Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System

UDI consultation paper 2

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TGA Health Safety Regulation

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Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA has issued this consultation paper as part of the Government's reform program.

This consultation paper is the second consultation paper published by the TGA relating to the proposed Australian implementation of a Unique Device Identification (UDI) System for medical devices. It builds on the first consultation paper, Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia, and we recommend that respondents read the first consultation paper prior to this one.

Background

In January 2019 the TGA consulted on a proposal to introduce a Unique Device Identification (UDI) System for medical devices in Australia.

The consultation sought feedback on the proposal to introduce a UDI System in Australia, with the requirements aligned with the International Medical Device Regulators Forum (IMDRF) UDI Application Guide. The consultation also sought feedback on whether the TGA should be responsible for establishing and maintaining an Australian UDI database (AusUDID), and the potential scope of regulatory amendments required to establish the UDI System in Australia.

Forty–nine submissions were received from a broad range of stakeholders, including industry, industry associations, research institutions/universities, professional bodies, consumer organisations, and government agencies. Submissions are available on the TGA website.

There was a strong consensus across all stakeholder groups for the need to introduce the UDI System in Australia. The majority of respondents also considered that the TGA should be responsible for establishing and managing the AusUDID, and that it should be linked to the Australian Register of Therapeutic Goods (ARTG), as well as other databases.

Most submissions also supported the use of the IMDRF guidance as the basis for establishing the system, with several respondents also suggesting that there should be consistency with other international jurisdictions.

Stakeholders also provided feedback on a number of other issues raised in the consultation, including:

- The Australian UDI requirements, including UDI labelling requirements, should be aligned with the IMDRF guidance, and be consistent with major jurisdictions.
- Australia should accredit internationally recognised Issuing Agencies (organisations that issue unique device identifiers for individual products), rather than establishing a new Issuing Agency.
- There is the need for clarity on who is responsible for submitting the UDI data into the AusUDID, especially where more than one sponsor holds pre–market authorisation for the same device.

Some respondents proposed the exemption of low–risk devices (Class I non–sterile with no measuring function) from the UDI requirements suggesting that there is minimal safety benefit (but some regulatory burden) in including them in this system. A few other responses suggested excluding other categories of devices (e.g. devices sold through retail outlets, custom–made devices, or investigational devices).

There was strong support for a staged implementation of the UDI system and alignment with the European timeframes. The European implementation is broken down into three key components, and our understanding of the timeframes (current as at 22 May 2020)[1] are:

(1) The obligation for **UDI assignment** applies from the date of application (DoA) of the two new Regulations, i.e. 26 May 2021 for medical devices and 26 May 2022 for In Vitro diagnostic (IVD) medical devices.

(2a) The obligation for **placing UDIs on device labels for devices as per the Medical Device Regulations (MDR)**:

MDR devices	Implantables and Class III	Class IIa and IIb	Class I
Placing UDI carriers[2] on the labels of devices	26 May 2021	26 May 2023	26 May 2025
Direct marking of reusable devices	26 May 2023	26 May 2025	26 May 2027

(2b) The obligation for placing UDIs on device labels for devices as per the In–Vitro Diagnostic Regulations (IVDR):

IVDR devices	Class D	Class C and B	Class A
Placing UDI carriers on the labels of devices	26 May 2023	26 May 2025	26 May 2027

(3) The obligation for **submission of UDI data in the EUDAMED database** applies mandatorily as from 26 November 2022 for medical devices and 26 November 2023 for In Vitro diagnostic medical devices (noting that if Eudamed is not fully functional at the date of application then these dates move to 24 months from when Eudamed becomes fully functional).

Several submissions also considered that proposed transition timeframes should take into account the time required to develop and implement an Australian UDI database.

Some respondents raised concerns about possible cost and resource impacts on industry associated with populating and maintaining the AusUDID, especially cost implications for some manufacturers and sponsors supplying low margin products. However other respondents saw positive impacts and broad savings in terms of improved ability of health systems to store and access information about individual devices, simplified device tracking and communication, the

[1] European Union, https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en, accessed on 22 May 2020.
[2] The UDI carrier is the means to convey the UDI by using machine and human-readable forms (such as a barcode, 2D data matrix for example).

ability to link device information to individual patients through registers, and the improvement in access to information about post-market issues.

The potential implementation of a UDI System in Australia is a significant undertaking, involving a broad range of stakeholders, changes to business processes and IT systems, and with a significant level of complexity; particularly around the areas of labelling, provision of data, transition periods, and the management of legacy devices.

Whilst acknowledging the benefits of a globally aligned UDI System, there is the need to consider characteristics unique to the Australian environment. Some of those characteristics include potential linkages between the AusUDID and the ARTG, and the number of manufacturers who supply devices across Australia and other international markets, who may be required to be compliant with other jurisdictions' regulations (the European Union (EU) and United States Food and Drug Administration (U.S. FDA) requirements in particular).

As a result, the TGA will undertake a series of consultations to inform the planning and design of a potential Australian implementation. Each consultation will be designed to cover key topic areas that we will need to consider as we progress with our planning. The consultation process is anticipated to include consultation papers, stakeholder workshops and discussions, and we will engage broadly across the health system – from supply, procurement and distribution through to clinical use, patients and consumers, registries and the use of device information for post-market analysis and research.

These consultations will inform the policy decisions that will be made by the Australian Government.

The Unique Device Identification (UDI) System

The introduction of the UDI System is an important means of improving the identification and traceability of medical devices. UDI will be a key enabler for other reforms designed to improve the effectiveness of pre-market assessments of medical devices and management of post-market safety-related activities.

The UDI System is the framework for:

- UDI production
- UDI application on the label or on the device
- The UDI Database which contains core UDI-related device data

When the UDI System is fully implemented, the label of most devices will include a UDI in both a human and machine-readable form (such as a barcode). In addition, globally harmonised, core data about those devices will be publically available through a UDI database (UDID).

Throughout the broader health system, the UDI and data stored in UDIDs are intended to be the identifiers also used in the context of business and clinical transactions, including traceability of devices in the post market setting (e.g. purchase orders, invoices, inventory maintenance/ management, clinical notes etc.).[3]

Important

Any requirement relating to Unique Device Identifiers **will not override** the Essential Principles requirements in the Medical Device Regulations relating to the safety and performance characteristics of medical devices; in particular, the requirement to provide patient information and instructions for use.

Definitions

In order to aid with understanding the UDI System, we have provided below a number of definitions—all of the relevant UDI definitions are aligned with those published by the IMDRF.

Term	Description
Unique Device Identifier (UDI)	A series of numeric or alphanumeric characters that is created through internationally accepted coding standards. **Note: The word 'Unique' does not imply serialization of individual production units, the UDI is unique to a model of device.** The UDI is comprised of two elements—the Device Identifier and Production Identifier.
Device Identifier (UDI-DI)	A unique numeric or alphanumeric code specific to a **model** of medical device. The Device Identifier is used as the 'access key' to information stored in a UDI database, and is the data that allows the linking of device information across other systems.

