	Question	Comment/rationale
1	Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?	Overall, we agree with TGA's proposal to establish a UDI system in Australia based on IMDRF principles because we believe the introduction of UDI for devices will be a benefit/beneficial for all healthcare stakeholders, including consumers, healthcare professionals, scientists, researchers, the medical device industry and regulators. For products that require UDI per Australian requirements, it is essential that the UDI system is compatible with all global UDI systems, because products from the same company can be sold in different market (AUS, EU, US…). The UDI system offers numerous benefits to all stakeholders in healthcare systems. The UDI is being developed to facilitate adequate identification and traceability of devices throughout the supply chain, this includes distribution and use on patients. When fully implemented, the system will allow more accurate reporting and analysis of vigilance incidents, fight against counterfeiting, better control of the supply chain and stock management etc. Implementation of the UDI system requires engagement of all actors in the distribution chain. The benefits and purpose of the UDI system will only be realised, if healthcare stakeholders integrate and obtain value in their systems from UDIs and data in the related UDI database. The benefits of the UDI system can only be achieved if the regulators purse a harmonised approach. Therefore, consistent approach to implementation at the global level is going to determine the success in achieving a single, globally harmonised positive identification of medical devices. It is recommended that regulatory authorities duly consider the impact of their agreements on global harmonisation. Regulatory authorities have a shared responsibility with the accredited issuing agencies/entities, manufacturers, and standards development organisations to strengthen the UDI as a global standard by committing to the ongoing harmonisation of the UDI systems. This includes rules for placement of UDI, definition and format UDID data elements, development of common vocabularies and exchange standards used in UDI implementation. There are some concerns with certain details of the proposal: Basic UDI-DI: Instead of adopting the Basic UDI-DI (BUDI) in Australia, TGA should investigate and consider utilizing the ARTG identification as a mechanism for grouping similar products by a single manufacturer. The European Union (EU) lacks a common approval/registration numbering (identification) system, like the ARTG in Australia. This lack of common approval/registration number is driving the development of the BUDI for use in the EU and the Eudamed database. It is worth noting that while the BUDI as described in EU document MDCG 2018-1, is intended to identify the devices (group) covered by that Basic UDI-DI in a unique manner, the BUDI will only be unique to the EU, not globally, as it will incorporate EU device risk classification and the economic operator Single Registration Number (SRN). Adoption of the EU BUDI by TGA could result in confounding data in the AusUDID. While we appreciate the staged implementation approach based on device risk classification, the proposed timeframe (implementation deadlines/ dates) should take into account the information technology (IT) readiness of the AusUDID.

	Question	Comment/rationale
		Based on our experience with the US GUDID and pilot database programs in other markets, two years from final IT technical specifications (or technical specifications of sufficient quality) prior to the first deadline for database upload is necessary to develop and validate these electronic systems, this time is also needed to give all stakeholders involved an opportunity to learn and improve the system and processes. Provisions should be made for sufficient time to deplete inventory of non-UDI-compliant medical devices in distribution channels and allowances for continued use of reusable medical devices (not direct marked) currently in use.
2	The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring	In general, we support the efforts to ensure international alignment, TGA's question on whether UDI requirements should apply to certain Class I devices (other than sterile or with measuring function) is a valid one. A procedure for applying for exemptions or alternatives from UDI requirements, should be included in the final regulation. We recommend TGA to follow the IMDRF final guidance "UDI Guidance. Unique Device Identification (UDI) of Medical Devices (IMDRF/UDI WG/N7FINAL:2013)" and specify exemptions for certain devices in alignment with other existing regulations. For example, US 21 CFR 801.30 defines general exceptions for certain device categories that should be considered as exemptions in Australia, as well. In addition to an exemption for custom devices, please consider exemptions for: - Devices for clinical investigation - Use of UPC Code for devices in the retail setting - Non-implant individual single-use devices, of a single version or model packaged together and not intended to be distributed/sold individually (UDI on carton/outer package only) - Individual devices in a convenience kit or tray to be used in a single procedure (on a single patient), when the kit or tray packaging contains the UDI. - Class I non-sterile, products classified as non-devices per Australian requirements regardless of device classification in another jurisdiction. Class I non-sterile devices already have adequate labelling and identification commensurate with their level of risk (low) therefore should not require UDI. For example, considering spectacle lenses, these should be in the scope of the UDI requirements. This is consistent with the decision by the US FDA whereby they accepted optical industry arguments that trying to apply UDI would be unworkable. The FDA have therefore deemed prescription lens manufacturers, optical laboratories and eye care professionals are not labellers and are therefore not responsible for meeting UDI requirements. This effectively makes prescription spectacle lenses exempt from UDI. Considering that spectacle lenses (Class 1, no measuring function) are a low risk device, these products should not be under the scope of UDI requirements.

