Sterilization in Australia

Volume 39 No. 1

Print Post Approved
PP255003/01725

Sterilization in Australia

Official Journal of Sterilizing Research & Advisory Council (NSW) Inc.

S.R.A.C.A. NSW Inc. Committee -

Sterilization in Australia is published 3 times per year on behalf of the Sterilizing Research and Advisory Council of Australia NSW Incorporated.

Sterilization in Australia is Print Post Approved PP255003/01725

Address all correspondence to
PO Box M71 Missenden Road, Camperdown NSW 2050

Web Address: www.sracansw.org.au
ISSN number 0725.7066
Electronic on-line version ISSN1444-8476
ABN 85 914 815 703

Contents -

PRESIDENT'S REPORT

Dear Members

Welcome to Volume 39 N0. 1 of Sterilization in Australia.

It is with great Honour and pleasure to write this report to our members.

A big thank you to our hard working volunteers in particular our committee members for their work over the year. In 2019 our focus is supporting our members with education and knowledge that promotes high standards of practice in the provision of Sterilizing and Disinfection Services.

There has been an amendment to the AS/NZS 4187 Reprocessing of reusable medical devices in Health service organizations. You can find the link on our website in the member's only zone.

We have been working closely with the clinical Excellent Commission and have project teams working together in small groups on everything from endoscopy, loans, and competencies etc.

We have representation with the HE-023 and FSRACA are working on a project in August watch this space for further information.

So far this year we have had a very informative workshop with hands on activities for members to help understand and how to create your product families. Thanks to the very knowledgeable Kerrie Crossie. This was held in March at the Hornsby RSL Club function room.

We once again have been offering scholarships to assist our members to attend our state conference. Four scholarships were granted at that particular workshop. All members have the opportunity to win our scholarships just by attending any of our workshops.

Over the last few years we have assisted members with world, National and state conferences utilizing our education funds it is fair to say we have issued well over 50 scholarships, it is great to see our members supporting this by attending our education sessions.

Our next State Conference will be held in Newcastle (NEX) the Newcastle Exhibition & conference Centre. Held in September 18, 19. & 20. This year the theme will be Masquerade and we will be having a masquerade ball it will be a lot of fun as usual.

I will give you a little inside information on the conference just to get you as excited as we are. We will be having a key note speaker and workshop that will be having a key note speaker and workshop that will change your life because the presentation is about you and setting goals. This presentation will help you not only in your work environment but your home life and your family can benefit from this also. Please do not miss this opportunity, otherwise you will have to hear your team members talk about this presentation for weeks. We are looking at having a manager, supervisor & team leaders luncheon to look at Quality Management ,section 2 of the standards and work through what this means , how to achieve it and to help each other with real live scenarios.

In addition we will look at surgical site infections and the critical role SSD has in this.

We have many other really worthwhile presentations and of course we will have our favourite MC Andrew Bailey who is sure to keep you very well entertained for the entire conference. We are offering more time with trade and encouraging the trade to have some workshops on their stands and of course we will have lots of prizes and lucky door prizes.

So please don't miss this opportunity for this really exciting event that will certainly support you with education and knowledge to promote high standard of practice in the provision of Sterilizing and disinfection therefore be sure to register we can guarantee there will be something for everyone. I will look forward to seeing all our members there.

