HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

July 2022

MEDICAL DEVICE GUIDANCE

GN-36: Guidance on Medical Device Unique Device Identification (UDI) System

Revision 2

HSA
Health Sciences Authority

CONTENTS

PREFACE 3
1. INTRODUCTION 4
1.1. Scope 4
1.2. References sources 4
1.3. Definitions 4
2. UDI SYSTEM 7
2.1. Unique Device Identifier (UDI) Format 8
2.2. AIDC and HRI Form of UDI 9
2.3. Labelling Requirements for UDI in Singapore 10
2.4. Data Elements for UDI Databases (UDIDs) 11
2.4.1. UDI Data Elements - SMDR 12
2.4.2. UDI Data Elements - Class A Medical Device Database 12
3. PROCESS OF IMPLEMENTING UDI 13
3.1. Developing and placement of UDI for medical devices 13
3.1.1. Issuing Agency (IA) 14
3.1.2. UDI-DI Triggers 15
3.1.3. Direct Marking 15
3.2. Submission of UDI Data Elements via MEDICS 16
3.2.1. Registered medical devices (via New e-service) 17
3.2.2. Registered medical devices (via Change notification) 26
3.2.3. Listed Class A medical devices (Voluntary basis) 32
3.2.4. Submitting UDI information during product registration 34
3.2.5. Submitting UDI information for Special Access Routes (SAR) 36
4. RULES FOR SPECIFIC DEVICE TYPES 38
4.1. Non-IVD kits 38
4.2. IVD kits 38
4.3. Standalone Software/ Software as a Medical device (SaMD) 38
5. UDI IMPLEMENTATION TIMELINE 39
5.1. Compliance Date for each Implementation Phase: 41
5.2. Transition period to comply with each Implementation Phase 41

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

REVISION HISTORY

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
GN-36: Revision 1 (27 August 2021)	R1
GN-36: Revision 2 (18 July 2022)	R2

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

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

Definitions that do not indicate they are set out in the Health Products Act 2007 (*Act*) or Health Products (Medical Devices) Regulations 2010 (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

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.

DIRECT-MARKING DEVICE IDENTIFIER (DM-DI): Direct marking is placing the UDI and, potentially the full UDI carrier, permanently on the 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.

STANDALONE MOBILE APPLICATION (*as set out in the Regulations*):
A software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

NOTE: These are commonly referred to as SOFTWARE AS A MEDICAL DEVICE (SaMD)

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.

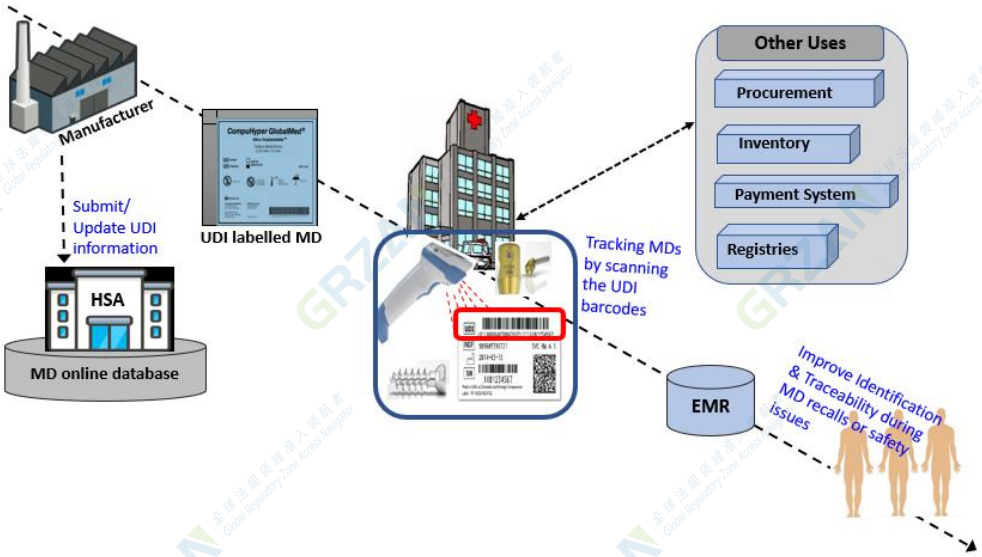


Figure 1: Applicability of UDI

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 (as applicable)

- 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 **both human readable interpretation (HRI) format** and **Automated Identification for Data Capture (AIDC) technology forms** (*Figure 3*). Examples of AIDC technologies include linear bar codes, two-dimensional 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.

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 unit of supply or in some cases directly marked on the devices.
- When space constraints are encountered for placement of UDIs on a device label, the UDI carrier may be placed on the next higher packaging level. However, in situation where there is limitation in the use of both AIDC and HRI on a label, the AIDC format shall be favoured. However, do note that in certain environment such as home care settings, the use of HRI over AIDC maybe required.

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 this UDI requirement.
- 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 element	Data format	Description	Note
Issuing agency (IA)	Checkbox	Selection options consisting of GS1, HIBCC, ICCBBA	If the issuing agency of one of the medical devices Model A is from GS1, and the issuing agency of the other Model B is from HIBCC, then registrant is required to select both GS1 and HIBCC in MEDICS form.
Sterile medical device	Radio Button	Yes or No	If any one of the medical devices listed under model info (s) section fulfil the conditions, registrant is required to indicate a "YES".
Description of sterile medical device: (e.g. sterilization methods)	Text area [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	
UDI-DI	String	UDI- Device Identifier	Information will be captured in excel file (i.e. Annex 2 list of configuration)
DM DI Number (only if different from UDI-DI)	String	Direct mark-Device Identifier (applicable only if available and 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	Information will be captured under **"Brief description"** column of Annex 2 List of Configuration
SaMD Version number/ software version number	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 element	Data format	Description	Note
UDI-DI	String	UDI- Device Identifier	Information will be captured in Class A medical device database If there are multiple UDI-DI or DM-DI for each model, a **new row** is to be added for each UDI-DI or DM-DI.
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 (IA)	Drop Down list	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 registered Class B, C and D medical devices or importer of listed Class A medical devices can submit the UDI information as is to the SMDR or Class A Medical Device Database. (Proceed to section 3.2).

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.

- 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.

Note: The designated issuing agency in Singapore is **GS1 and HIBCC**
For more information, please refer to https://www.gs1.org.sg/ and https://www.hibcc.org/

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. Various

technologies are available for applying direct marking which includes both intrusive methods (e.g., dot pin; etching; direct laser marking) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; permanent adhesive label). However, it is the responsibility of the manufacturer/device labeller to ensure that the UDI is readable for the expected service life.

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.

Note: Registrants/Importer/local manufacturer can update the Direct marking-Device Identifier (DM-DI) to SMDR and/or Class A Medical Device Database as and when the information is available (refer to section 3.2).

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.

For implantable devices, it is generally not required to be direct marked with UDI carrier on the device itself. However, the UDI of the implantable medical device must still be identifiable prior to implantation.

3.2. Submission of UDI Data Elements via MEDICS

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) to allow submission of UDI related 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. Registered medical devices (via New e-service)

The new e-service "Submission of Update of Unique Device Identifier (UDI)" allows registrants to update specific UDI data elements for their registered medical devices. Please note that only the following **UDI data elements** can be updated using this service.

- UDI-Device Identifier (UDI-DI)
- Direct Mark-Device Identifier Number (DM-DI)
- Issuing Agency (IA)

Registrants can update UDI data elements for multiple device listings in a single submission and these updates will be reflected in the SMDR upon successful submission via MEDICS.

Note: Updating of UDI-DI, DM-DI and IA for the registered medical devices in device listing should not change any of the device registration information.

How to submit the UDI information

1. Registrant is required to select and add the device listing (e.g. DE###) for which they wish to update the UDI information. A maximum of 30 device listings can be selected in a single submission.