	Question	Comment/rationale
	function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?	- clearly express that the UDI needs to be on the packaging in any case but on the devices itself only in case of reusable products that need a reprocessing between two patients. - Further exemptions shall be provided for those cases where a direct marking impose the safety and effectiveness of the device or where it is technically not feasible to apply a readable UDI to the product. In this context it should be mentioned that technically feasible does not mean a design change just to apply a UDI.
3	It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?	Accreditation should ensure that the Issuing Agency will employ unique device identifiers that will adequately identify a device through its distribution and use in conformance with recognized international standards, such as ISO/IEC 15459-2, ISO/IEC 1549-4, ISO/IEC 1549-6 and ISO/IEC 646. We appreciate that TGA has referenced and is considering the three leading global Issuing Agencies of GS1, HIBCC and ICCBBA. The requirements should align with the ones in the draft IMDRF UDI Application guide (UDI WG(PD1)/N48, section 10.3): "(…) Conditions for designation of agencies/entities shall include that: – the agency/entity operates a system for the issuance of UDIs which conforms to the relevant international standards; – the agency/entity undertakes to operate its system for the assignment of UDIs for a period which should be no less than 3 years; – the agency/entity undertakes to make available to the relevant national authorities, upon request, any information concerning its system for the assignment of UDIs; Jurisdictions may opt for setting additional agencies/entities' responsibilities. In this case, those jurisdictions might consider establishing agreements with the issuing agencies/entities, upon their designation, under which these entities would be required: – to make available to regulators their tools that validate that the UDI-DI is meeting the issuing agency/entity's specification for a valid UDI-DI – to work in cooperation with regulators and manufacturers to avoid problems listed below and correct, if needed:

	Question	Comment/rationale
		1. deficiencies in UDI creation (e.g. tests for validity, uniqueness, check digit) 2. deficiencies in UDI placement and use (e.g. print quality, scannability, types of UDI carriers, surface and substrate impact) – to have procedures in place to take necessary follow-up actions up to and including revoking the use of their system for the issuance of UDIs, whenever they become aware that manufacturers or labellers do not meet their requirements related to UDI – to maintain a maximum level of stability regarding their requirements for data formats on UDI-DI and UDI-PI and their encoding in an AIDC – to involve regulators when planning additions or changes to their specifications, particularly when those specifications have an impact on the construct of a UDI and the way it is captured – to have the relevant global standards implemented consistently across their regional members – to continuously supply to regulators educational materials, application forms, and access to other materials the issuing agency/entity provides for its members It is recommended that regulatory authorities duly consider the impact of their agreements on global harmonization."
4	Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the AusUDID - what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market	We recommend the manufacturer be permitted to upload data in an automated fashion machine-to-machine. This approach is consistent with approaches seen in other mature regulatory markets. For example, in the US and EU a foreign manufacturer is able to enter required data into the database. Regarding further amendments to clarify responsibilities between the sponsor and manufacture, we recommend language that allows flexibility that would enable parties to define this relationship and clarify obligations by contract or other legally binding agreement. This is consistent with how other aspects of regulation often are handled between parties. Some companies also request the possibility to have the data fed by a third-party data provider. Manufacturers should remain responsible for their data even it is submitted by a third party.