[3] IMDRF, IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide, page 9

Term	Description
Production Identifier (UDI-PI)	A numeric or alphanumeric code that identifies the **unit of device production**. The Production Identifier may include the serial number, lot or batch number, software identification, date of manufacture or expiry date (or both of these dates). The Production Identifier will change from one production run to the next, and therefore it is considered the 'variable' element of the UDI, and it is not stored in the UDI database.
Unique Device Identification Database (UDID)	A data repository that contains identifying information and other elements associated with the UDI. The Device Identifier is the 'access key'.
Unique Device Identifier Carrier (UDI carrier)	The physical representation of the UDI on the device label, in both a machine-readable (Automatic Identification and Data Capture (AIDC)) and human-readable (Human Readable Interpretation (HRI)) form. Machine-readable carriers can include barcodes, 2D data matrix, and radio-frequency identification (RFID).
Label	Written, printed or graphical information appearing on the medical device itself, on the packaging of each unit, or on the packaging of multiple devices.
Basic UDI-DI	The Basic UDI-DI is the main access key for device-related information in the EUDAMED database and it is referenced in relevant documentation (e.g. certificates (including certificate of free sale), EU declaration of conformity, technical documentation and summary of safety and (clinical) performance). It is intended to identify and connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item. Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner. In addition, a UDI-DI shall be associated with one and only one Basic UDI-DI.

UDI production

Issuing Agencies

An Issuing Agency[4] is an organisation accredited by a regulatory authority to operate a system for the provision of UDIs according to specified global standards.

Global Standards One (GS1), the Health Industry Business Communications Council (HIBCC) and the International Council for Commonality in Blood Banking Automation (ICCBBA) are accredited Issuing Agencies in a number of jurisdictions, including in both the U.S. and EU.

UDI application on the label or device

This component of the UDI System covers all aspects of the UDI carrier and its placement on the device.

This includes: the assignment of the UDI to packaging levels; and rules for specific device types (such as implantables, reusable devices that are reprocessed between uses, IVD kits, software that is a medical device, and so on). It also includes defining exceptions, and potentially a process for managing exceptions on an ad-hoc basis.

We propose to consult separately on these specific requirements at a future date.

UDI database

AusUDID

As part of our first consultation in 2019, we sought feedback on whether the TGA should be responsible for establishing and maintaining an Australian UDI database (AusUDID).

The majority of respondents considered that the TGA should be responsible for establishing and managing the AusUDID, and that it should be linked to the Australian Register of Therapeutic Goods (ARTG), as well as other databases.

The TGA will seek further input into the operational aspects of the AusUDID as part of the ongoing consultation process.

Core data elements

Each regulatory authority has specific needs relating to data it may require to be provided as part of its UDI database. The EU and the U.S. FDA have made publicly available the core data elements that must be submitted to each of those jurisdiction's UDID (for the U.S. GUDID, and for the EU EUDAMED). We have listed below those data elements that the IMDRF has published as the minimum elements needed to identify a medical device through distribution and use.

[4] In the EU the term Issuing Entity is used, but the scope of responsibilities is very similar.

IMDRF core data elements

All of the core UDID data elements are mandatory, unless marked “optional”. “If applicable” means the information is mandatory (i.e. must be provided to the database) if it is included on the label.

Data elements and their definitions are listed below:

1. For every device packaging level—the following shall be provided in a related way (for entire packaging hierarchy):
   - ✓ UDI-DI (UDI type, e.g.:

     Global Standards One – Global Trade Item Number (GS1 GTIN),

     Health Industry Bar Code – Labeller Identifier Code (HIBC LIC),

     International Society of Blood Transfusion – 128 Processor Product Identification Code (ISBT PPIC)),
   - ✓ Quantity per package configuration: (e.g., each, 10 each, 5 shelf packs),
   - ✓ Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128;
2. The Unit of Use UDI-DI code;
3. Manufacturer’s name (if applicable);
4. Manufacturer’s address (if applicable);
5. Manufacturer's customer service contact information (country/region specific, could be multiple);(If applicable)
6. Authorised Representative's name (regional representatives responsible for the medical device) (country/region specific, could be multiple) (if required by the local/regional regulatory authority));
7. Authorised Representative's contact information (country specific, could be multiple);
8. Global Medical Device Nomenclature (GMDN) preferred code/term (valid at the time of the UDI submission);
9. Brand Name (if applicable);
10. Software as a Medical Device (SaMD) version;
11. Device model or version;
12. Reference and/or catalogue number (if applicable);
13. How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) or software version or software released date or ISBT-128 – check boxes (if applicable);
14. Clinical Size (including Volume, Length, Gauge, Diameter) (if applicable) (e.g. 8F catheter);
15. Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque;

16. Storage conditions, as labelled or in the Instructions for Use (IFU) (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
17. Handling conditions (if different than storage conditions), on the label or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;
18. Labelled as single use? (Yes/No);
19. Packaged sterile? (Yes/No);
20. Need for sterilization before use? (Yes/No) – if yes, then the method of sterilization should be indicated;
21. Restricted number of reuses (if applicable);
22. License and/or marketing authorization or registration number (if required by the relevant regulatory authority)
23. Uniform Resource Locator (URL) for additional information, e.g. electronic IFU (optional);
24. Critical warnings or contraindications (as labelled) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device
    a. [e.g.: Labelled as containing latex? (Yes/No),
    b. Labeled as containing Diethylhexyl phthalate (DEHP)? (Yes/No)
    c. Labeled as Magnetic Resonance Imaging (MRI) compatible? (Yes/No)].
25. Date of discontinuance (referring to devices no longer placed on the market).

Please note

As previously mentioned, different jurisdictions have different rules about the type of data that must be entered into their UDIDs.

A comparison of regulatory requirements for UDID data across the IMDRF Guidance, U.S. FDA and EU Regulations can be found in IMDRF/UDI WG/N53 FINAL:2019 – Use of UDI Data Elements across different IMDRF Jurisdictions 21 March 2019. It is included at Appendix 1.

Benefits of the UDI system

From our work as a member of the IMDRF UDI Working Group, and from consultations with key stakeholder groups, we anticipate the key benefits of implementing a UDI System in Australia will include:

- Better visibility for recalls, and reduced time and effort to locate and remove recalled devices
- Improved post-market surveillance due to the ability to unambiguously identify models of devices on a national, regional and global basis
- Ability for patients and consumers to more easily find information relating to devices, through the AusUDI Database (AusUDID), ARTG and other similar services and databases
- Improved ability to detect fraudulent devices through the supply chain
- Improved ability to automatically capture device information, reducing time and risk of data errors and inconsistencies
- Improved ability to manage inventory due to ability to automatically capture production information by scanning a label
- Reduction of the risk of device shortages
- Improved ability for data sharing across regulators and research organisations
- Improved ability for medical staff to accurately identify devices and device characteristics, leading to a reduction in medical errors.

