Frequently asked questions (FAQs)

Medical Device UDI System

1) What is the timeline to update other UDI data elements (e.g. radiobuttons for DEHP, sterility, latex, measuring function, clinical sizes, volume, etc) for the registered medical devices.

   All UDI data elements of the registered medical devices should be updated by the compliance date in accordance to the respective implementation phase. For example, if the registered medical devices belong to Phase 1, all the UDI data elements should be updated by 1 Nov 2022.

2) Will there be a possibility to do a machine-to-machine upload?

   Currently, machine-to-machine upload is not available as we are using the existing databases (Singapore Medical Device Register (SMDR) and Class A medical device database) for UDI information to be updated.

3) What kind of information is required under 'Brief description' column of the Annex 2 List of Configuration (LoC)?

   The information to be captured in the 'Brief description' column of LoC are:
   • Clinical Size: (Volume, Length, Gauge, Diameter),
   • SAMD/ Software Version number,
   For example, if the registered device does not have a software version number or the registered medical device is an IVD, clinical size" is not applicable, there is no need to provide them.
   Registrant may add any additional information as necessary.

4) Is direct marking mandatory in Singapore?

   Direct marking is not mandatory in Singapore. For more information on the consideration for direct marking, please refer to section 3.1.3 of the UDI guidance.

5) In a situation where the older stocks of the registered medical device have a different UDI from the new stocks (e.g. a new UDI-DI is triggered by the manufacturer) can both versions still be supplied concurrently after the effective UDI compliance date?

   For the purpose of phasing out of old inventory stock with old-label UDI, company should retain both old and new versions with their respective UDI-DI on the SMDR. A change notification can be submitted to remove the version with old UDI-DI label from SMDR after stock has depleted.

6) Will devices supplied via Special Access Routes (SAR) be subject to UDI labelling?

   Medical devices authorised for supply via Special Access Routes ((GN26, GN27, GN29)) are required to comply with UDI requirement according to the UDI implementation timeline. All devices authorised under SAR, that are meant for supply locally are required to be labelled with UDI.

7) For Class A medical devices which are accessories to registered medical devices that are listed on the SMDR, are they required to be updated with UDI information.

Submission of UDI data elements for Class A medical devices is on a voluntary basis and is not mandatory.

8) Are shipping containers required to be labelled with UDI?

UDI Carrier shall be on the label (i.e. primary label) and on all higher levels of device packaging (e.g. secondary packaging, etc) or on the device itself (i.e. direct mark). However, shipping containers are not deemed as higher levels of packaging, therefore, they are not required to be labelled with UDI.

Updated on: 31 May 2022

9) Noted that the UDI requirement is applicable to devices imported via GN26, GN27 and GN29. Do we need to submit UDI-DI (e.g. devices in Phase 1) for approved SAR licenses that are still valid past Phase 1 compliance date, 1 Nov 2022?

The submission of UDI information is not required for approved SAR licences that are valid past UDI compliance date (e.g. 1 Nov 2022 for devices phase 1). It is important to note that all medical devices imported and supplied in Singapore must be labelled with UDI from the respective UDI compliance dates.

Companies are provided with an 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.

As such, companies are highly encouraged to plan your submission accordingly or update the UDI-DI information via MEDICS during submission, where available.

For more information, please refer to section 5.2 of the UDI guidance.

10) Is the UDI compliance timelines based on overall risk class of license or risk class of individual items within a license, eg. overall risk class of a license is Class D but contains accessories which are Class B devices.

The UDI-DI information may be updated based on the risk class of individual items as per the compliance timelines. As such, for the above-mentioned scenario, Class D devices should be UDI compliant and updated in MEDCS by 1 Nov 2024. UDI-DI of lower risk class can be updated via MEDICS when available, as long as compliance timelines are followed accordingly.

Note: submission of UDI-DI for Class A medical device/accessory registered as part of a system is on a voluntary basis and not mandatory.

11) If the range of Intraocular lens (IOL) to be registered have a common model identifier (e.g. AU00T0) but each diopter have its own UDI-DI assigned, please advise how do I fill in the Annex 2 LOC for my range of Intraocular lens (IOL)?

For the above scenario,
- Each diopter shall be listed separately in the Annex 2 LOC, with the identifier for each diopter updated to the format of "<Common identifier><dioptre>".
- Please follow the below device model listing format for IOL when completing the Annex 2 LOC and upload the completed Annex 2 LOC in MEDICS:

For illustration purpose:

Name as per Device Label	Identifier	UDI-DI	Brief description of item
<Name per label>	<Common identifier><dioptre>	<dioptre-specific>	
ACRYSOF IQ IOL	AU00T0 (+6.00D)	Xxxx1234	
ACRYSOF IQ IOL	AU00T0 (+7.00D)	Xxxx5678	

For registered IOL models on SMDR, if the IOL listing format for Annex 2 LOC need to be amended in order to update the UDI information, you may 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). Please ensure that there is no change to any of the device information.

For further information on UDI submission, please refer to **Section 3.2.2 Registered medical devices (via Change notification)** of the Guidance on Medical Device Unique Device Identification System

12) What is the UDI requirement for devices that have already been loaned to healthcare facilities prior to UDI compliance date?

For existing loaner units (i.e., units that have already been loaned out to healthcare facilities in Singapore), that do not comply with EU or USA UDI requirement, these devices can continue to be used by the healthcare facilities to minimise disruption to our local healthcare services and facilities. As such, companies are advised to maintain documentary evidence of the date when these devices were loaned out. This information shall be submitted to the Authority when called for. Any new replacement of these loan units moving forward, that would potentially be in continued use after the respective compliance date of the device should be labelled with UDI.

As UDIs applied on the medical device labels for EU or the USA markets can be used in Singapore, from now on, when considering the import and supply of a new medical device unit for loan or supply in Singapore, companies are encouraged to supply UDI compliant units in preparation for the potential continued use of these devices after their respective UDI compliance dates of the devices.