Kind regards,

Lynne Noring

NSW SRACA President

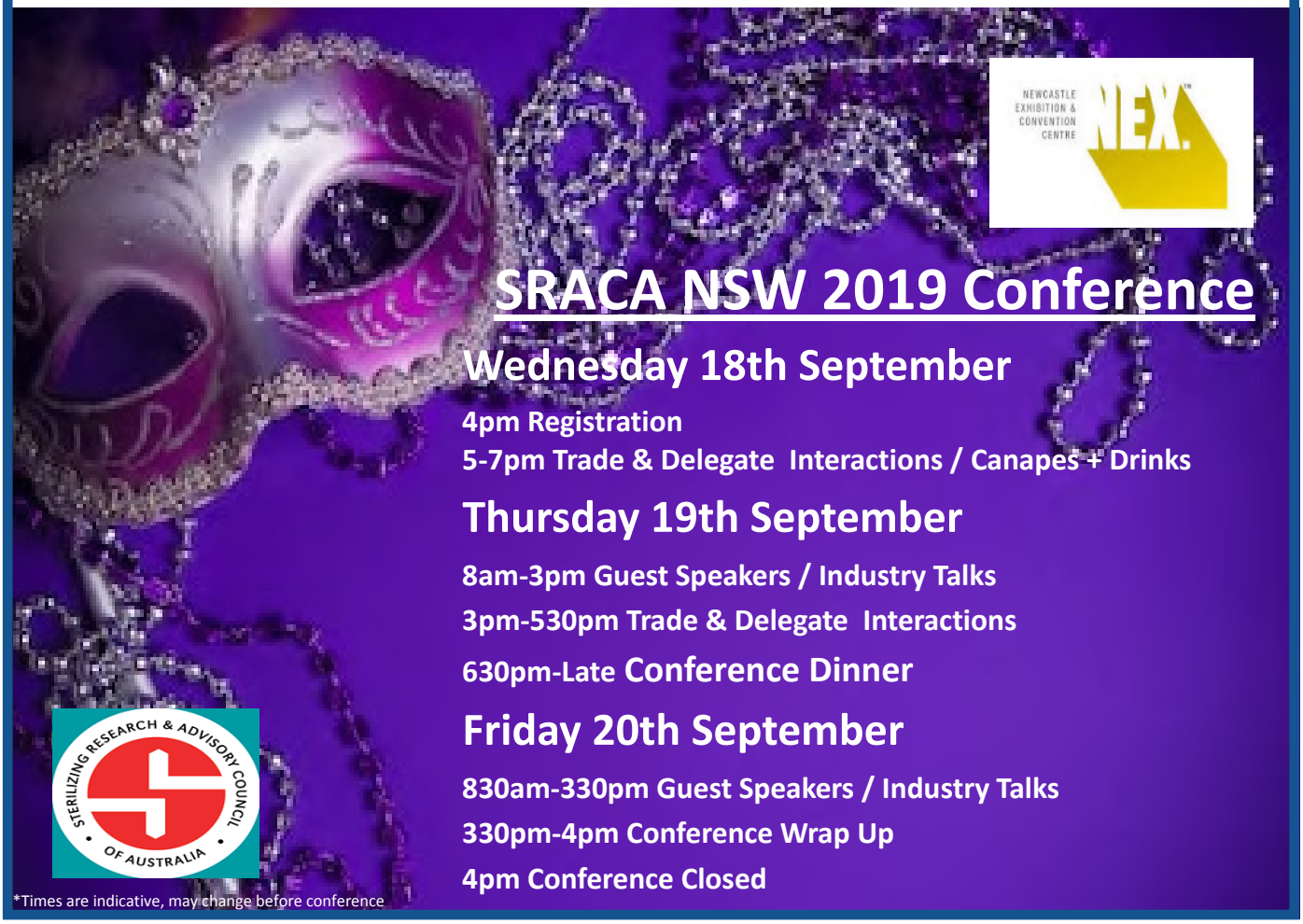
Save The Date

2019 NSW SRACA STATE CONFERENCE

When: 18th to 20th September 2019

Where: NEX—Newcastle

Theme: Masquerade



SRACA NSW WORKSHOP

Wednesday, May 15th 2019

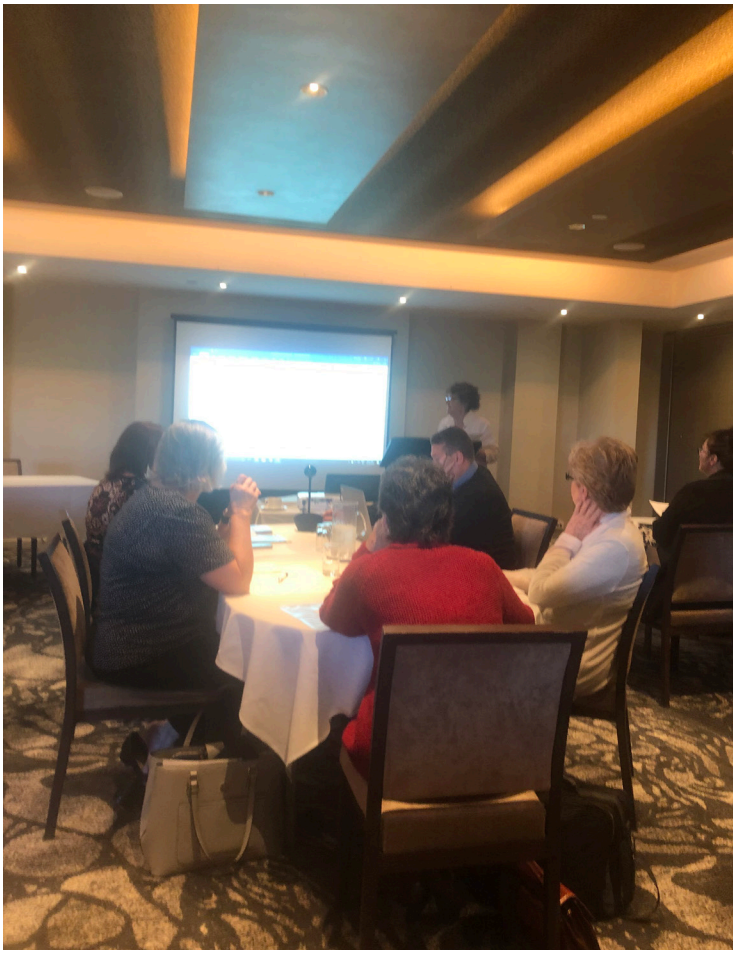
Product Families – a Practical Approach

On Wednesday 15th May, SRACA NSW held the most interactive workshop ever. The venue was the Hornsby RSL and as