We are seeking your feedback on these benefits later in this paper (see Question 1).

International activities and alignment

Globally, Unique Device Identification is either fully implemented, in the process of being implemented or is being planned for, in a number of jurisdictions including the U.S., the EU, Canada, and Japan.

As outlined in the first UDI consultation paper, the TGA proposes that the UDI System in Australia be based on internationally harmonised principles (as outlined by the IMDRF) and informed by the work done by the EU, and the U.S. FDA in particular (and potentially other regulatory authorities).[5]

As a result, the TGA will continue to explore the similarities and differences across these jurisdictions to inform the planning for an Australian implementation. Both the U.S. and the EU implementations are aligned with the principles of the IMDRF guidance.

The International Medical Device Regulators Forum (IMDRF)

The IMDRF identified at an early stage the lack of global definitions on what constitutes a UDI or UDI System. It noted that as a consequence, discrepancies between different national approaches do exist and will most likely increase. Common globally harmonized UDI System requirements would offer significant benefits to manufacturers, healthcare providers, patients, and regulatory authorities. In addition, a globally harmonized UDI System will limit the cost of regulatory compliance.

As a result, the IMDRF published UDI guidance: Unique Device Identification (UDI) of Medical Devices in December 2013. This document provided a high–level conceptual framework of the 'basic core concepts' of a UDI System. However, it was recognised that further IMDRF guidance was required to better facilitate consistent implementation of UDI Systems internationally, in order to achieve benefits globally.

Accordingly, the IMDRF UDI Working Group—which is comprised of IMDRF members and representatives from relevant international industry bodies—was established in December 2017 to develop the UDI Application Guide, which is intended to be used as a supplement to the 2013 guidance and provides the details and specifications necessary to ensure consistent development of UDI Systems in different jurisdictions. The Application Guide was published in March 2019.

Whilst recognising the benefits of a globally aligned system, the IMDRF guidance acknowledges the need for country-specific regulatory requirements.[6] It is also important to note that the IMDRF guidance does not cover all aspects of UDI implementation. Aspects not covered include implementation of high–volume Class I devices (such as contact lenses), linking of records where the UDI is changed (such as where there is a change in brand name due to a company merger), and the transition for legacy devices (that is, those devices already on the market prior to the implementation of the new requirements).

[5] TGA Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia, page 8 Proposed Implementation in Australia (2019)
[6] IMDRF, IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide, page 24 Section 10.1 (2019)

The United Kingdom (UK)

The UK is currently in a transition period following exit from the EU, during which time it will continue to follow the EU law, however the delay to the commencement of the new EU medical device and in vitro diagnostic regulations means they will not come into force during the transition period. In February 2020 *The Medicines and Medical Devices Bill 2019-21 (Bill 136*) was introduced into UK Parliament which provides a power to create a more comprehensive register of medical devices in the future, collecting appropriate levels of information about the medical devices available on the UK market, and allows for the details of the register to be provided in the regulations. The register would support the MHRA's critical market surveillance and oversight functions to ensure the ongoing safety of medical devices once they reach the market.[7]

The medical devices register is also discussed in more detail in the UK Department of Health and Social Care's policy paper *How a Medical Device Information System Might Work in Practice*. It includes discussion around a register of medical devices which is intended to allow for the capture of information about medical devices available on the UK market. In addition it references how the Bill will facilitate tracking medical devices by their unique identifier, to a patient's individual record, and how the capture and use of patient and procedure data on implanted medical devices will create over time a future system of clinical registries.[8]

A register of medical devices is also one of the recommendations in *First Do No Harm*, the recently released report of the Independent Medicines and Medical Devices Safety Review. The report makes a number of recommendations in relation to the traceability of medical devices, including recommending that a public-facing UDI database for UK devices based on GUDID should be scoped.[9]

The United States Food and Drug Administration (U.S. FDA)

The U.S. FDA introduced its UDI System in 2013 (the UDI Rule).

The UDI Rule requires the label and packaging of every medical device distributed in the U.S. to bear a Unique Device Identifier unless an exception or alternative applies. The Unique Device Identifier must be issued by a U.S. FDA-accredited Issuing Agency (IA) that operates a coding system conforming to international standards. The Unique Device Identifier must appear in two forms on the label and device packaging: easily (human) readable plain text, and automatic identification and data capture (AIDC) technology. The U.S. FDA requires that a Unique Device Identifier is permanently fixed on certain devices; a process called direct marking. In these cases, the Unique Device Identifier may be in readable plain text or in AIDC form.

Specific device-related information and key data elements must be submitted to the U.S. FDA's Global Unique Device Identification Database (GUDID), unless the device is subject to an exception or alternative. Currently, the GUDID contains information for a majority of medical devices manufactured in the U.S.. Most of the information submitted to the GUDID is available to the public through AccessGUDID, which allows consumers, healthcare professionals, industry and other stakeholders to search for medical device UDI information and download data from the database (for inclusion in other systems for example).

[7] Factsheet: medical devices information sharing and device register accessed on 6 July 2020
[8] Department of Health and Social Care How a medical device information system might work in practice Updated 18 June 2020 accessed 6 July 2020
[9] The Independent Medicines & Medical Devices Safety Review Report page 52, accessed on 15 July 2020

The European Union (EU)

Two EU Regulations of the European Parliament and Council on medical devices and in vitro diagnostic medical devices came into force on 25 May 2017. Both Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (the EU Regulations) include relevant provisions for the establishment of the UDI System in the EU including: definitions; implementation timeframes; the requirement that a Unique Device Identifier be placed on the device, labelling and packaging; and the requirement that certain information be entered into the EU's UDID, EUDAMED.

Specifically, the EU Regulations provide that: the UDIs will be provided by Issuing Entities (four have been accredited to date); the UDI-DI should be assigned by manufacturers for all devices.

The EU Regulations also require the inclusion of UDI information in certain types of documentation including: certificates issued to manufacturers by notified bodies; manufacturers' declarations of conformity; distribution records; clinical evidence; and implant cards.

Key high-level similarities and differences

Key high-level similarities across the IMDRF, EU and U.S. FDA include:

- Phased-in implementation based on level of risk (high risk devices first)
- The UDI carrier is not technology-specific (that is, it can be a one dimensional or linear barcode, two dimensional barcode such as a data matrix, or RFID)
- UDI on the device or packaging in both machine and human readable form
- UDIs provided by Issuing Agencies according to international standards
- Direct marking of reusable devices.

Key high-level differences across the IMDRF, EU and U.S. FDA include:

- The addition of new identifiers (for example the EU's Basic UDI)
- Differences in the data elements to be provided to the UDID
- Nomenclature standards
- The rules that trigger UDI changes
- Labelling requirements
- Exemptions.