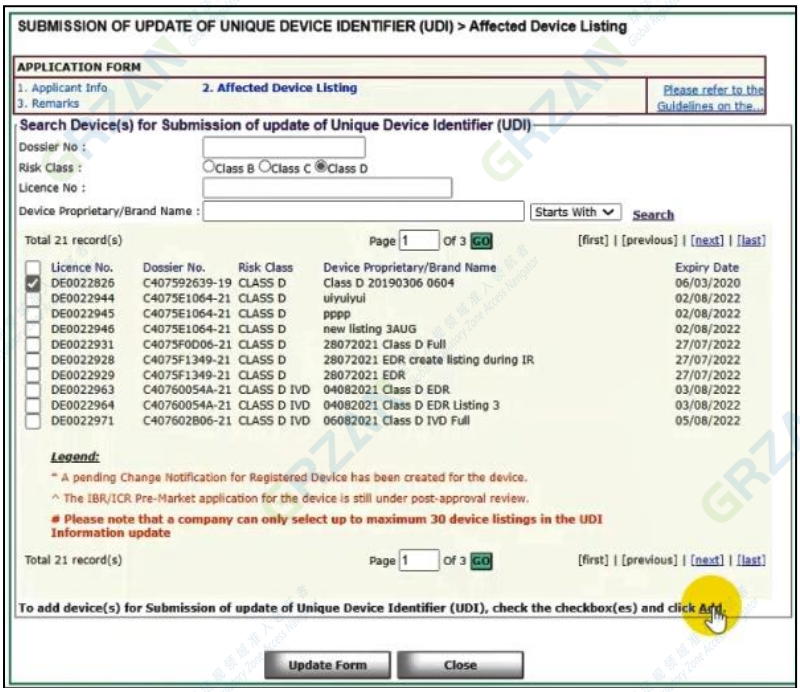


Figure 4

2. Click on the hyperlink “Update UDI Info”.

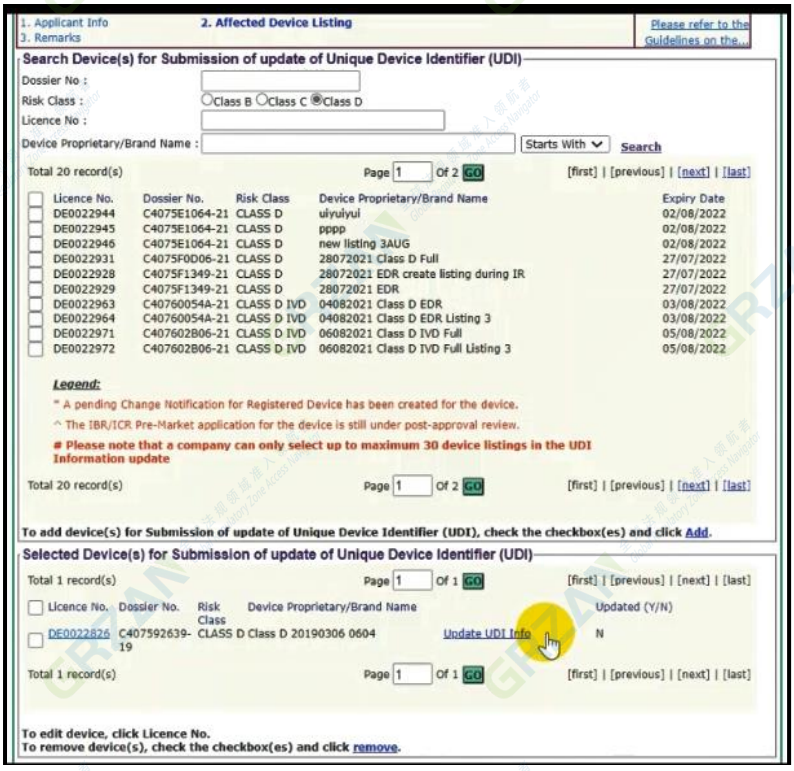


Figure 5

3. Registrant should be able to view the list of current medical devices registered under the device listing you have selected to update UDI info.

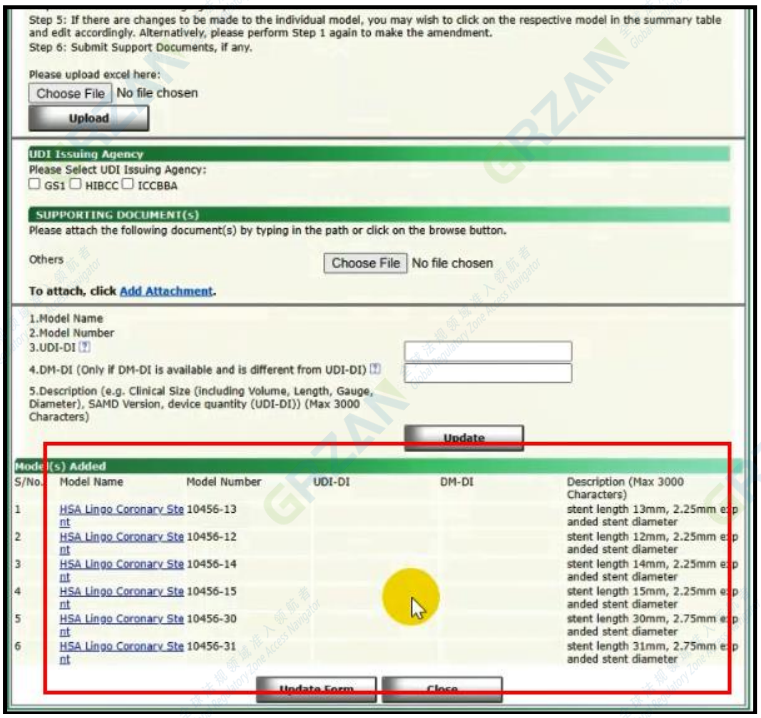


Figure 6

4. Download the excel file containing the list of medical devices currently registered under the device listing selected.

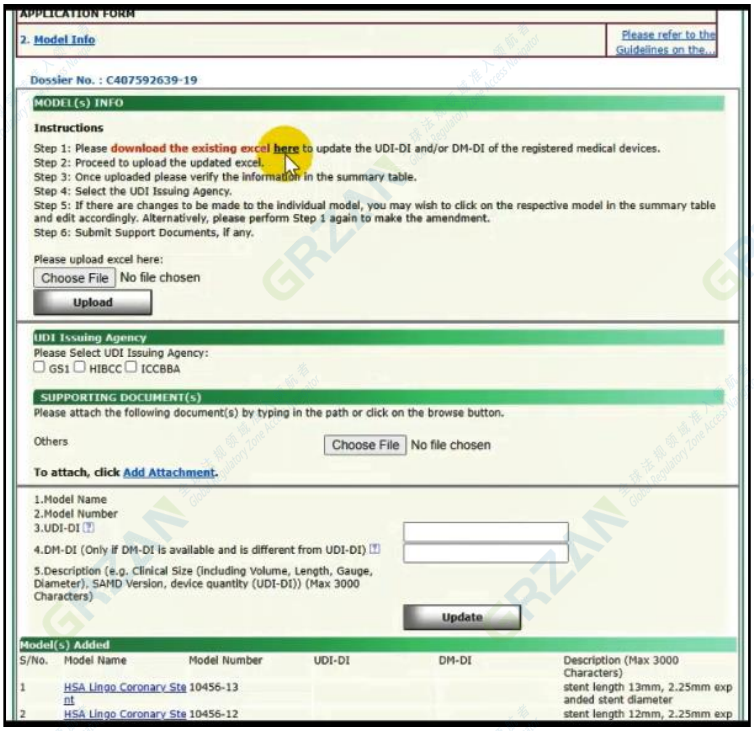


Figure 7

5. Open the downloaded excel file and fill in the corresponding UDI-DI and DM-DI (where available).

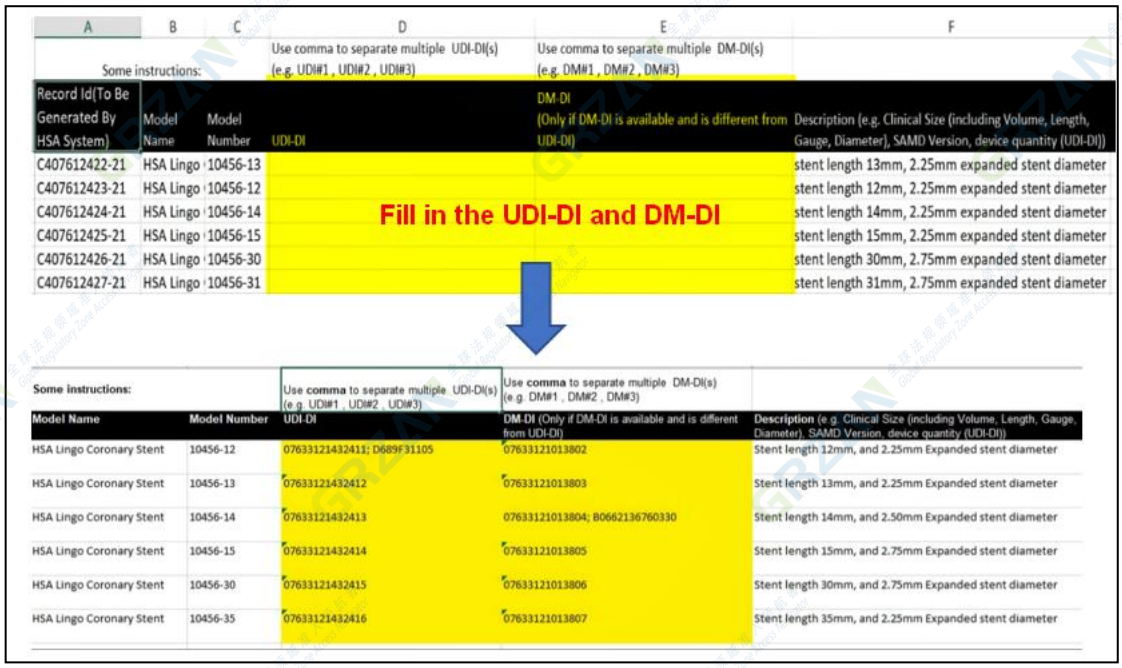


Figure 8

Data element	Data Input guideline
UDI-DI	• 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 comma (,) to separate each UDI-DI.
DM-DI Number (only if different from UDI-DI)	

Table 3

Note: Please note that the "Model Name, Model number" and "Brief Description" columns of the excel file are disabled. No amendments to this information can be made under this e-service.

