row** is to be added. • 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. 

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

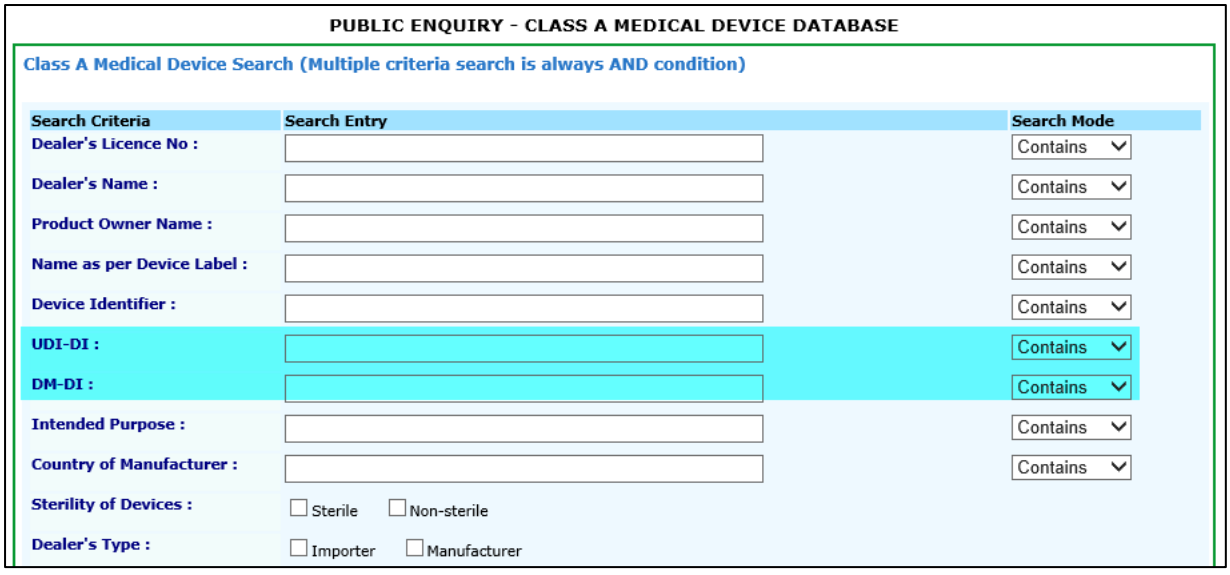


Figure 6: Class A Medical Device Database

4 UDI Implementation Timeline

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

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

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

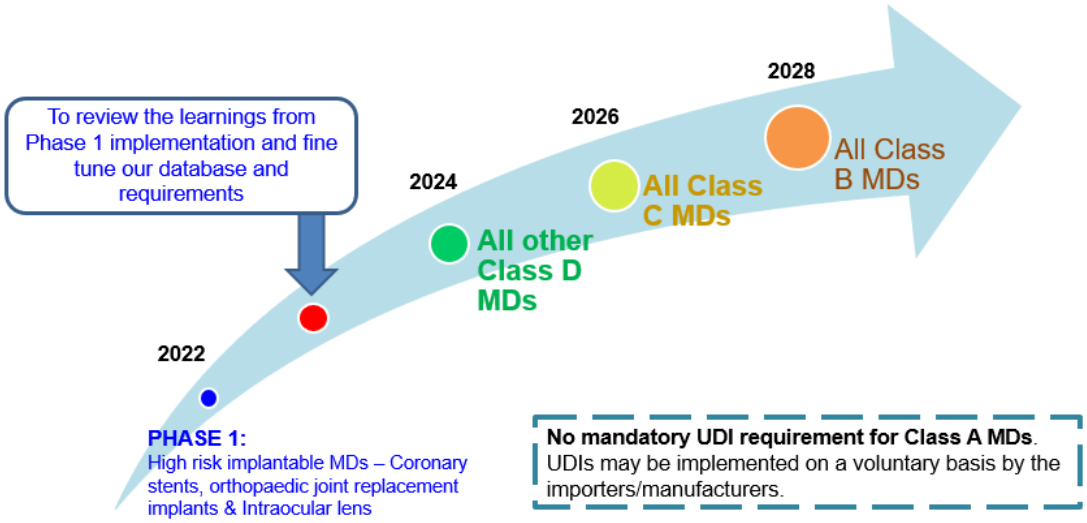


Figure 7: Overview of UDI Implementation timeline in Singapore

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

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
--	• 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	

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.

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HEALTH SCIENCES AUTHORITY

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Applied Sciences Group

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