References

We appreciate that as part of this paper we are requesting feedback in relation to the implementation of UDI in other countries, as well as work undertaken by an international body (the IMDRF). We have provided the core information in the body of this consultation paper, however we recommend you read some of the following documents prior to preparing your response.

TGA resources

The initial TGA consultation:

- Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Results and submissions from that consultation:

- Submissions received: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

IMDRF resources

The IMDRF has released a number of papers on UDI. The following two papers outline the base model for the UDI System:

- IMDRF/UDI WG/N7FINAL:2013 UDI guidance: Unique Device Identification (UDI) of medical devices
- IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide

This document provides a comparison of data elements across the EU, U.S. FDA and IMDRF definitions:

- IMDRF/UDI WG/N53 FINAL: 2019 Use of UDI Data Elements Across Different Jurisdictions (annexe)

Other documents are available on the IMDRF website:

- IMDRF website

U.S. FDA resources

This link is the home page for UDI:

- Unique Device Identification System (UDI System)

Benefits of a UDI System:

- Benefits of a UDI System

GUDID is the U.S. FDA UDI database. The data is publicly available and can be accessed here:

- AccessGUDID

EU resources

The EU has released a number of papers and guidance on the UDI implementation, including:

- MDCG 2018-1 v3 Guidance on BASIC UDI-DI and changes to UDI-DI
- Unique Device Identification (UDI) System – FAQs

The EU legislation is broken into two parts:

- Medical devices – REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
- In vitro diagnostic medical devices – REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

BASIC-UDI papers include:

- The approach to transition and legacy devices: MDCG 2019-5 Registration of legacy devices in EUDAMED
- Details for Issuing Agencies: MDCG 2019-1 MDCG guiding principles for issuing entities rules on Basic UDI-DI

Notification and details of EU nomenclature:

- The European Medical Device Nomenclature (EMDN)

Other documents, guidelines and information are available on the main website:

- Medical Devices – Sector
- Medical Devices – Sector - New Regulations

The European database on medical devices is EUDAMED.

UK resources

The UK has released some information relating to the Medicines and Medical Devices Bill:

- Medicines and Medical Devices Bill: Medical Devices Information Sharing and Device Register
- Fact Sheet: Medicines and Medical Devices Bill: Medical Devices Information System

Department of Health and Social Care Policy paper:

- How a medical device information system might work in practice

Other documents

- MedTech Europe UDI Systems in the US and in the EU – Mapping of the differences (January 2019)

This consultation

For the purposes of this second UDI consultation paper, the focus is to obtain your feedback on:

1. **What are the benefits of an Australian UDI System across the broader health system?**
2. **Should the first phase of an Australian implementation be limited to a small number of high-risk devices?**
3. **If the Australian implementation fully aligns with the IMDRF guidance what will the impact be?**
4. **What mechanisms should be considered for submitting the UDI data to the TGA?**
5. **What might the benefits be for implementing the EU Basic UDI-DI in Australia?**
6. **What are the benefits of the Global Medical Device Nomenclature (GMDN) and how is it being used?**

Additional background information on each of these six topic areas, as well as a place for responses, is included later in this document.

Future consultations will cover other, more detailed, aspects of UDI such as labelling, potential exceptions, the database and data elements, transition arrangements, legacy products.

How to submit your feedback

Your input and feedback will help inform the planning and design of an Australian UDI implementation. In addition to the scope of this consultation, we will welcome other feedback on UDI, as well as feedback on our consultation process.

You can submit your feedback using our **online survey tool** https://consultations.health.gov.au/, or via email by sending your response to devicereforms@tga.gov.au.

Please direct any queries via email to devicereforms@tga.gov.au.

This consultation closes at 5pm on 18/11/2020

Question 1 – What are the benefits of an Australian UDI System across the broader health system?

Introduction

The TGA would like to obtain further information on the benefits that an Australian implementation will provide across the broader health system—from supply and distribution, procurement and inventory management, to patient and clinical use, monitoring and recalls.

The U.S. FDA's implementation of UDI began in 2013/14, and it lists the following benefits on its website.[10]

When fully implemented, the Unique Device Identification System will offer a range of benefits to industry, FDA, consumers, health care providers and health care systems by:

- *Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.*
- *Reducing medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.*
- *Enhancing analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.*
- *Providing a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.*
- *Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.*

From our work as a member of the IMDRF Working Group, and from consultations with key stakeholder groups, we anticipate the key benefits will be along the lines of:

- Better visibility for recalls, and reduced time and effort to locate and remove recalled devices
- Improved post-market surveillance due to the ability to unambiguously identify models of devices on a national, regional and global basis
- Ability for patients and consumers to more easily find information relating to devices, through the AusUDID, ARTG and other similar services and databases
- Improved ability to detect fraudulent devices through the supply chain
- Improved ability to automatically capture device information, reducing time and risk of data errors and inconsistencies

[10] U.S FDA, Benefits of a UDI System | FDA, accessed on 1/3/2020

- Improved ability to manage inventory due to ability to automatically capture production information by scanning a label
- Reduction of the risk of device shortages
- Improved ability for data sharing across regulators and research organisations
- Improved ability for medical staff to accurately identify devices and device characteristics, leading to a reduction in medical errors.

We are seeking your input as to where you see the benefits accruing across the whole health system—for your organisation, your industry, and across the broader health system.

Your response

Please indicate below your feedback on how the UDI will facilitate traceability of medical devices and what are the anticipated benefits. You might like to comment on benefits in areas such as patient and consumer safety and confidence, improved ability to identify and remove recalled devices, efficiency savings, supply chain benefits, and so on.

Group	Anticipated benefits
Patients and consumers	
Medical professionals (e.g. nurses, doctors, surgeons, pharmacists)	
Clinical practices, operating theatres	
Hospitals (private and public)	
Manufacturers	
Sponsors	
Distributors/Supply chain	
Procurement	
Patient management and record systems	
Inventory management, warehousing and stock control	
Health care administrative systems (e.g. invoicing/billing)	
Registries (e.g. the Australian Breast Registry or the Australian Orthopaedic Association National Joint Replacement Registry)	
Health researchers	
Medical funders (private healthcare	
The Therapeutic Goods Administration (TGA)	
Other regulators	

Group	Anticipated benefits
Are there any key groups that will also benefit that are not listed above?	○ Yes ○ No
If you have answered 'Yes' please list those groups here	
Do you have any suggestions on how we might measure the benefits?	

Question 2 – Should the first phase of an Australian implementation be limited to a small number of high–risk devices?

Introduction

The IMDRF notes the huge diversity of medical devices, and considers a risk-based implementation approach essential for the successful development and implementation of a globally harmonised UDI System. General considerations to facilitate an effective UDI implementation include that requirements be phased in over a period of years based on risk classes, starting with the highest risk class, to reduce the burden of implementation.[11]

Both the U.S. FDA and the EU have approached their implementations in this way, and the TGA also plans a similar risk-based phased implementation, starting with the highest risk devices.

