

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 be subject to UDI labelling?

Medical devices authorised for supply via Special Access Routes (SAR) 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.