always, they provided great support and service, and a delicious morning tea and light lunch.

Members travelled from near and far, the SRACA NSW committee is very grateful for the support of all attendees, delegates and trade.

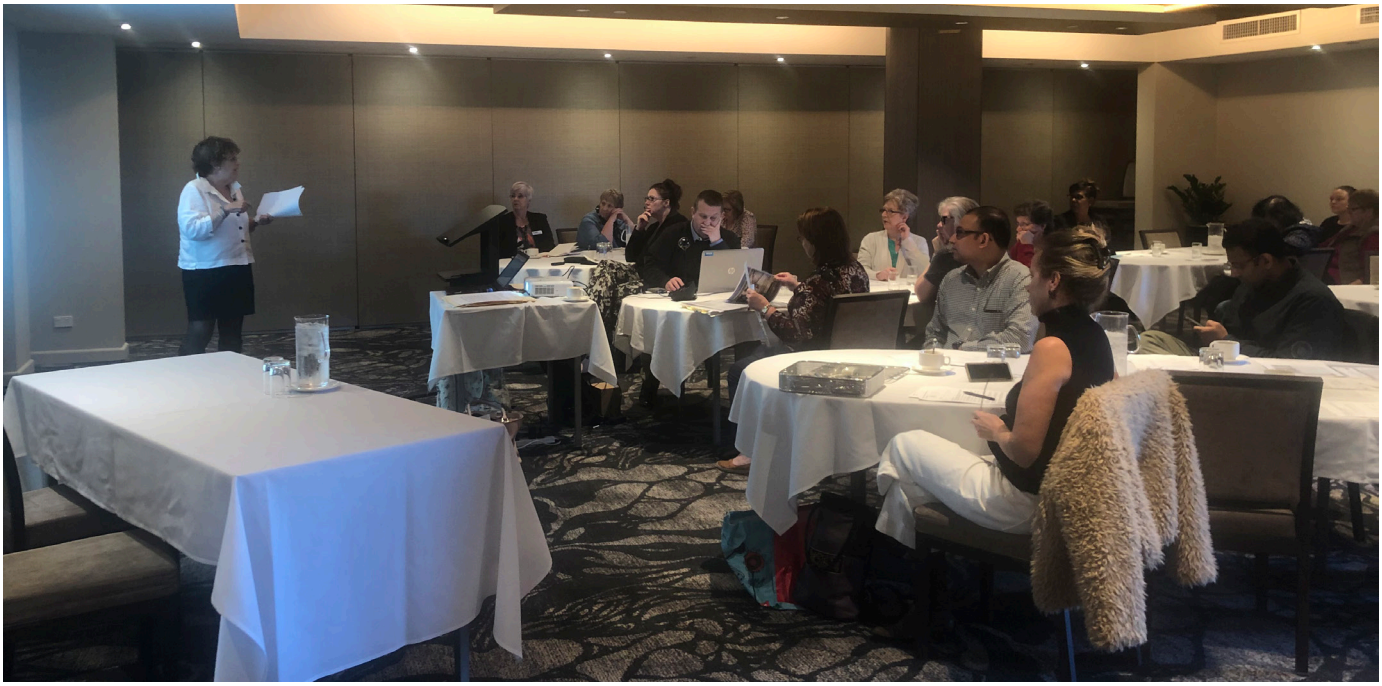
Members were encouraged to bring their own instrument trays and/or checklists and learn how to assign medical devices to Product Families using the table at the back of ISO17665.3 and ISO17664.