Early consultation has indicated that implementing a first phase that is limited to a small subset of high-risk devices will provide benefits for both manufacturers and across the broader health system (such as hospitals, clinical use and procurement) in allowing the early discovery and resolution of any issues prior to the next phase.

[11] IMDRF, IMDRF/UDI WG/N7FINAL:2013UDI guidance: Unique Device Identification (UDI) of medical devices, page 5 Section 2.6 Other considerations (2013)

Your response

We are interested in your thoughts on the potential of a limited first phase—please provide your responses below:

Question	Response
Do you think a limited first phase is a good idea?	○ Yes ○ No ○ Not sure
What do you see as the benefits of this approach?	
What might the disadvantages be?	
Do you have suggestions on the scope?	
Who should be involved?	☐ Manufacturers/sponsors ☐ Hospitals ☐ Distributors ☐ Procurement ☐ Consumers and patients ☐ Registries ☐ Researchers ☐ Other
If you have answered 'Other' who is missing from the list?	
How long should the first phase run?	○ 6 months ○ 12 months ○ > 12 months ○ Other
If you have answered 'Other' please add your comments here	
How will we measure success?	

Question	Response
What would industry participants need to do to prepare?	
What would be required from the TGA in order for industry participants to prepare?	
What lead-time might be required before the start of the first phase	○ 6 months ○ 12 months ○ > 12 months ○ Other
If you have answered 'Other' please suggest an alternative lead-time and any additional comments	
What oversight should be in place (i.e. across all participants)?	☐ Working Group ☐ Steering Committee ☐ Other
If you have answered 'Other' please provide any additional comments	
Would you be interested in being involved?	○ Yes ○ No
If so in what capacity?	
Do you have any other comments or feedback?	

Question 3 – If the Australian implementation fully aligns with the IMDRF guidance, what will the impact be?

Introduction

Whilst recognising the benefits of a globally aligned system, the IMDRF guidance also acknowledges the need for country-specific requirements. While the guiding principles for a UDI System are essentially the same across the IMDRF, EU and U.S. FDA, there are differences in the UDI implementations. The EU is still in early stages of operationalising the UDI, and as such may provide additional guidelines and operational clarity as the implementation progresses.

Notable high-level differences include:

- The addition of new identifiers (the EU's Basic UDI)—see Question 5
- Differences in the data elements to be provided to the UDID
- Nomenclature standards
- The rules that trigger UDI changes
- Labelling requirements.

Differences in data elements

There are differences in the data elements required to be submitted to the regulator across the IMDRF, the U.S. FDA and the EU. Direct comparison across all three is made more difficult where data requirements include the registration of the device model (such as in the EU/EUDAMED) as well as the UDI specific data. In Australia registration of the device (in the ARTG) is a separate process.

Notable differences include:

U.S. FDA	EU
Data elements additional to the IMDRF Guidance	
Kit Combination product	System/Procedure pack or kit
Labeler Data Universal Numbering System (DUNS) number	Authorised representative's Single Registration Number (SRN) Additional trade names
Previous DI number (for Mergers/Acquisitions) Issuing Agency (previous DI)	

U.S. FDA	EU
FDA product code FDA product code name FDA listing function FDA premarket submission number Device exempt from premarket subscription Device subject to direct marking but exempt Supplement number	Basic UDI-DI Issuing Entity (Basic UDI-DI) Risk class Measuring function
Package status Package discontinue date Package type	Package status
Data elements specified in the IMDRF guidance but not implemented	
SAMD version Maximum number of reuses Reprocessed single use device	SAMD version Method of sterilisation
URL for additional information	

Nomenclature standards

The European Commission (EC) announced in March 2019 that the European Medical Device Nomenclature (EMDN) will be the nomenclature of use for manufacturers registering their devices in the EUDAMED database.[12] The nomenclature selected for use by the EC is based on the Italian Classificazione Nazionale dei Dispositivi medici (CND) which is currently used by Italy, Greece and, Portugal.

The European nomenclature announcement reflects a divergence from the Global Medical Device Nomenclature (GMDN) which is embedded within the Australian Medical Device Regulations, as well as the medical device regulatory frameworks of several other comparable overseas regulators, including the U.S. FDA and Health Canada. The IMDRF guidance also includes the use of the Global Medical Device Nomenclature (GMDN).

IMDRF	U.S. FDA	EU
Global Medical Device Nomenclature	Global Medical Device Nomenclature	European Medical Device Nomenclature

[12] EU DG Health and Food Safety, The European Medical Device Nomenclature (EMDN) (Jan 2020)

The rules that trigger UDI-DI changes

At a high level the rules defining what triggers a UDI-DI change are guided by a set of principles. These include changes that:

- might change product safety and/or performance
- could lead to misidentification of the medical device and/or ambiguity in its traceability
- impact manufacturers or other organisations such as company mergers, acquisitions and divestitures.

In addition, the IMDRF notes that to date, those with experience implementing a UDI System into regulatory and healthcare systems have identified a significant challenge with the assignment of multiple UDI-DIs to products, which share essential design and manufacturing characteristics.[13]

The table below shows the differences in the key data elements that trigger the requirement for a new UDI-DI.

IMDRF	U.S. FDA	EU
Changes to any one of eight data elements:	**Changes to any one of twelve data elements:[14]**	**Changes to any one of ten data elements:[15]**
Brand name	Brand name	Name or trade name
Need for sterilization before use	Requires sterilisation prior to use	Need for sterilisation before use
Packaged sterile	Device packaged as sterile	Packaged sterile
Critical warnings or contraindications: e.g. containing latex or Bis (2–ethylhexyl) phthalate (DEHP)	Contains rubber latex or dry natural rubber	Critical warnings or contra-indications: e.g. containing latex or DEHP
Labelled as single use	For single use	Labelled as single use
Quantity of devices provided in a package	Device count	Quantity of devices provided in a package
Device version or model[16]	Version or model number	Device version or model
Clinical size (including volume, length, gauge, diameter)		

[13] IMDRF, IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide, Page 22 Section 8.4 UDI-DI triggers (2019)
[14] U.S. FDA GUDID Data Elements Reference Table - FDA
[15] European Commission MDCG 2018-1 v3 Guidance on BASIC UDI-DI and changes to UDI-DI
[16] In some jurisdictions, catalogue/REF number are included in the UDID and any change to the catalogue/REF number (when provided on the label) will trigger a new UDI-DI.