	Question	Comment/rationale
	authorisation for the device?	
5	It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?	Establishment and management of a database program is a large undertaking for any entity. The AusUDID should be established and managed by TGA due to the need to manage commercially sensitive information, for that reason data security must be a priority. Options for both manual and bulk electronic data entry are essential to cover both small and large medical device manufacturers.
6	What core data elements and other relevant information should be entered into AusUDID?	Core data elements should be limited to those that are essential to meet the regulatory goals of TGA, and aligned with those listed in the IMDRF final guidance "UDI Guidance. Unique Device Identification (UDI) of Medical Devices (IMDRF/UDI WG/N7FINAL:2013)"in chapter 9.2): "9.2 The core UDID data elements All the core UDID data elements are mandatory, unless marked "optional". "If applicable" means the information is mandatory to be in the UDID if it is on the label. Data elements and their definitions for the UDID 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. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC),

	Question	Comment/rationale
		- 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 (see section 7.6) 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. 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); 7. Authorized 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. SaMD version; 11. Device model or version; (see section 10.6) 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 labeled or in the 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. Labeled 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. URL for additional information, e.g. electronic IFU (optional); 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 a. [e.g.: Labeled as containing latex? (Yes/No), b. Labeled as containing DEHP? (Yes/No) c. Labeled as MRI compatible? (Yes/No).] 25. Date of discontinuance (referring to devices no longer placed on the market)."

	Question	Comment/rationale
		This list may be supplemented by a limited number of local data elements (i.e. local device registration number) in order to link the UDI data to other existing databases. However, we urge TGA to avoid data elements that are unique to, or implemented by other jurisdictions to compensate for a lack of systemic categorization. Inclusion of additional data elements in the AusUDID may have a confounding effect of change to a UDI in one jurisdiction may necessitate a change to a UDI in another. If a local regulatory requirement triggers a different UDI-DI, it may have an unintentional effect on the global supply chain. To avoid this, manufacturers may create a UDI-DIs specific to one jurisdiction so they could prevent changing their international registrations and labels. If more than one UDI-DI for a product exist then the globally harmonised positive identification of medical devices is no longer possible for the authorities and for the public which makes collecting the information on the same device difficult. Rules for what changes would trigger a change to the UDI-DI must be developed, again we encourage TGA to consider the IMDRF guidance in this area and minimize the number of types of changes that would require a change to the UDI-DI.
7	How should we link the ARTG and the UDI database? What information should they share?	Recommendation for the TGA to consider whether the ARTG and UDI systems can be linked somehow so that the users do not have to enter the data twice and to ensure integrity of data. This will avoid duplicate information, unnecessary redundancies and potential inconsistencies between the two data bases. Recommendation to include the ARTG reference number as a mandatory data field when populating the UDID. This way ARTG can serve as key data element within AusUDID, to be used instead of Basic UDI-DI.
8	Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?	We fully support the staged implementation approach based on device risk classification, the proposed timeframe (dates) should take into account the information technology (IT) readiness of the AusUDID. Based on industry experience with the US GUDID and pilot database programs in other markets, two years from final IT technical specifications (or technical specifications of sufficient quality) prior to the first deadline for database upload is necessary to develop and validate these electronic systems, this time is also needed to give all stakeholders involved an opportunity to learn and improve the system and processes. Once the database is in place we believe that the European UDI labelling/marking timeline could also work (1-3-5 years after depending on the risk class). Due to the technical challenges in terms of direct marking (reusable devices), the timelines per risk class should be 2 years after the compliance date. Aligning the transitional timeframe for UDI labelling/marking compliance with the EU transitional times may not be appropriate due to the different timelines for the Eudamed and the AusUDID. For database milestones, it will only be