Kerrie Crossie - Sterilising & Endoscopy Manager, Orange/Bathurst Base Hospitals PPP kindly offered her expertise and guidance to the members to achieve this complicated task.



Kerrie explained her experience in identifying differences in her pre-vacuum sterilising cycles across the two sites she is responsible for.

Despite the instrument trays being tested had the same contents in both facilities, the steriliser validation reports showed different results. There was evidence that some medical devices being tested had not reached 134 degrees when the cycle had moved into its' sterilisation phase. This resulted in the development of Product Families and consequent changes to the steriliser cycles.



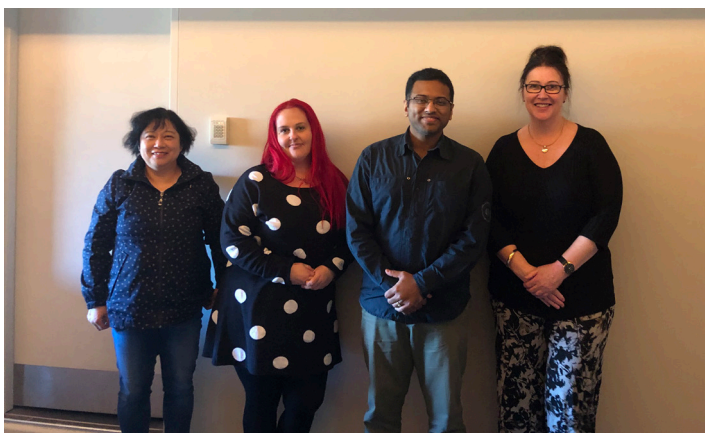
Longer conditioning phases were introduced to the cycles, allowing time for all internal and external surfaces to reach 134 degrees prior to the sterilisation phase commencing, therefore ensuring all surfaces are sterilised by mandatory and standard requirements.

Kerry kindly and patiently explained and demonstrated how to use the formula provided in ISO17665.3 to develop product families. It was a challenging but valuable exercise and all participants were very grateful for the hands on experience.

The AGM was held and members were encouraged to participate with discussions about the upcoming SRACA NSW conference, to be held at the NEX-Newcastle in September 2019. Members were welcomed to bring forward their topics of interest that SRACA NSW could include in future workshops and the 2019 conference. The SRACA NSW website will soon provide all the information for delegates wishing to attend. Delegates were reminded that membership fees will now be effective from July 1st until June 30th of each year. Next membership fees are due on June 30th.

The SRACA NSW Financial information was available and provided by the Treasurer and two new members were welcomed into the committee.

There were 4 x Conference Scholarships given away by lucky door draw throughout the day. Congratulations to Janine McCaffrey, Jin Johansson, Migu Matthews and Niki Phillips. We look forward to seeing you in Newcastle in September.



Certificate III in Sterilisation Services

TAFE NSW Course No: HLT37015-01V01
National Course Code: HLT37015
Nominal Hours: 455

Course structure and units

This course includes 14 units. Use the links below to go to your online learning resources for each unit.

BSBFLM312 – Contribute to team effectiveness

BSBINM301 – Organise workplace information

CHCCOM005 – Communicate and work in health or community services

CHCDIV001 – Work with diverse people

BSBADM311– Maintain business resources

HLTINF001 – Comply with infection prevention and control policies and procedures

HLTSTE001 – Clean and disinfect reusable medical devices

HLTSTE002 – Inspect and pack reusable medical devices

HLTSTE003 – Sterilise loads HLTSTE004 – Manage sterile stock

HLTSTE005 – Care for reusable medical devices

HLTSTE006 – Chemically disinfect reusable medical devices

HLTWHS001 – Participate in workplace health and safety

HLTWHS005 – Conduct manual tasks safely

wsi.tafensw.edu.au

For full details on TAFE NSW fees and money matters please visit our website: wsi.tafensw.edu.au/fees

Australian Government
Department of Health
Therapeutic Goods Administration

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

January 2019

TGA Health Safety Regulation

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, TGA regulates therapeutic goods, and is responsible for implementing the Government's reforms. The Therapeutic Goods Administration (TGA) has issued this consultation paper as part of the Government's reform program.