IMDRF	U.S. FDA	EU
	Primary DI Number	
	Kit status	
	Combination product status	
	MRI safety information	
	Issuing agency	
		Manner in which production is controlled if there is a change to the label
		Direct marked (if changes from yes to no)
		Change in CMR/endocrine disruptors
Specific changes relating to software		
		Whenever there is a modification that changes: (a) the original performance (b) the safety or the intended use of the software (c) interpretation of data
Other		
	Whenever changes to a device result in a new version or model[17]	Whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability
New packaging configurations	Whenever you create a new device package, you must assign a new device identifier to the new device package	

[17] U.S. FDA Code of Federal Regulations Title 21Food and Drugs Section 830.50 Changes that require use of a new device identifier

Labelling requirements, including direct marking and exemptions

As we are in the early stages of our planning, this paper seeks input into broader considerations. Future consultation will be dedicated to addressing differences in labelling requirements; there are a number of differences in the labelling requirements across the IMDRF, the U.S. FDA, and the EU.

For the purposes of this paper we have provided a few high-level examples below.

IMDRF	U.S. FDA	EU
Direct marking (where the UDI of reusable devices is on the device itself, and is required to be readable after each reprocessing).		
The UDI of these products shall be on the device and be readable after each reprocessing.	Devices only need to be direct marked where they are intended for different uses on or by different patients. Devices that are only intended to be cleaned or undergo low levels of disinfection between uses are not required to be directly marked.	The UDI of these products shall be on the device and be readable after each reprocessing.
Requests for labelling exemptions		
Regulators should include a robust and transparent mechanism for manufacturers to apply for exceptions in alternative placements of UDI-DI and UDI-PI.[18]	Allows labellers to submit a request for exception in relation to labelling requirements.	Does not envisage an adjudication process for ad-hoc exemptions. There are exemptions if particular circumstances are met.
Exemption from placing the UDI carrier on device packaging		
No exemption exists.	If the UDI carrier is readable or scannable through the devices packaging, the placing of the UDI carrier on the packaging is not required.	No exemption exists.

[18] IMDRF, IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide, page 10 Section 6 Guidance for a UDI System

Other differences

Some of the other differences include:

- Legal responsibility (manufacturer in IMDRF and EU, labeller in the US)
- Classification of devices
- Class I devices: (both DI and PI in the EU (DI is sufficient the US))
- Definitions of, and requirements for, kits, packs, configurable devices, systems etc.
- UDI for implantables.

Your response

We are interested in your views on Australia's alignment with the IMDRF as a foundational model. Please provide your feedback below:

Group	Anticipated benefits
What do you see as the benefits from a globally aligned system?	
What do you see as the disadvantages from a globally aligned system?	
If the IMDRF is taken as the foundational model, what is the potential impact for your organisation in complying with the additional requirements of multiple jurisdictions?	☐ Complexity in IT systems ☐ Complexity in business processes ☐ Requirement for additional staff ☐ Cost ☐ Need to purchase equipment ☐ Other
If you have answered 'Other' please provide any additional information	
What are the potential impacts on organisations that span multiple international markets and are therefore required to comply with multiple jurisdictions?	
Are there any data elements or other aspects of the U.S. FDA implementation (outside the IMDRF requirements) that we should consider?	○ Yes ○ No
If you have answered 'Yes' please provide additional information	
Are there any data elements or other aspects of the EU implementation (outside the IMDRF requirements) that we should consider?	○ Yes ○ No
If you have answered 'Yes' please provide additional information	

Group	Anticipated benefits
Are there any gaps in the IMDRF guidance you think we should be aware of?	○ Yes ○ No
If you have answered 'Yes' please provide additional information	
Would there be any requirement/do you plan to use UDIs unique to each country or market?	○ Yes ○ No ○ Not sure
If you have answered 'Yes' please provide further detail on what would drive that requirement	
How many markets do you sell in (or plan to sell in)?	○ 0 ○ 1 ○ 2-5 ○ > 5 ○ Prefer not to answer
How many of those markets either have already implemented, are in the process of implementing or are planning to implement a UDI System?	○ 0 ○ 1 ○ 2-5 ○ > 5 ○ Prefer not to answer
Please list those countries	
Please provide any other feedback	

Question 4 – What mechanisms should be considered for submitting the UDI data to the TGA?

Introduction

The timely provision of current and correct data into a UDI database will be critical to achieving the full benefits of a UDI System. When considering how data is provided to the AusUDID and the maintenance over the device's lifetime, a number of components need to be taken into account, including:

- Who is best-placed to provide the data?
- What technical mechanisms will need to be in place for providing the data?
- How much can be automated (machine to machine for example?)
- How might that data be validated?
- Will the complexity and maturity of IT systems vary, and does that mean multiple methods might be required?
- How might we ensure the validity of the data, and avoid its degradation over time?
- The current responsibilities and role of the sponsor
- Are there any complexities that we will need to take into account? (for example for devices that are rebranded, repackaged or relabelled?)

Your response

As we continue with our planning activities, we will need to explore many of these aspects in more detail. However, for the purposes of this consultation paper we would like to focus specifically at the broader, high level, and would appreciate your response to the following:

Question	Your response
Who is best placed to provide the data to the AusUDID?	☐ Sponsor ☐ Manufacturer ☐ Brand owner ☐ Other
Please provide any comments to support your response	
What mechanisms might need to be in place to enable the provision of data?	☐ Machine to machine bulk upload ☐ Web interface ☐ Other
If you have answered 'Other' please provide more details	
Do you foresee any complexities we might need to take into account where more than one sponsor holds pre-market authorisation for the same device?	○ Yes ○ No ○ Not sure
If you have answered 'Yes' please provide more details	
Are there any interfaces (such as Health Level 7 Structured Product Labeling (HL7 SPL) that you use now or plan to use in the future that the TGA should consider or be aware of?	○ Yes ○ No ○ Not sure
If you have answered 'Yes' please provide more details	
Do you see a requirement for the ability to download data you have submitted to the AusUDID for validation or other purposes?	○ Yes ○ No ○ Not sure

Question	Your response
If you have answered 'Yes' please provide additional details	
Are there additional aspects the TGA should consider? For example are there other data stores or sources the TGA should take into consideration as potential means of providing data into the AusUDID?	

Question 5 – What might the benefits be for implementing the EU Basic UDI-DI in Australia?

Introduction

As part of our consideration of an Australian UDI System, the TGA is exploring aspects of other implementations that may have benefits in Australia. One of these is the EU's introduction of an identifier known as the Basic UDI Device Identifier (Basic UDI-DI).

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.

In addition, a UDI-DI shall be associated with one and only one Basic UDI-DI.

The EU has released guidance on the BASIC UDI-DI: MDCG 2018-1 v3 Guidance on BASIC UDI-DI and changes to UDI-DI, and it is included in this Frequently Asked Questions (FAQ) publication: Unique Device Identification (UDI) System – FAQs.