6. Save the excel file and upload the updated file.

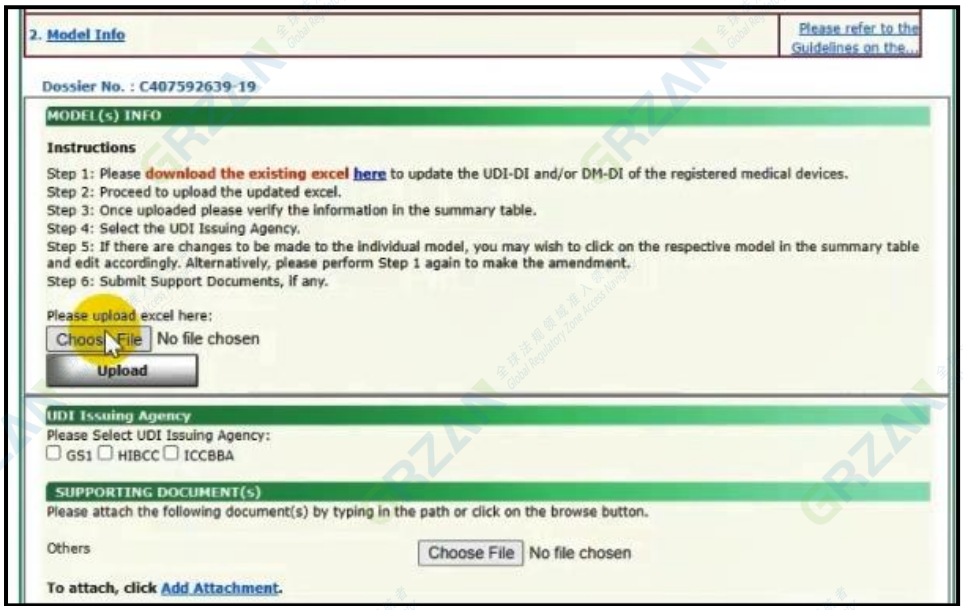


Figure 9

7. Once the excel file is uploaded, registrant can view and verify that the UDI information has been updated successfully

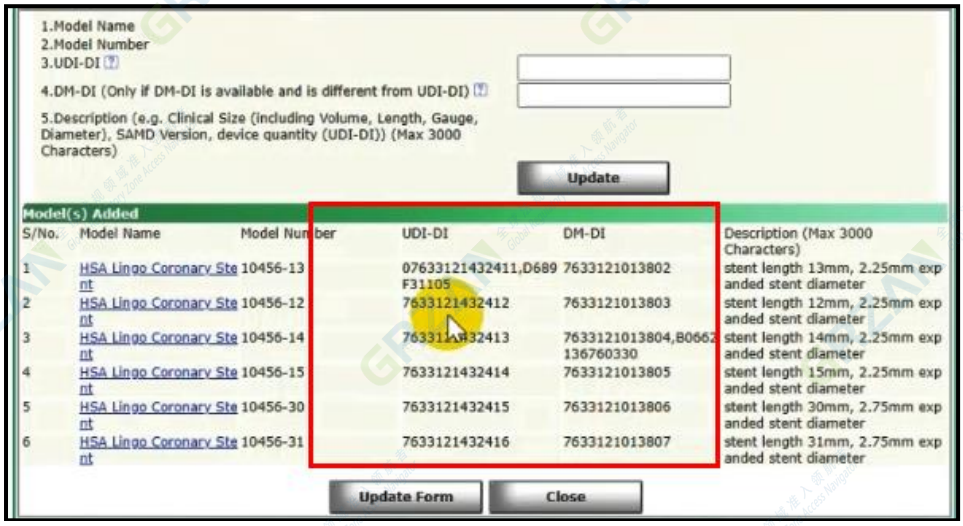


Figure 10

8. Next, select the applicable Issuing agency by checking the box.

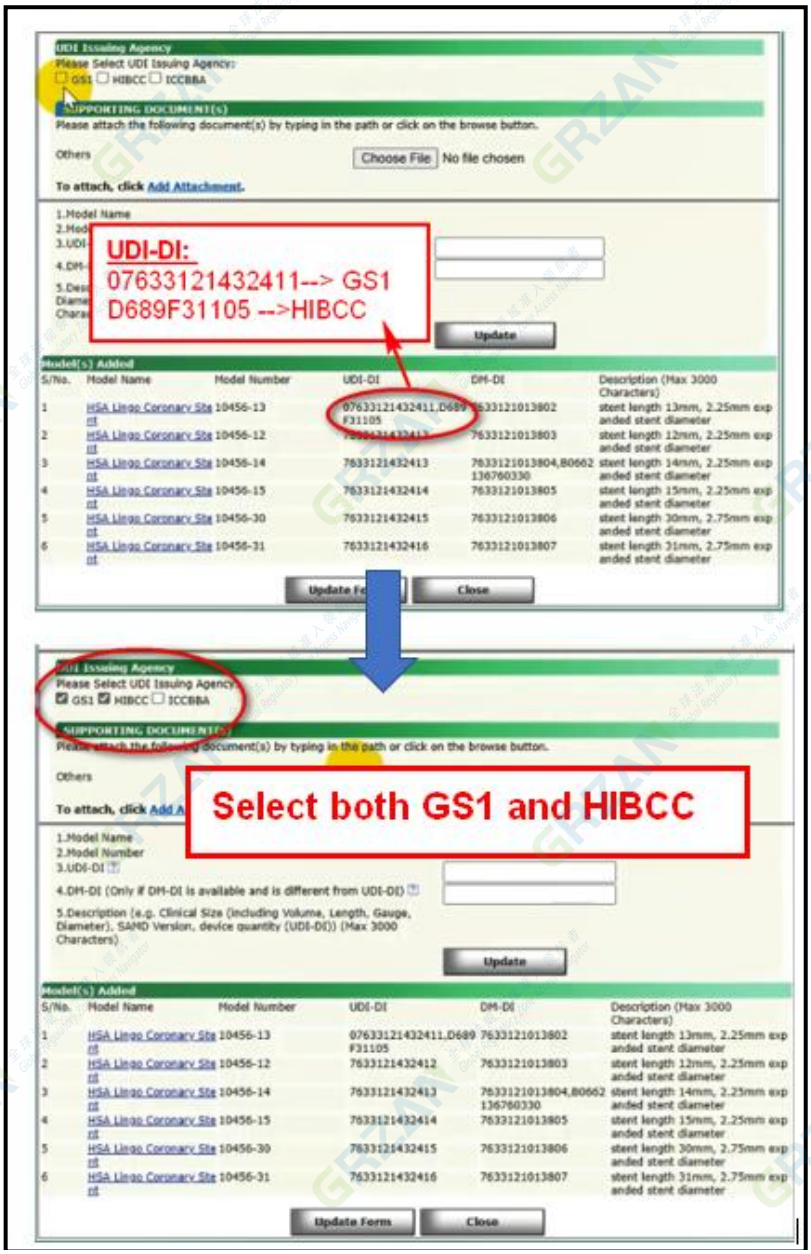


Figure 11

Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	• Registrant is required to select the applicable issuing agency of the UDI for the medical devices listed in Annex 2 List of configuration. *E.g. If the Issuing agency of Model A is GS1, and the issuing agency of Model B is HIBCC, then registrant is required to select both GS1 and HIBCC in MEDICS form.*

Table 4

9. Next, click on “Update form”.

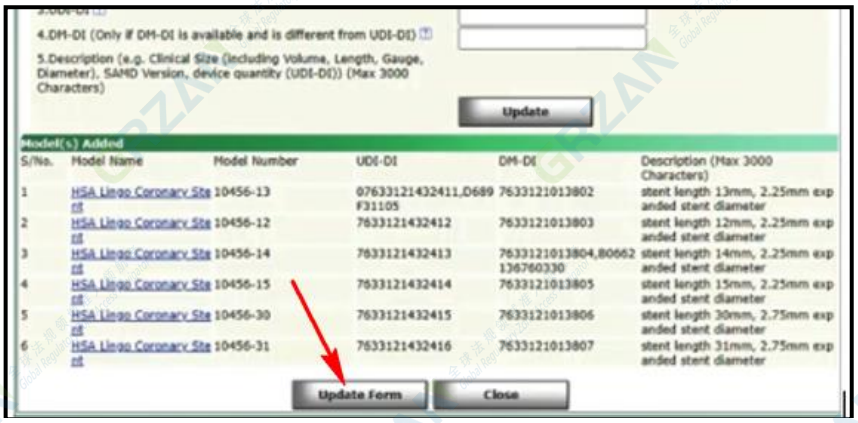


Figure 12

10. It will lead back to the original page where registrant had selected the list of device listing to be updated. For device listings that have been updated the status will be updated to “Y”.

    Once the registrant has completed the UDI updates for the relevant device listings, click on “Update Form”