Background

Demand is growing for improved traceability of medical devices in the supply chain. There is now worldwide recognition that, in the interests of patient safety and improved industry outcomes, the ability to unambiguously identify medical devices is essential. The development and implementation of the Unique Device Identification System (the UDI System) is widely acknowledged by the industry and regulators as an effective mean of ensuring timely access to complete, accurate and consistent information about medical devices.

The International Medical Device Regulators Forum (IMDRF) - a group of the major medical device regulators from around the world, including Australia - is working to advance and strengthen international medical device regulatory frameworks, including those governing Unique Device Identification (UDI). IMDRF guidance documents (IMDRF UDI Guidance) provide a framework within which regulatory authorities and manufacturers can develop and implement their own UDI systems. The aim is to secure 'a single, globally harmonized system for positive identification of medical devices'.

Several international regulatory authorities have already implemented the UDI System, commenced work on implementation, or introduced enabling legislation. This includes authorities from the USA, Europe, Japan, Brazil and some members of the Asian Harmonization Working Party.

The focus of this to seek your feedback on:

- the proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
- whether the TGA or another body should be responsible for establishing and maintaining the Australian UDI database (AusUDID)
- the potential scope of regulatory and legislative amendments required to establish the UDI System in Australia.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

The introduction of any mechanism that allows unambiguous identification of medical devices in supply chains will impact many stakeholders significantly, especially if UDI is fully integrated into the Australian healthcare system.

In recognition of this proposal's complexity and broad impact, we plan to hold other consultations on further aspects of the UDI System's introduction in Australia, including more detailed discussion on the regulatory requirements and seeking more targeted views on the impact of this change on specific groups of stakeholders.

Proposed implementation measures: summary

Aim

The implementation of a globally harmonised UDI system in Australia.

Proposal That the Therapeutic Goods Act 1989 (the Act) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the Medical Device Regulations) be amended to include the legislative and regulatory powers allowing the TGA to establish UDI system in Australia.

Effect

Sponsors of all medical devices supplied in Australia would be required to ensure that their devices carry Unique Device Identifiers and that relevant information and data is entered into the AusUDID.

Your feedback

Are you a patient, manufacturer, healthcare provider, industry representative body, consumer advocacy group, scientist, researcher or other interested party?

We seek your views on the proposed regulatory changes that would facilitate the adoption of the internationally harmonised principles for introduction of the UDI system in Australia. Your input will assist us to address any unintended consequences and to better inform the proposal.

This paper is not intended to be a consultation on the application and use of UDI within the broader healthcare system; however, we will welcome comments on these wider issues.

At the end of this paper (on page 21) is a list of questions to help you address the proposal in your feedback.

Please submit your feedback directly to the TGA by email (See How to submit on page 23).

Please note

This consultation closes on 18 February 2019.
Before providing feedback, it is important to read the explanatory material that follows.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

The UDI System

The introduction of the UDI System is an important means of improving the identification and traceability of medical devices. UDI can provide significant support to 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 consists of three interrelated parts:

- the development and application of UDI globally harmonised standards
- the requirement for manufacturers of medical devices to create and place a Unique Device Identifier on a device, its labelling and packaging
- the requirement to enter specified information or certain data elements into a UDI database (UDID).

The Unique Device Identifier is a series of numeric or alphanumeric characters created by applying globally accepted device identification and coding standards. The Unique Device Identifier has two parts, the Device Identifier (UDI-DI) and Production Identifier (UDI-PI).

Important

Any requirement to include a Unique Device Identifier 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.

A UDID contains essential information specific to the model of a medical device (UDI-DI and some key data elements) and allows access to this information.

Further explanation about these and other concepts is provided in the ‘Definitions’ section on page 16.

What are the benefits of implementing the UDI System?