The European database on medical devices is EUDAMED. The current version of EUDAMED is being updated to align with the new regulations for medical devices. The new EUDAMED will be multipurpose, in that it will function as a registration system, a collaborative system, a notification system, a dissemination system (open to the public), and will be interoperable. The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available by May 2021.[19]

[19] https://ec.europa.eu/health/md_eudamed/overview_en accessed on 24 July 2020

Your response

Please provide your responses below:

Question	Your response
Are there any potential benefits for Australia in introducing the Basic UDI-DI?	○ Yes ○ No ○ Not sure
If you have answered 'Yes' what might these potential benefits be? How might we quantify or measure those benefits?	
If you have answered 'No' please provide further information	
If Australia was to implement the Basic UDI-DI what might the potential impacts be on organisations that span multiple international markets (including the EU), and therefore have to comply with multiple jurisdictions requirements?	
Are there any potential negative impacts in Australia introducing the Basic UDI-DI?	○ Yes ○ No ○ Not sure
If you have answered 'Yes' please provide further information	
Are there other aspects of the Basic UDI-DI you believe we should explore further or consider?	

Question 6 – What are the benefits of the Global Medical Device Nomenclature (GMDN), and how is it currently being used?

Introduction

The Global Medical Device Nomenclature (GMDN) is a list of generic names used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety. The GMDN Agency maintains these Terms, and they form a living data set that is constantly evolving to meet the needs of manufacturers and regulators. Currently there are approximately 24,000 Terms in the dataset.[20]

Each GMDN Term comprise three elements—the Term Name, Code and Definition. The five-digit numeric GMDN Code is used as a cross-reference to a precisely defined Term Name and Definition. For example:

- GMDN Code: 47569
- GMDN Term Name: Scalpel, single-use
- GMDN Definition: A hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

As one of the attributes used in defining whether a device is of the 'same kind' as another medical device (and therefore allowing it to be grouped under a single Australian Register of Therapeutic Goods (ARTG)) the GMDN is a key element of the Australian medical devices regulatory framework.

Within the GMDN data set, Terms are grouped based on similar characteristics using Collective Terms, which are used to provide better navigation and the ability to group and compare devices with common features.

Utilising these similarities, a subset of Collective Terms from the GMDN dataset has been selected for use in Australia for the purpose of identifying Class 1, 2 or 3 in vitro diagnostics (IVDs), or class 4 immunohaematology reagents (IHRs) of 'the same kind' within the ARTG.[21] Other regulators, such as the U.S. FDA, have also implemented the GMDN as part of their regulatory systems (including UDI Systems), and it is one of the IMDRF UDI core data elements.

Further information is available on the GMDN Agency and TGA websites.

We are interested in obtaining more information about how the GMDN codes, terms and definitions are used more broadly in other health systems (such as procurement, clinical and registry systems), and the benefits that accrue from that use.

[20] GMDN Agency website, https://www.gmdnagency.org/Services/GMDN accessed on 10 July 2020
[21] TGA website, https://www.tga.gov.au/overview-regulatory-framework-vitro-diagnostic-medical-devices and https://www.tga.gov.au/publication/use-gmdn-codes-ivd-medical-devices-australia accessed on 1 July 2020

Your response

Please provide your responses below:

Question	Your response
Are you currently using GMDN Terms?	○ Yes ○ No ○ Not sure
If yes, please indicate how you are using them:	☐ Identify issues related to devices or device use ☐ Include in patient records for improved post-operative follow-up ☐ Identify products to use in a clinical setting ☐ Identify the most effective devices ☐ Manage inventory ☐ Identify suppliers (for example compare volumes of products supplied by each supplier) ☐ Identify supply changes or bottlenecks ☐ To meet regulatory requirements ☐ As mandatory information for procurement ☐ Identify devices that have specific training needs ☐ Identify devices that require servicing to help establish maintenance cycles ☐ Identify devices that require utilities (such as electricity or compressed air for example) ☐ Identify and manage hazardous materials and waste ☐ For research or academic study ☐ Other

Question	Your response
If you have checked any of the above boxes can you please provide more information and/or examples on how you are using the GMDN Terms?	
If you are using the GMDN, please provide more information on the benefits:	☐ Benefits for patient safety in identifying best devices for use and identifying device issues ☐ Improved inventory management ☐ Improved supply management ☐ Improved device management ☐ Reduced wastage ☐ Facilitate analysis through the ability to identify and group devices ☐ Other
If you have answered 'Other' can you please provide more details?	
If you are using the GMDN, are there any particular issues or challenges?	
If you are not using the GMDN, is there a specific reason?	☐ IT systems require modification ☐ Alternative coding or reference systems used ☐ Other (please provide further information below)
If you use an alternative or additional coding or reference system, which one(s) do you use and why?	
Please provide any other comments here	

Appendix 1 – Comparison of data elements

This comparison of data elements was published (as the Annexe) in IMDRF/UDI WG/N53 FINAL:2019 – Use of UDI Data Elements across different IMDRF Jurisdictions 21 March 2019.

Key:

R	The data element is **REQUIRED** for submissions to that UDI database.
C	The data element is **CONDITIONALLY REQUIRED** for submissions to that UDI database. See the individual tab for that UDI database for a conditions under which this element must be provided.
O	The data element is **OPTIONAL** for submissions to that UDI database.
A	The data element is **AUTO-POPULATED** in the UDI database based on another attribute which has been provided.
––	The data element is not recognized by that UDI database and should not be included in submissions.
	A red highlighted cell indicates that changes to this data element are not allowed; a **new Device Identifier is required**.

Jurisdiction	IMDRF			European Union		United States	
Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/medical-devices/new-regulations/guidance_en		http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
Date revised				18-Feb-2019		18-Feb-2019	
	Data element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Device Identification & Description	––	––	––	Basic UDI-DI	R	––	––
	1	UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC)	R	UDI-DI	R	Primary DI Number	R
				Issuing Entity (UDI-DI)	R	Issuing Agency	R
				Issuing Entity (Basic UDI-DI)	R	––	––
	––	––	––	Single Registration Number	R	––	––
	9	Brand Name	C	Name or Trade name (name of product)	R	Brand Name	R
	11	Device model or version	R	Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity	R	Version or Model	R
	12	Reference and/or catalogue number	C	Reference, article or catalogue number	R	Catalog Number	O
	15	Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque	O	Additional product Description	O	Device Description	O
	––	––	––	Direct Marking (DM) DI	R	DM DI Different from Primary DI	C
	––	––	––	––	––	DM DI Number	C
	––	––	––	Issuing Entity (Secondary DI)	C	Issuing Agency (Secondary DI)	O
	1	Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128	C	Secondary UDI-DI	C	Secondary UDI Number	O
	––	––	––	––	––	Issuing Agency (Previous DI)	O
	––	––	––	––	––	Previous DI Number	O
	2	Unit of Use UDI-DI	R	Unit of Use (UOU) UDI-DI	C	Unit of Use DI Number	C
	––	––	––	Quantity of devices	R	Device Count	R
	––	––	––	Additional Trade Names	C	––	––