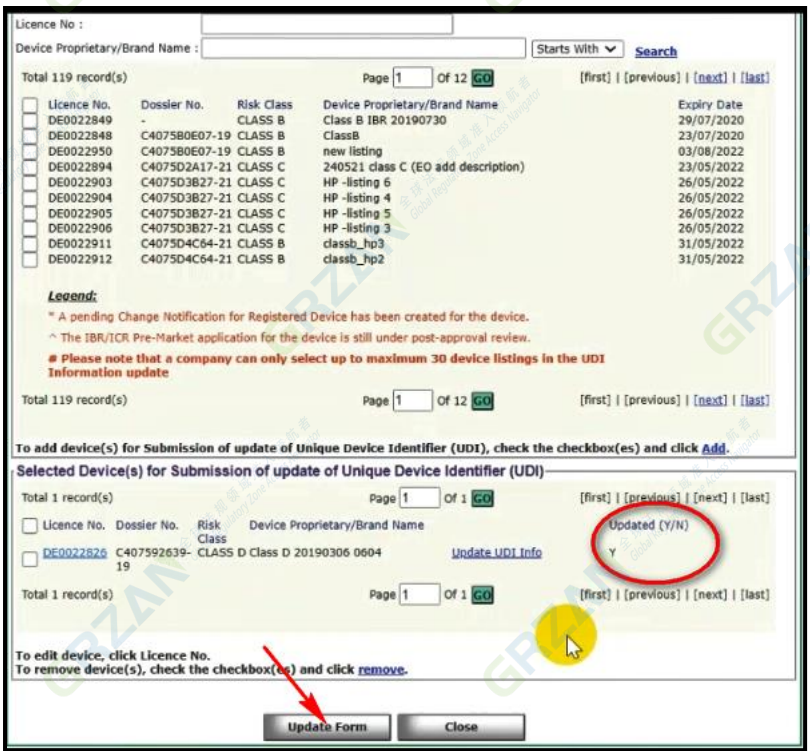


Figure 13

11. To complete the submission, click “Confirm”

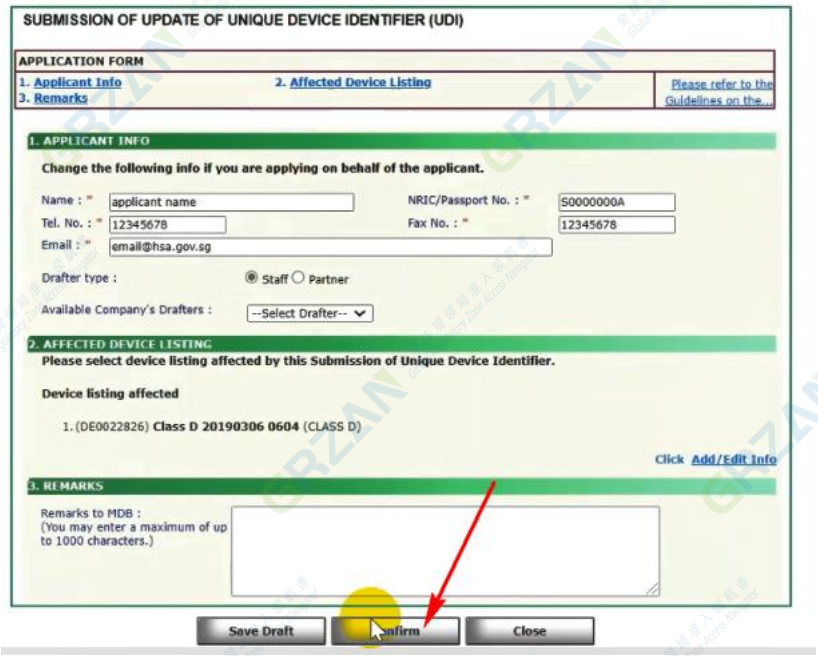


Figure 14

12. Upon clicking “Confirm”, a prompt will appear and by selecting “OK”, the registrant acknowledges the declaration.

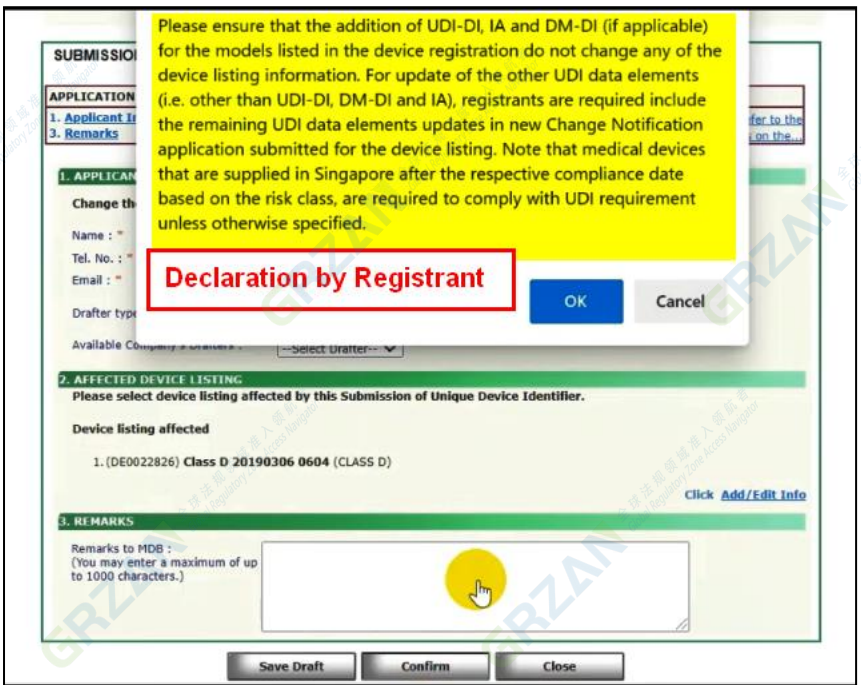


Figure 15

13. Next, select “Submit” and upon successful submission, a job reference number will be generated.

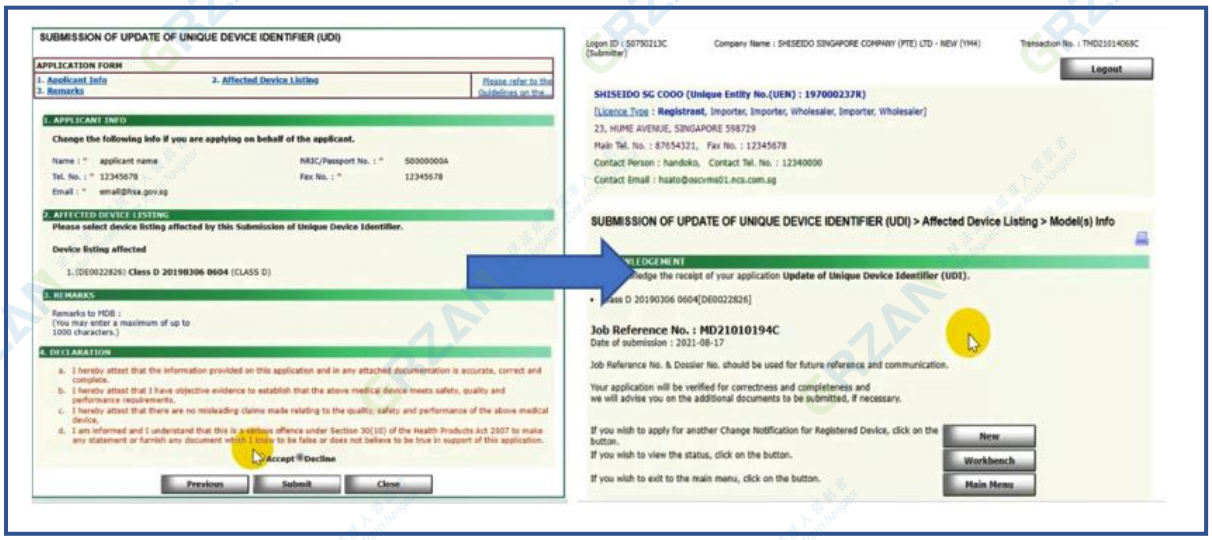


Figure 16

14. Upon submission , the UDI-DI, DM-DI will be updated on the SMDR.

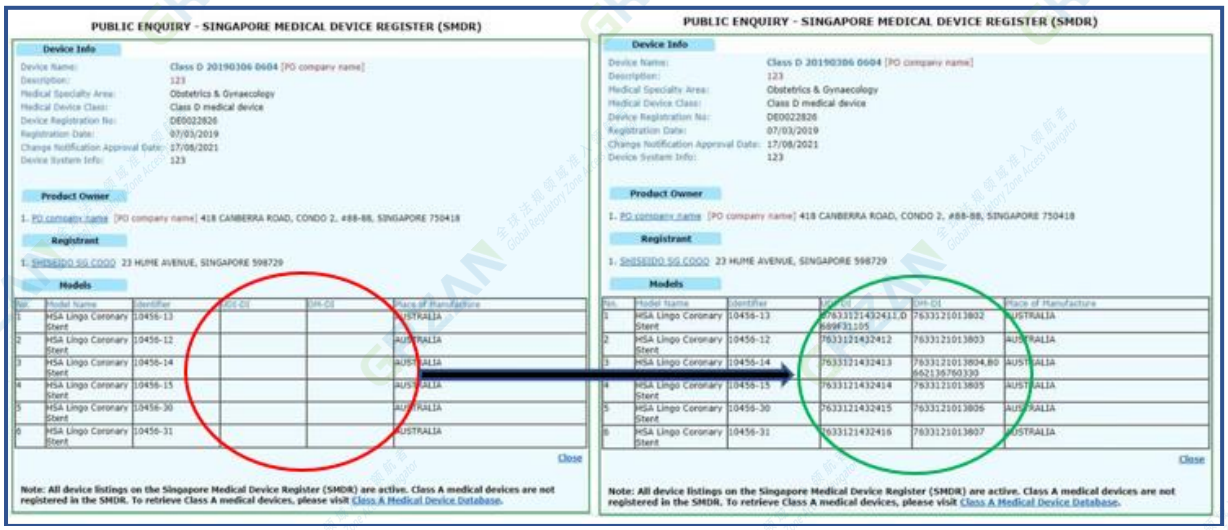


Figure 17

Note: You may also refer to the video guide and the MEDICS E-guide available on HSA website for better view of the screenshots shown above.

3.2.2. Registered medical devices (via Change notification)

The Change notification MEDICS e-service also allows updating the UDI data elements for registered medical devices. This service allows all **UDI data elements** of the registered medical devices to be updated.

- Issuing agency
- UDI-DI
- DM DI Number (only if different from UDI-DI)
- Sterile medical device
- Description of sterile medical device: (e.g. sterilization methods)
- Device containing latex
- Device containing DEHP
- Device with measuring function
- Clinical Size (including Volume, Length, Gauge, Diameter), SaMD version number/ software version number

Please follow the following steps in the change notification e-service in MEDICS to update UDI data elements for registered medical devices that:

- Do not have changes that require Submission of Change Notification as per GN-21 Guidance on Change Notification for Registered Medical Devices *and*
- To solely update the above UDI data elements for the registered medical devices.

Note: Update in UDI information only for registered medical devices may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.