Identification of medical devices using the UDI System offers significant benefits throughout the supply chain, including:

- enhanced effectiveness of post-market safety-related activities, such as: faster and more accurate identification of problems; improved functionality in the reporting of incidents and adverse events; and more effective management of medical device recalls
- a more robust pre-market assessment of medical devices due to the availability of better quality evidence-based data that is presented consistently and which includes post-market data and analysis
- a reduction in medical and surgical procedural errors by allowing healthcare professionals and others to quickly trace a device and obtain vital information about its characteristics

Consultation

Proposal to introduce a UDI system for medical devices in Australia

• enhanced analysis and research through the uniform documentation of devices in electronic health records, clinical information systems, registries and other data sources • a more robust and secure global distribution chain, which helps to tackle diversion and counterfeiting, and facilitates preparation for medical emergencies
• better sharing of medical device information around the world.

For these reasons, we anticipate that the proposed establishment of the UDI System in Australia will benefit consumers, healthcare professionals, scientists, researchers, the medical device industry and regulators.

International activities related to the UDI System

The following provides an overview of international activities related to the UDI system.

International Medical Device Regulators Forum (IMDRF)

The IMDRF published UDI guidance: Unique Device Identification (UDI) of medical devices (UDI Application Guide) in December 2013. This document provided a high-level conceptual framework of the 'basic core concepts' of a UDI system. However, it has been recognised that further IMDRF guidance is required to better facilitate consistent implementation of UDI systems internationally.

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. It is intended to be used as a supplement to the 2013 guidance and will provide the details and specifications necessary to ensure consistent development of UDI systems in different jurisdictions.

A draft of the UDI Application Guide, together with other relevant information, was published in July 2018 for three months public consultation until 12 October 2018.

Important

The IMDRF recognises that national regulation may differ when dealing with certain aspects of the guidance.

While some UDI-related terminology and regulatory requirements are jurisdiction-specific, the regulators participating in the IMDRF UDI Working Group aim to reach in-principle agreement on the fundamentals underpinning the UDI System. This will include those requirements specifically related to UDI standards, data elements to be included in UDI-DI and UDI-PI, and basic principles for building the UDID.

U.S. Food and Drug Administration

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

Labelling

The U.S. FDA's UDI Rule requires the label and packaging of every medical device distributed in the United States 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.

The Global Unique Device Identification Database (GUDID)

Specific device-related information and key data elements must be submitted to the U.S. FDA's 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 USA. 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.

The European Union (EU)

Regulation (EU) 2017/745 and Regulation (EU) 2017/746

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 time frames; the requirement that a Unique Device Identifier be placed on the device, labelling and packaging; the requirement that certain information be entered into the EU's UDID, and registered in the Eudamed.

Specifically, the EU Regulations provide that: the Issuing Entities should be designated by the end of 2018; UDI-DI should be assigned by manufacturers for all devices; and UDI core data elements must be registered in Eudamed by 26 May 2020 for non-IVD medical devices, or 26 May 2022 for IVD medical devices, or within six months after the date when Eudamed becomes fully functional (whichever is the latest). The implementation of the requirement to place UDI carriers on devices and packaging will be staged, depending on a device's classification.

The EU Regulations also require the inclusion of UDI information in certain types of documentation

Consultation

Proposal to introduce a UDI system for medical devices in Australia

including: certificates issued to manufacturers by notified bodies; manufacturers' declarations of conformity; distribution records; clinical evidence; implant cards.

Significantly, the EU Regulations require that, to the extent possible, guidance developed for medical devices at the international level (in particular guidance from the Global Harmonization Task Force (GHTF) forerunner of the IMDRF) should be taken into account to promote the global convergence of regulations. Specifically the guidance should, in particular, cover those provisions on UDI, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations. The EU Regulations note that this work contributes to a high level of safety protection worldwide and facilitates better trade.

Proposed implementation in Australia

We propose that the UDI System in Australia be based on internationally harmonised principles as outlined in IMDRF UDI Guidance and informed by the work done by the EU, the U.S. FDA and other regulatory authorities.

It is proposed that the Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other medical 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 I(m) (with measuring function) and/or Class I(s) (devices supplied sterile)?

While it is highly desirable to align internationally, we seek stakeholders' feedback on proposals for possible exemptions from UDI requirements.