Jurisdiction	IMDRF			European Union		United States	
Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/medical-devices/new-regulations/guidance_en		http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
Date revised				18-Feb-2019		18-Feb-2019	
	Data element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Contact Information	––	––	––	––	––	Labeler DUNS Number	R
	3	Manufacturer's name	C	Name of Manufacturer	A	Company Name	A
	4	Manufacturer's address	C	Address of Manufacturer	A	Company Physical Address	A
	5	Manufacturer's customer service contact information (country/ region specific, could be multiple)	C	––		––	––
				Authorized representative's Single Registration Number	C		
	6	Authorized Representative's name (regional representatives responsible for the medical device) (country/region specific, could be multiple) (if required by the local/ regional regulatory authority) (see GHTF/SG1/N55:2009)	R	Authorized representative's name	A	––	––
	7	Authorized Representative's contact information (country specific, could be multiple)	R	Authorized representative's address	A	––	––
	23	URL for additional information, e.g. electronic IFU	O	URL for additional information, e.g. electronic IFU	O	––	––
	––	––	––	Name, address and contact details of the legal or natural person	C	––	––
	––	––	––	––	––	Customer Contact Phone	C
	––	––	––	––	––	Customer Contact Email	C

Jurisdiction	IMDRF			European Union		United States	
Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/medical-devices/new-regulations/guidance_en		http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
Date revised				18-Feb-2019		18-Feb-2019	
	Data element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Device Packaging & Status	––	––	––	Status of the device	R	––	––
	––	––	––	––	––	DI Record Publish Date	R
	25	Date of discontinuance (referring to devices no longer placed on the market)	R	––	––	Commercial Distribution End Date	O
	––	––	––	––	––	Commercial Distribution Status	A
	––	––	––	––	––	Device Subject to Direct Marking (DM), but Exempt	C
	1	Quantity per package configuration: (e.g. each, 10 each, 5 shelf packs)	R	––	––	––	––
	––	––	––	Quantity per package	C	Quantity Per Package	C
	––	––	––	––	––	Package Type	O
	––	––	––	––	––	Package DI Number	C
	––	––	––	Package Status	C	Package Status	A
	––	––	––	––	––	Package Discontinue Date	C
	––	––	––	Contains DI Package	C	Contains DI Package	C

Jurisdiction	IMDRF			European Union		United States	
Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/medical-devices/new-regulations/guidance_en		http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
Date revised				18-Feb-2019		18-Feb-2019	
	Data element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Device Characteristics	13	How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) or software version or software released date or ISBT-128	C	Manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number, software identification,) – Type of UDI-PI	R	Lot or Batch Number (Production Identifier(s) in UDI)	R
						Manufacturing Date (Production Identifier(s) in UDI)	R
						Serial Number (Production Identifier(s) in UDI)	R
						Expiration Date (Production Identifier(s) in UDI)	R
						Donation Identification Number (Production Identifier(s) in UDI)	R
	14	Clinical Size (including Volume, Length, Gauge, Diameter)	C	Clinical Size	C	Clinical Size Type	C
						Clinical Size Value	C
						Clinical Size Unit of Measure	C
						Clinical Size Type Text	C
	16	Storage conditions, as labelled or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;	C	Storage & Handling	C	Storage and Handling Type	O
	17	Handling conditions (if different than storage conditions), on the label or in the IFU (if applicable) – to include temperature range, needs	C			Low Value (Storage and Handling)	C
						High Value (Storage and Handling)	C
						Unit of Measure (Storage and Handling)	C

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		to be refrigerated, relative humidity range,				Special Storage Conditions	C
	18	Labeled as single use? (Yes/No)	R	Labeled as single use	R	For single-use	R
	--	--	--	Maximum number of reuses	C	--	--
	--	--	--	Reprocessed single-use device	R	--	--
	19	Packaged sterile? (Yes/No)	R	Device labeled sterile	R	Device Packaged as Sterile	R
	20	Need for sterilization before use? (Yes/No) – if yes, then the method of sterilization should be indicated	R	Need for sterilization before use? (Yes/No)	R	Requires Sterilization Prior to Use	R
	20	Method of sterilization	C	--	--	Sterilization Method	C
	24	Critical warnings or contraindications (as labeled) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device	R	Critical warnings or contraindications	C	--	--
	24a	Labeled as containing latex? (Yes/No)	R	Containing Latex	R	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 087.437)	R
	--	--	--	--	--	Device labeled as "Not made with natural rubber latex"	O
	24c	Labeled as MRI compatible? (Yes/No)	R	--	--	What MRI safety information does the labeling contain?	R
	--	--	--	CMR	C	--	--
	--	--	--	Endocrine disruptor	C	--	--

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	24b	Labeled as containing DEHP? (Yes/No)	R	--	--	--	--
	21	Restricted number of reuses	C	--	--	--	--
	10	SAMD version	R	--	--	--	--
	--	--	--	Specification as to whether the intended purpose of the device is other than a medical purpose	R	--	--
	--	--	--	Presence of Human tissues and Cells	R	Human Cell, Tissue or Cellular or Tissue Based Product (HCT/P)	O
				Presence of Animal tissues and Cells	R		
	--	--	--	System/Procedure pack or Kit	R	Kit	O
	--	--	--	Information on substances; Substance that may be a medicinal product; Substance that if used separately may be considered to be a medicinal product derived from human blood or human plasma;	C	Combination Product	O
	--	--	--	--	--	Prescription Use (Rx)	O
	--	--	--	--	--	Over the Counter (OTC)	O

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	Data element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Licensing, Classification & Nomenclature	22	License and/or marketing authorization or registration number (if required by the relevant regulatory authority)	R	--	--	--	--
	8	Global Medical Device Nomenclature (GMDN) preferred code/term (valid at the time of UDI submission)	R	--	--	GMDN Code	R
	--	--	--	--	--	GMDN Name	A
	--	--	--	--	--	GMDN Definition	A
	--	--	--	Medical Device Nomenclature Code	R	--	--
				Medical Device Nomenclature Term	A		
	--	--	--	Medical Device Nomenclature Description	A	--	--
	--	--	--	--	--	FDA Product Code	C
	--	--	--	--	--	FDA Product Code Name	A
	--	--	--	Risk Class	R	--	--
	--	--	--	--	--	Device Exempt from Premarket Submission	C
	--	--	--	--	--	FDA Premarket Submission Number	C
	--	--	--	--	--	Supplement Number	C
	--	--	--	--	--	FDA Listing Number	C
				Measuring function	R		
				Reusable surgical instrument	R		

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				Active device	R		
				Intended to administer/remove a medical product	R		
	--	--	--	Implantable	R	--	--
	--	--	--	Intended for self-testing	R	--	--
	--	--	--	Intended for near-patient testing	R	--	--
	--	--	--	Companion diagnostic	R	--	--

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	September 2020

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Reference/Publication #