How to submit the UDI information

1. Under PART 2 – Change Notification
    a. Select the Type of Changes as “Other Changes-Applicable only upon receipt of email from HSA, authorising submission under this category” then select “Other Notification Changes (verified by HSA prior to submission)

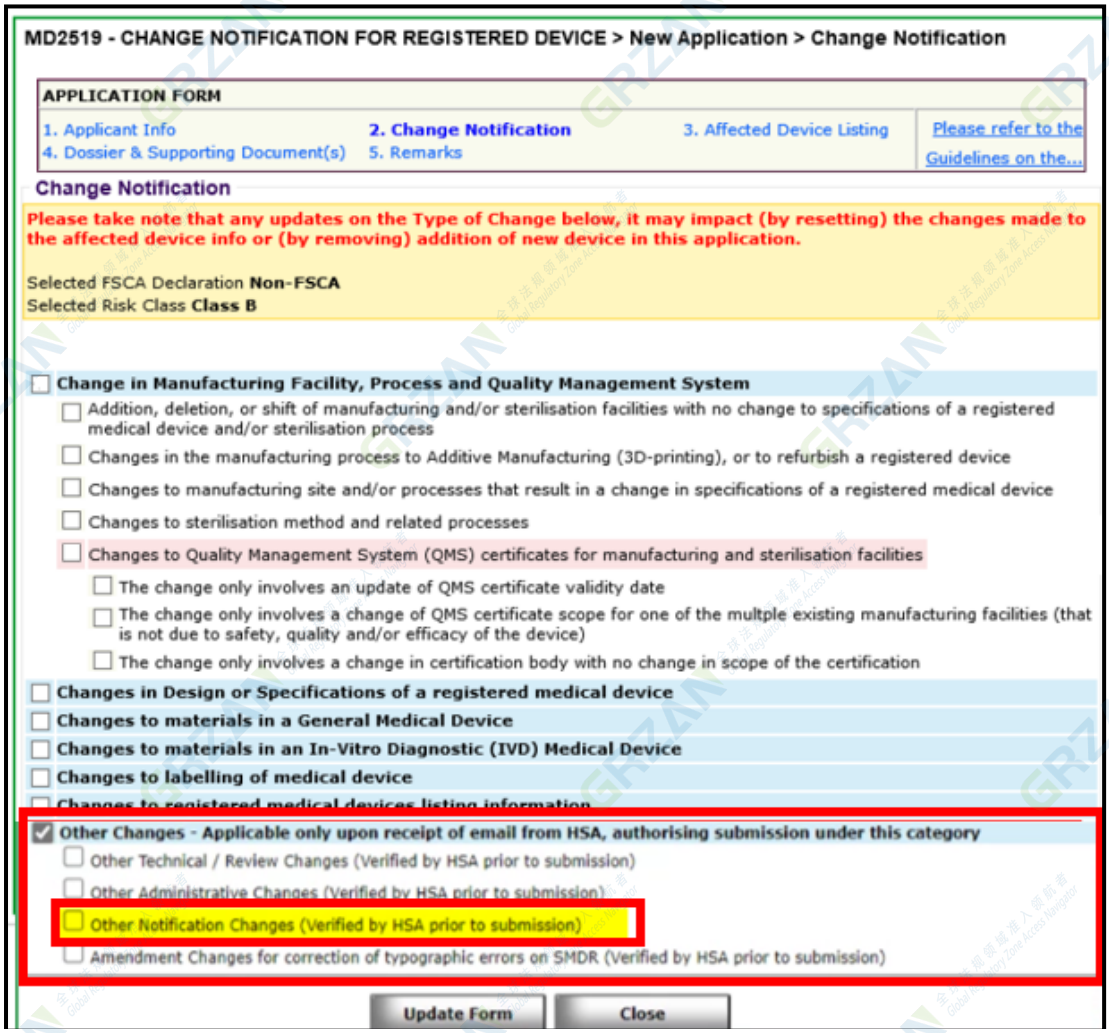


Figure 18

2. Under PART 3 – Affected Device Listing.
    a. Select and add the device listing device listing (e.g. DE###) that the registrants wish to update the UDI information.

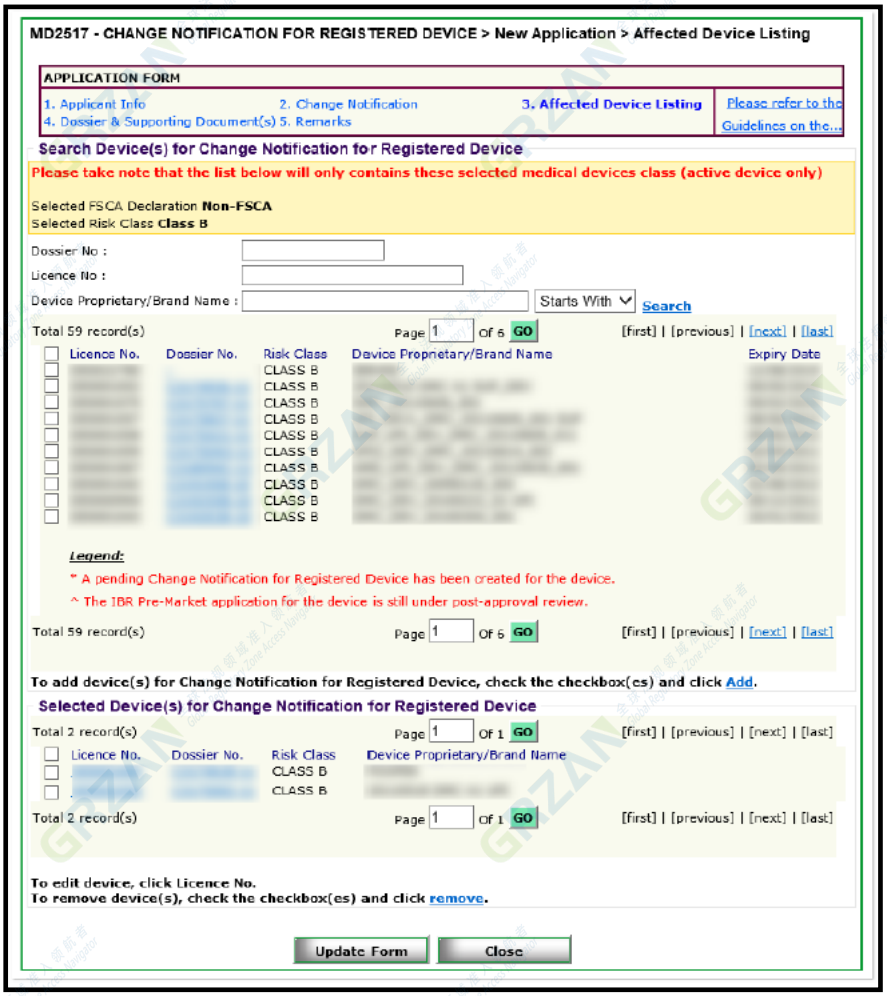


Figure 19

3. Under section 2. Device Info, click Add/ Edit Info



Figure 20

4. Based on the registered medical devices in the selected device listings, please update the radio buttons and text field accordingly as applicable for the registered devices. Once the information has been updated, click “Update form”