Sponsors will be responsible for ensuring their devices comply with the relevant requirements.

Sponsors who import or supply medical devices in Australia will need to verify that, where applicable, device manufacturers have assigned a Unique Device Identifier to their devices and placed Unique Device Identifier carrier on the device, labelling and packaging as required.

Sponsors must have an agreement with the manufacturer authorising the sponsor to include the key data elements and other relevant information in AusUDID.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Proposed first actions

It is proposed that the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002 be amended to enable the establishment of the UDI System and include provisions to:

- allow the designation of Issuing Agencies (or Issuing Entities) and provide these with the power to issue Unique Device Identifiers

  Note: Further explanation on Issuing Agencies (or Issuing Entities) is provided on page 18.

- prescribe requirements for the placing of Unique Device Identifiers on a device, its labelling and packaging

- establish the AusUDID (potentially within the TGA infrastructure, see below) and link it to the Australian Register of Therapeutic Goods (ARTG).

Consultation on the introduction of the UDI System will be a staged process. The TGA will undertake further consultations on the proposal in order to clarify the design, scope, cost and information technology interface processes needed to implement the UDI System in Australia.

The TGA is also aware that there are already views of different stakeholders that consider and discuss the need and feasibility of introducing UDI system in Australia.

The proposed UDI System

The following is a broad description of a potential Australian UDI System—the proposed core definitions, key data elements and main principles for establishing AusUDID. We are seeking feedback about which of these will best contribute to optimal UDI system implementation and operation in the Australian context.

Definitions

Subject to advice from public consultation, the list of definitions below provides the terms necessary to establish and implement the UDI System in Australia.

The definitions are largely consistent with the IMDRF UDI Guidance, U.S. FDA legislation and the EU Regulations. We note some instances of divergence and these mostly relate to definitions that are specific to the EU Regulations. Publication of the IMDRF's UDI Application Guide in 2019 will further inform this work.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Important

It is important to think about how these definitions will operate within the wider context of the Australian legislative and regulatory framework for medical devices.

Term	Description
Unique Device Identifier (UDI)	A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards. The Unique Device Identifier allows unambiguous identification of specific devices on the market.
Device Identifier (UDI-DI)	A unique numeric or alphanumeric code specific to a model of medical device. The UDI-DI is used as the 'access key' to information stored in a UDI database (UDID). The UDI-DI is a 'fixed' portion of the Unique Device Identifier and identifies a manufacturer's specific products and package configurations. For example, the UDI-DI may include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number) and ICCBBA ISBT 128-PPIC (Processor Product Identification Code).
Production Identifier (UDI-PI)	A numeric or alphanumeric code that identifies the unit of device production. The UDI-PI is a 'conditional, variable' portion of the Unique Device Identifier and may include the serial number, lot or batch number, software identification, date of manufacture or expiry date, or both of these dates.
Basic UDI-DI	The primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity. **Note:** This term is unique to the EU Regulations; it is not used in IMDRF documents or by the U.S. FDA.
Unit of Use (UOU) DI	An identifier assigned to an individual medical device. It serves to associate the use of a device with a patient in instances in which a Unique Device Identifier was not labelled on the individual device at the level of its unit of use, for example, in the event of several units of the same device being packaged together.

Term	Description
Unique Device Identification Database (UDID)	Contains identifying information and other elements associated with the UDI-DI specific to the model of a medical device.
Unique Device Identifier Carrier (UDI carrier)	The means to convey the Unique Device Identifier by using AIDC and, if applicable, it's Human Readable Interpretation (HRI). Carriers can include 1D/linear barcodes, 2D/matrix barcodes and radiofrequency identification (RFID).
Automatic Identification and Data Capture (AIDC)	Technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and 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.
Human Readable Interpretation (HRI)	A legible interpretation of the data characters used to create the Unique Device Identifier, including the qualifiers UDI-DI and UDI-PI if applicable. The UDI System provides that the label of medical devices include a Unique Device Identifier in AIDC and HRI form and that specified data elements identifying these devices are entered into the AusUDID.
Third party	A company or individual that, based on a contract with a manufacturer, is authorised by that manufacturer to carry out certain operations on their behalf, such as submission of data to the UDI database or the placing of the UDI carrier on the device label. **Note**: It is proposed that in Australian legislation and regulations, the procedure for drawing up a written agreement between the sponsor and manufacturer will include the responsibilities of both parties (see 'Principles for the UDI System' below)
Configurable device	A device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves. Configurable devices include computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological monitoring systems and the radiology information systems (RIS).