	Question	Comment/rationale
		appropriate to align with the EU if the AusUDID is available and validated on the same timeline as the Eudamed UDID. Based on experience in other jurisdictions, we would encourage TGA to conduct a pilot database program prior to full implementation, so any potential issues can be avoided.
9	What impacts (including unintended impacts) do you anticipate for you and other stakeholders?	Industry appreciates TGA posing this question and is committed to working with TGA to implement UDI. In order to implement the TGA UDI system, manufacturers will need to extend their internal UDI IT System and update UDI QMS processes. These updates will require time and financial resources. For that reason, we encourage the TGA to continue its transparent approach to development of a UDI system, with clear and reasonable transition timelines. Some products may be considered medical devices in Australia while they might not have the same regulatory status in other jurisdictions, this may cause additional effort in assigning a UDI and maintaining the relevant information. In addition, establishment of a UDI system implies major label update and the related manufacturing and printing delays associated with such change across the majority of products within portfolio. Additional cost (resource) to the business for issuance and maintenance of UDIs in a market that is already cost driven, therefore potentially increasing the cost of healthcare within Australia. Impact should also be considered on local manufacturers, especially small and medium enterprises that may not have been exposed to UDI requirements in other jurisdictions because they are present only on the local or national market. There is a learning curve to UDI implementation in any jurisdiction, so we recommend that this consideration is taken into account.
10	Are there any other issues and questions we need to consider when implementing this change? (If you are referring to any specific part of the document, please include a page number and section of the document in the 'Comment/rationale section')	Based on the feedback form several companies, we would like to urge TGA to consider having an additional data element to utilize the existing ATRG and eliminate the concept of Basic UDI-DI from UDI requirements. We believe that TGA's use of Basic UDI-DI derives from the concept introduced in the EU planned for implementation in 2020. However, it should be noted that while the concept has been introduced in both IVDR and MDR, it is not yet implemented and there remains significant confusion regarding the Basic UDI-DI concept. The purpose and function of the EU database differs materially from AusUDID. In contrast to the AusUDID, EUDAMED is not limited to UDI data and also includes pre-market and post-market data (e.g., clinical performance studies, vigilance). Because EUDAMED hosts both pre-market and post-market data, the concept of Basic UDI-DI was proposed to simplify certain tasks in EUDAMED. However, the AusUDID does not host the same data sets, and therefore would not see the same potential benefits that are anticipated with EUDAMED. As a result, adding Basic UDI-DI to AusUDID would add complexity to the implementation of UDI in Australia without serving the function of public health and safety.

	Question	Comment/rationale
		Even though Basic UDI-DI can be found in the EU regulations, the concept of the Basic UDI-DI is not yet complete, and industry is awaiting further clarification regarding the requirements and how it is going to be implemented before being able to proceed with assigning the Basic DUI-DIs. With this consideration in mind, we recommend that TGA removes the concept of Basic UDI-DI from the AusUDID requirements and adopts international standards and guidelines including IMDRF's final "UDI Guidance. Unique Device Identification (UDI) of Medical Devices (IMDRF/UDI WG/N7FINAL:2013)" which does not include the concept of Basic UDI-DI. In any case, regarding page 13, it is important that the TGA is aware that the definition/interpretation of the Basic-UDI-DI (EU regulation) has changed. The sentence *'...primary identifier of the device model, assigned at the device unit of use'* was misleading. The Basic-UDI-DI will be assigned to a product family (that's the IMDRF Common Data Elements definition of a 'Model'). With that the Basic-UDI-DI serves as an 'aggregator' between EUDAMED modules. Extract from the EU MDCG 2018-1 document (guidance on BASIC UDI-DI and changes to 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. In addition, the proposed changes need to be enforced throughout the supply chain i.e. hospitals must use the information that is being provided, recorded on patient records etc. The regulation should also envisage guidance related to the transition period for those products that are already with the sponsor but do not fulfil the UDI requirements (being manufactured before the UDI regulation becomes applicable). It should be prevented that such products need to be returned to the manufacturer and be repacked/re-sterilized. The guidance should also include a transition period related to the application of direct marking (DM), that is how long those products are allowed to be sold (to end-customers) that have been manufactured without DM before the DM-compliance date. When describing DM requirements, please describe exception rule.