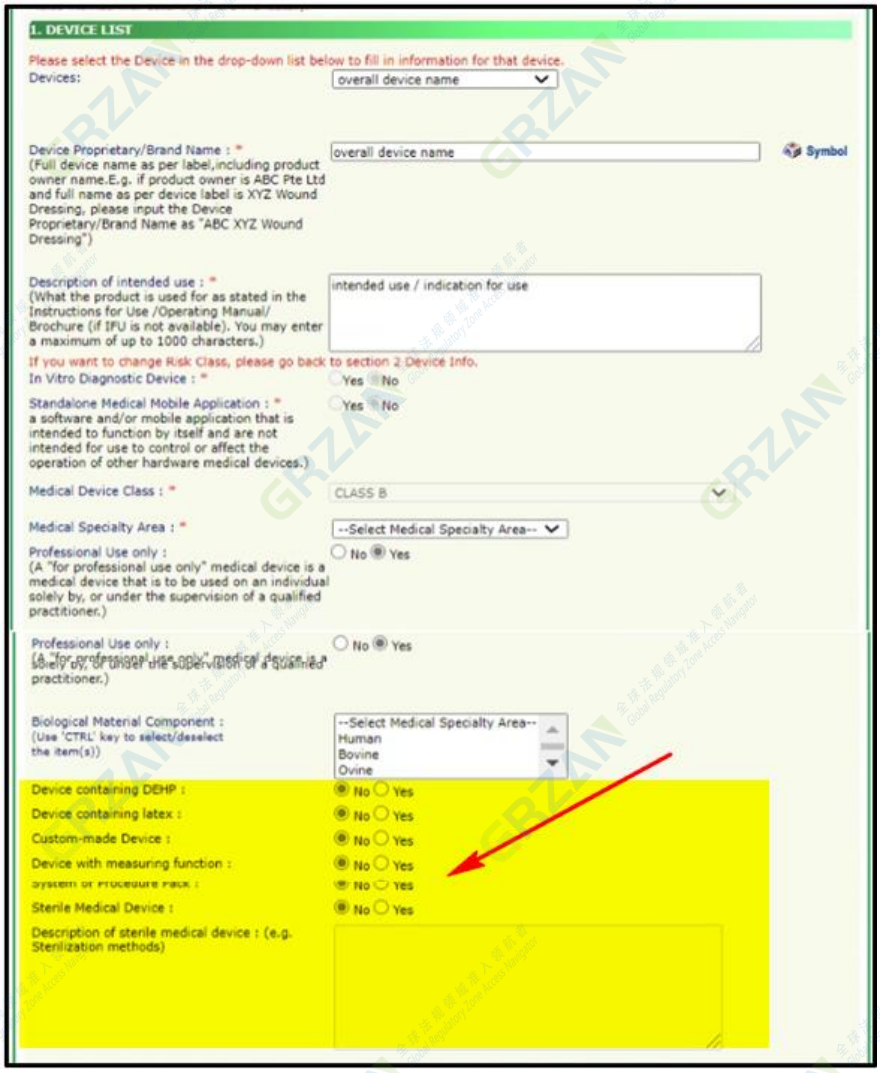


Figure 21

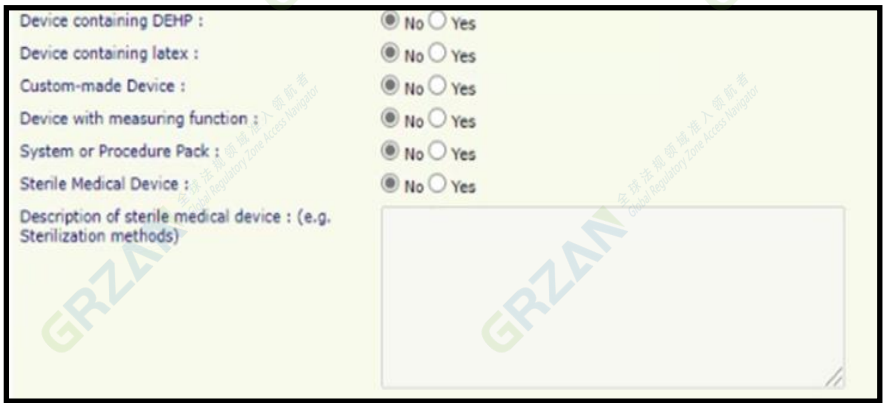


Figure 22

Data element	Data Input guideline
Sterile medical device	• Highlighted fields (radio buttons) are additional UDI data element fields added to the product registration e-service to be captured . **Note**: If <u>any one</u> of the medical devices listed under model info (s) section fulfil the conditions, registrant is required to indicate a "YES".
Description of sterile medical device: (e.g. sterilization methods)	
Device containing latex	
Device containing DEHP	
Device with measuring function	

Table 5

5. Next, under section 5. Model Info(s), click Add/Edit Info

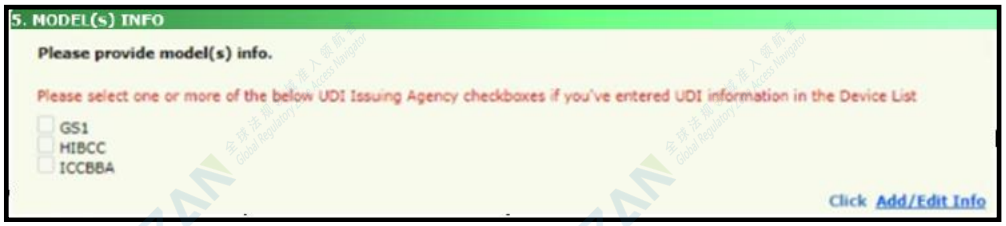


Figure 23

Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	• Registrant is required to select the applicable issuing agency of the UDI for the medical devices listed in Annex 2 List of configuration. *E.g. If the Issing agency of Model A is GS1, and the issuing agency of Model B is HIBCC, then registrant is required to select both GS1 and HIBCC in MEDICS form.*

Table 6

6. Download the excel file from MEDICS and fill in the corresponding UDI-DI, DM-DI (where available) and brief description information.

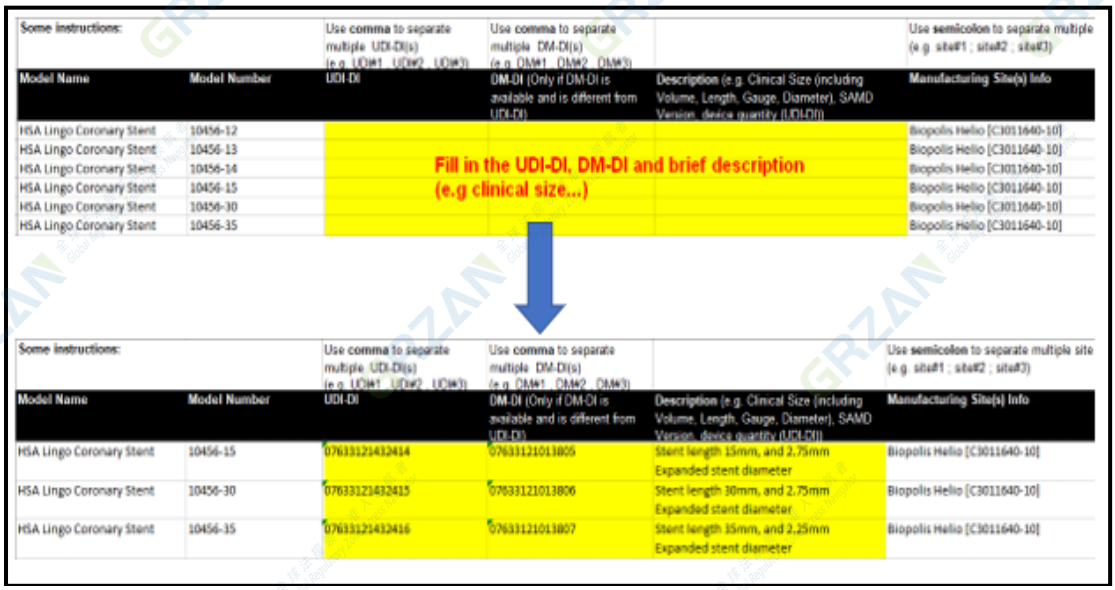


Figure 24

Data element	Data Input guideline
UDI-DI	• 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 comma (,) to separate each UDI-DI or DM-DI.
DM DI Number (only if different from UDI-DI)	
Clinical Size (including Volume, Length, Gauge, Diameter)	• Additional information for each model of medical device should be clearly indicated in "Description" column. **Note**: Only information that is applicable to the medical devices need to be updated. (E.g. If there is no software, then software version will not be required.)
SaMD Version number/ software version number	

Table 7

7. Save the excel file and upload the updated excel file. Then Click "Update form"
8. Under PART 4 – Dossier & Supporting Document(s), Registrant is required to upload the following supporting document under "HSA Email" section.
   - **Signed copy of Declaration on company letterhead by registrant** to confirm that change notification application is only for the addition of UDI information for the models listed in the device listing and there is no change to any of the device listing information.

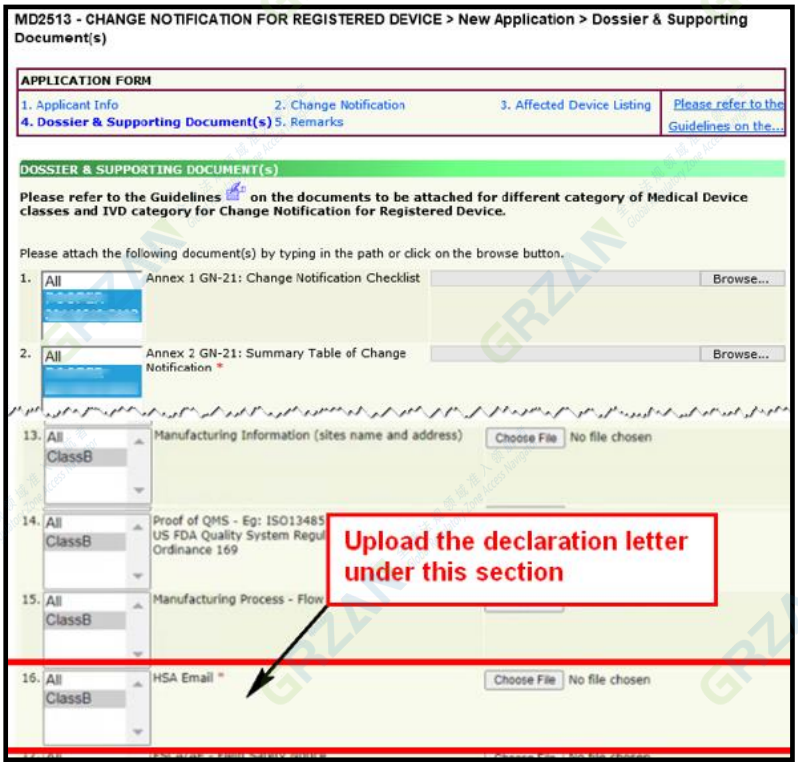


Figure 25

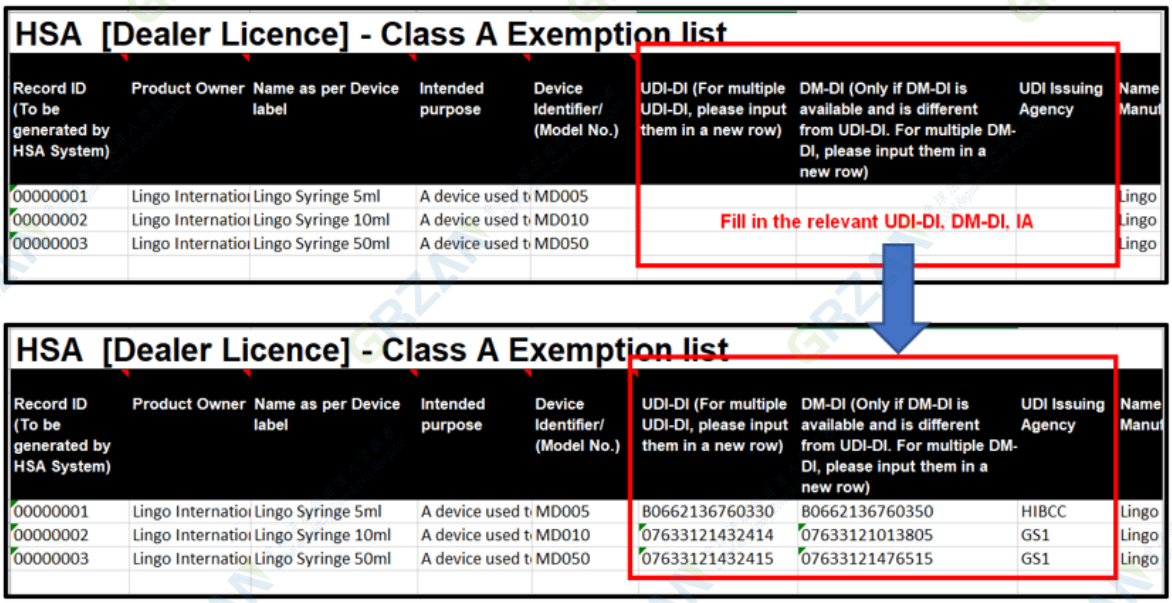
9. Once the documents are uploaded, click on Update form.
10. Submit the Change notification application.

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.

3.2.3. Listed Class A medical devices (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 updating the database. Please note that submission of UDI data elements for Class A medical devices is **not mandatory**.

For submission of data to Class A Medical Device Database via MEDICS e-service "Submission of update of Class A medical device exemption list", local manufacturers and/ or importers are required to download the previously submitted excel file from MEDICS to input the UDI related information based on below (*Table 3*) for the medical devices included in the Class A list. After completing the information, the excel file should be uploaded as per current process. Upon completion of the submission, information will be reflected in the Class A medical device database.



HSA [Dealer Licence] - Class A Exemption list

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 Manu
00000001	Lingo Internatio	Lingo Syringe 5ml	A device used t	MD005				Lingo
00000002	Lingo Internatio	Lingo Syringe 10ml	A device used t	MD010				Lingo
00000003	Lingo Internatio	Lingo Syringe 50ml	A device used t	MD050				Lingo

HSA [Dealer Licence] - Class A Exemption list

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 Manu
00000001	Lingo Internatio	Lingo Syringe 5ml	A device used t	MD005	B0662136760330	B0662136760350	HIBCC	Lingo
00000002	Lingo Internatio	Lingo Syringe 10ml	A device used t	MD010	07633121432414	07633121013805	GS1	Lingo
00000003	Lingo Internatio	Lingo Syringe 50ml	A device used t	MD050	07633121432415	07633121476515	GS1	Lingo

Figure 26

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)	• 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 for each UDI-DI or DM-DI.

Table 8

3.2.4. Submitting UDI information during product registration

For new pre-market application, there is no change to the submission procedure. Registrant is required to log in to MEDICS and complete the online Application Form.

In order to capture the additional UDI information, the online MEDICS application form and the List of configuration of medical devices, LoC (i.e. excel file) have been updated with the below new UDI related data fields as follows:

Online Application form

- Sterile medical device
- Description of sterile medical device: (e.g. sterilization methods)
- Device containing latex
- Device containing DEHP
- Device with measuring function

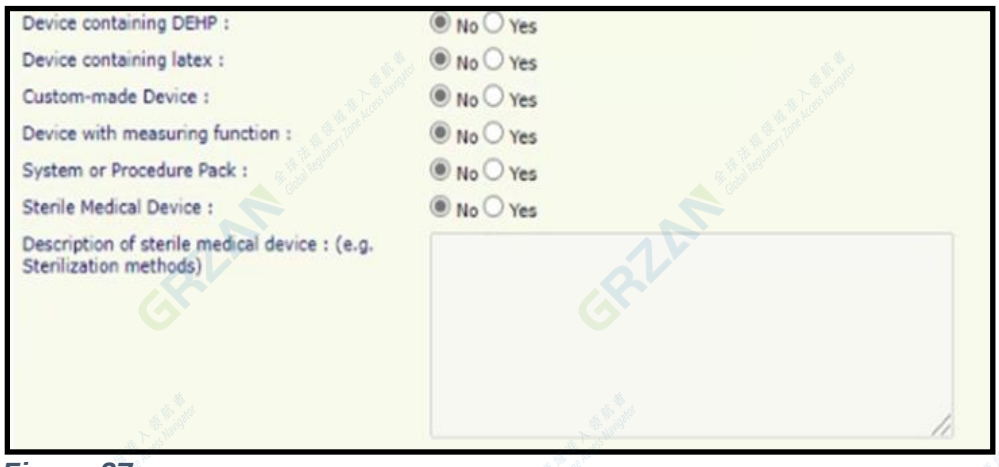


Figure 27

Data element	Data Input guideline

Sterile medical device Description of sterile medical device: (e.g. sterilization methods) Device containing latex Device containing DEHP Device with measuring function	• Highlighted fields (radio buttons) are additional UDI data element fields added to the product registration e-service to be captured . **Note**: If <u>any one</u> of the medical devices listed under model info (s) section fulfil the conditions, registrant is required to indicate a "YES".

Table 9

- Issuing agency

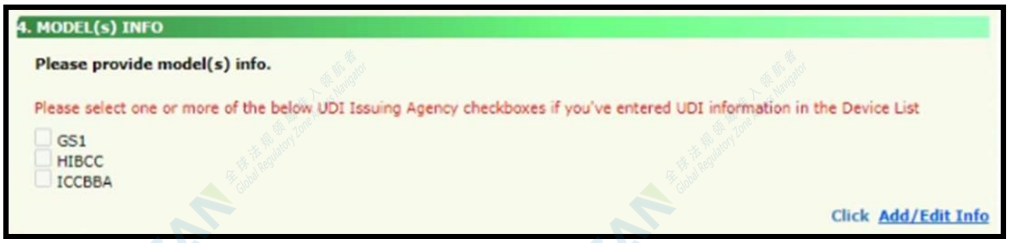


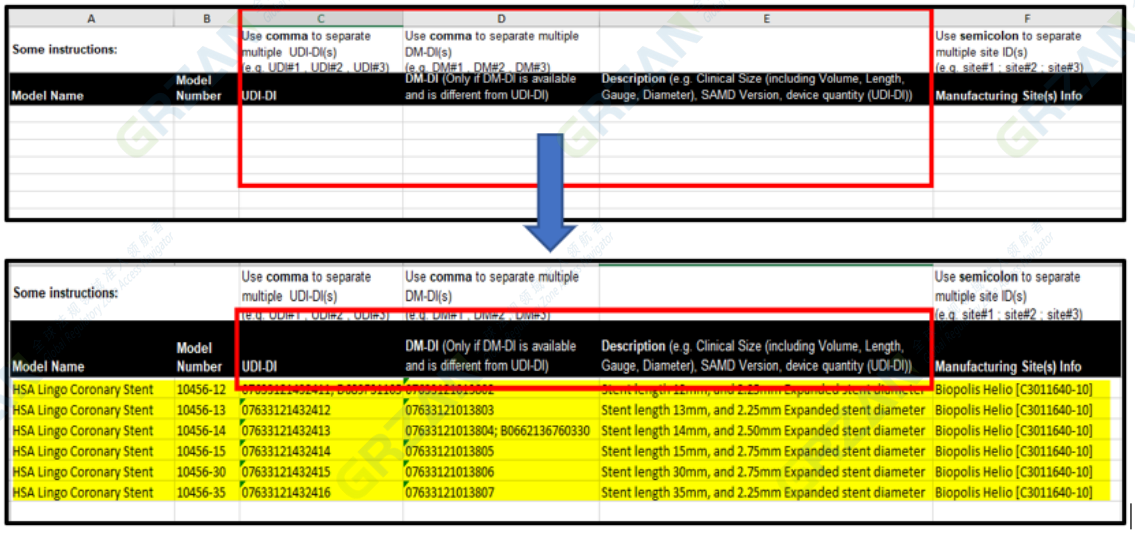
Figure 28

Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	• Registrant is required to select the applicable issuing agency of the UDI for the medical devices listed in Annex 2 List of Configuration. *E.g. If the Issuing agency of Model A is GS1, and the issuing agency of Model B is HIBCC, then registrant is required to select both GS1 and HIBCC in MEDICS form.*

Table 10

<u>List of Configuration of medical devices, LoC (i.e. excel file)</u>

- UDI-DI
- DM DI Number (only if different from UDI-DI)
- Clinical Size (including Volume, Length, Gauge, Diameter), SaMD version number/ software version number



A	B	C	D	E	F
Some instructions:		Use **comma** to separate multiple UDI-DI(s) (e.g. UDI#1 , UDI#2 , UDI#3)	Use **comma** to separate multiple DM-DI(s) (e.g. DM#1 , DM#2 , DM#3)		Use **semicolon** to separate multiple site ID(s) (e.g. site#1 ; site#2 ; site#3)
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))	**Manufacturing Site(s) Info**

Some instructions:		Use **comma** to separate multiple UDI-DI(s) (e.g. UDI#1 , UDI#2 , UDI#3)	Use **comma** to separate multiple DM-DI(s) (e.g. DM#1 , DM#2 , DM#3)		Use **semicolon** to separate multiple site ID(s) (e.g. site#1 ; site#2 ; site#3)
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))	**Manufacturing Site(s) Info**
HSA Lingo Coronary Stent	10456-12	[illegible]	[illegible]	[illegible]	Biopolis Helio [C3011640-10]
HSA Lingo Coronary Stent	10456-13	07633121432412	07633121013803	Stent length 13mm, and 2.25mm Expanded stent diameter	Biopolis Helio [C3011640-10]
HSA Lingo Coronary Stent	10456-14	07633121432413	07633121013804; B0662136760330	Stent length 14mm, and 2.50mm Expanded stent diameter	Biopolis Helio [C3011640-10]
HSA Lingo Coronary Stent	10456-15	07633121432414	07633121013805	Stent length 15mm, and 2.75mm Expanded stent diameter	Biopolis Helio [C3011640-10]
HSA Lingo Coronary Stent	10456-30	07633121432415	07633121013806	Stent length 30mm, and 2.75mm Expanded stent diameter	Biopolis Helio [C3011640-10]
HSA Lingo Coronary Stent	10456-35	07633121432416	07633121013807	Stent length 35mm, and 2.25mm Expanded stent diameter	Biopolis Helio [C3011640-10]

Figure 29

Data element	Data Input guideline
UDI-DI	• 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 comma (,) to separate each UDI-DI or DM-DI.
DM DI Number (only if different from UDI-DI)	
Clinical Size (including Volume, Length, Gauge, Diameter)	• Additional information for each model of medical device should be clearly indicated in "Description" column. **Note**: Only information that is applicable to the medical devices need to be updated. (E.g. If there is no software, then software version will not be required.)
SaMD Version number/ software version number	

Table 11

3.2.5. Submitting UDI information for Special Access Routes (SAR)

For Special Access Routes (SAR) application (i.e GN-26, GN-27 and GN-29), there is no change to the submission procedure. Importer is required to log in to MEDICS and complete the online Application Form as per requirement stated in SAR Guidance.

In order to capture the additional UDI information, the online SAR application form and the SAR Device List (i.e. excel file) have been updated with the below new UDI related data fields as follows:

- Issuing Agency

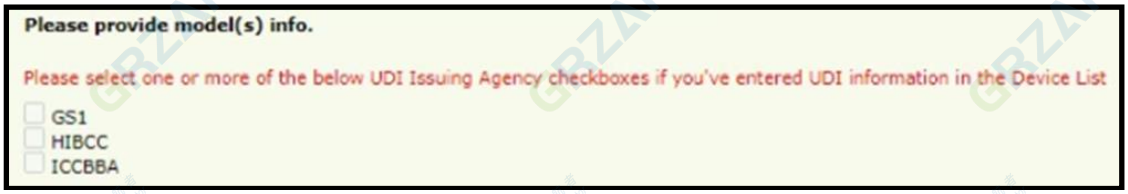


Figure 30

Data element	Data Input guideline
Issuing agency (i.e. GS1, HIBCC, ICCBBA)	• Registrant is required to select the applicable issuing agency of the UDI for the medical devices listed in Annex 2 List of configuration. *E.g. If the Issing agency of Model A is GS1, and the issuing agency of Model B is HIBCC, then registrant is required to select both GS1 and HIBCC in MEDICS form.*

Table 12

SAR Device List (i.e. excel file)

- UDI-DI
- DM DI Number (only if different from UDI-DI)

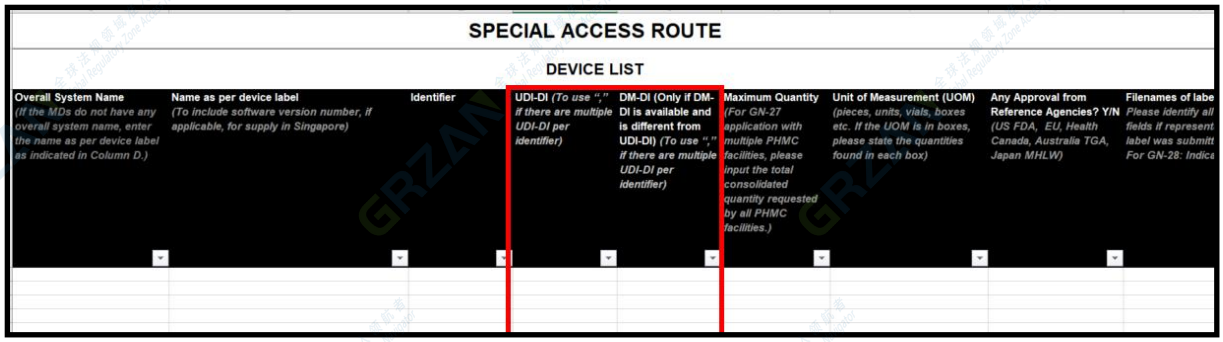


Figure 31

Data element	Data Input guideline
UDI-DI	• 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 comma (,) to separate each UDI-DI or DM-DI.
DM DI Number (only if different from UDI-DI)	
SaMD Version number/ software version number	

Table 13

4. RULES FOR SPECIFIC DEVICE TYPES

4.1. Non-IVD kits

The UDI carrier of the kit is usually placed on the outside of the packaging and should be readable (i.e: HRI) or scannable (i.e. AIDC). If the contents within the kits are medical devices, they should have a UDI Carrier on their packaging or on the device itself. However, for individual single-use disposable medical devices packaged within a Kit, which are meant for use solely as part of the kit and not used or supplied individually, are not required to have their own UDI Carrier.

For example, if a kit or a procedure pack containing several medical devices (e.g. Needles, Gauze swab, film dressing, applicator) are labelled and supplied in a single packaged unit and have a common intended purpose, this kit or procedure pack should be identified with one UDI.

4.2. IVD kits

The UDI of an IVD kit is usually placed on the outside of the packaging and should be readable (i.e: HRI) or scannable (i.e. AIDC). If the contents within the IVD Kits are medical devices, note that they should have a UDI Carrier on their packaging or on the device itself. However, for IVD kit components such as reagents which are not intended for individual use outside the context of the IVD Kit, they do not require their own UDI Carrier.

4.3. Standalone Software/ Software as a Medical device (SaMD)

The UDI of a Standalone Software/ SaMD should contain both the UDI-DI and UDI-PI. The assignment of UDI should be at the system level of the standalone software/SaMD. As software version number is considered a manufacturing control mechanism, this information can be displayed in the UDI-PI.

Examples

- For Standalone Software/ SaMD that are supplied via physical medium (i.e CD or DVD)
  - The UDI should be assigned for each package level and shall bear the HRI and AIDC representation of the complete UDI.
  - The UDI assigned to the first packaging of the physical medium and the system level Standalone Software/ SaMD should be identical.
- UDI of Standalone Software/ SaMD should be provided on a readily accessible screen by the user in an easily readable plain-text format (e.g. an “about” file or included on the start-up screen).
- Only the human readable portion of the UDI is required in electronic displays of the Standalone Software/ SaMD. For Standalone Software/ SaMD that are not being distributed by physical medium (i.e. CD or DVD), AIDC is not required.

5. 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 14*).

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.

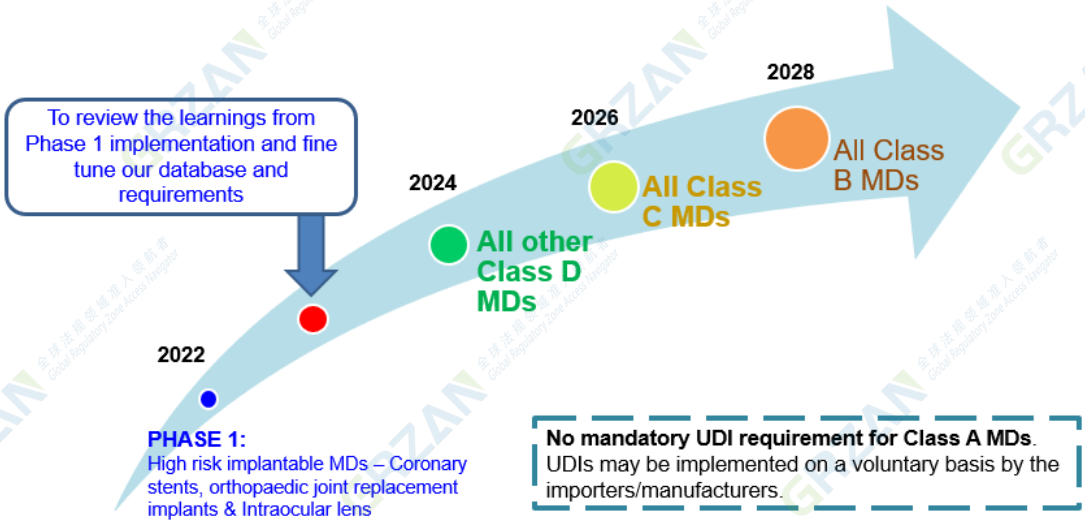


Figure 32: Overview of UDI Implementation timeline in Singapore

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

5.1. 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
--	All 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 • Medical devices authorised for supply via Special Access Routes (GN26, GN27, GN29) are required to comply with UDI requirement on a risk-calibrated approach	

Table 14: Compliance date

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

Note: Please ensure that the updates for the other UDI data elements are completed before the compliance date for each implementation phase comes into effect.

5.2. Transition period to comply with each Implementation Phase

All medical devices imported into Singapore must be labelled with UDI from the respective UDI compliance dates. However, companies will be given additional **6 months** from the compliance date to deplete the respective medical devices that have been imported prior to the compliance date and exist in their current supply chain. For instance, for medical devices that belong to phase 1, all medical devices imported into Singapore from 1 Nov 2022 should be UDI compliant. Any local stocks of these medical devices that were previously imported before 1 Nov 2022, should be supplied before 1 May 2023. From 1 May 2023, any supply of medical devices that are in phase 1 should be UDI compliant.

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

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

HSA
Health Sciences Authority