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Principles for the UDI System

The principles below outline the basic requirements in the proposed UDI System for manufacturers and sponsors and also outline the requirements of the System's key components including AusUDID data elements.

Manufacturers and sponsors

Manufacturers must comply with all obligations relating to the UDI System.

The manufacturer must ensure that their quality management system uses an appropriate verification mechanism to assign a Unique Device Identifier to all relevant devices. The manufacturer must ensure the consistency and validity of information entered on the device, labelling and packaging. They must ensure they have provided all information required for entry into AusUDID to sponsors.

A manufacturer of implantable medical devices must also provide patient information leaflets and implant cards (as required) with the respective information on the implant. In particular, that information must include the Unique Device Identifier.

Sponsors must verify that where applicable, Unique Device Identifiers have been assigned by the manufacturer to all devices they supply in Australia, and that they have established procedures with the manufacturer that allow them to enter all required information in AusUDID.

Please note

We will consult separately to clarify the definition of the sponsor in the Therapeutic Goods Act 1989. Here we propose to consider sponsors' specific obligations in the context of the UDI requirements, specifically in the context of the matters certified under section 41FD of the Act and conditions of inclusion of a 'kind of medical device' in the ARTG.

Issuing Agency/Entity

Issuing Agency/Entity is an organisation accredited by a regulatory authority to operate a system for the assignment of Unique Device Identifiers according to specified requirements.

GS1, the Health Industry Business Communications Council (HIBCC) and the International Council or Commonality in Blood Banking Automation (ICCBBA) are accredited issuing agencies/entities in some jurisdictions.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Please note

The terminology used by the U.S. FDA (Issuing Agency) and in the EU Regulations (Issuing Entity) is different. However, the scope of responsibilities is largely similar.

The U.S. FDA's UDI Rule permits accreditation of multiple Issuing Agencies (IA) and provides a process through which an applicant can seek FDA accreditation as an IA. U.S. FDA has accredited GS1, HIBCC, and ICCBBA. Pending the European Commission's decision on designation, GS1, HIBCC and ICCBBA are deemed the designated Issuing Entities in Europe.

AusUDID

It has been proposed by peak industry bodies that the TGA be responsible for developing and maintaining the UDI database, AusUDID, consistent with the principles outlined in the IMDRF UDI Guidance.

Under this option there would be public access to the core data elements entered into the UDI database but no UDI-PI or commercial information will be made available. We seek stakeholders' input as to whether these arrangements are appropriate or whether there are preferable alternative options.

Core data elements

The EU Regulations require manufacturers to enter the Basic-UDI-DI into the UDI database to be used as the primary identifier of the device model, assigned at the device unit of use. It is the main identification code for records in the UDI Database and is referenced in relevant certificates and EU Declarations of Conformity.

The Basic UDI-DI will be linked to other device information via a link between the UDI database and Eudamed. Eudamed contains other information about medical devices including: registration details, certificates, adverse incidents, clinical investigation and market surveillance.

The U.S. FDA requires UDI-DI and some other core data elements to be entered into the GUDID.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Core UDID data elements

The EU Regulations require that the UDI-DI and the following information relating to the manufacturer and the device be provided to the UDI database:

1. quantity per package configuration
2. the Basic UDI-DI as referred to in Article 29 and any additional UDI-DIs
3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number)
4. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient)
5. name and address of the manufacturer (as indicated on the label)
6. the SRN issued in accordance with Article 31(2)
7. if applicable, name and address of the authorised representative (as indicated on the label),
8. the medical device nomenclature code as provided for in Article 26
9. risk class of the device
10. if applicable, name or trade name
11. if applicable, device model, reference, or catalogue number
12. if applicable, clinical size (including volume, length, gauge, diameter)
13. additional product description (optional)
14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)
15. if applicable, additional trade names of the device
16. labelled as a single-use device (y/n)
17. if applicable, the maximum number of reuses
18. device labelled sterile (y/n)
19. need for sterilisation before use (y/n)
20. containing latex (y/n)
21. where applicable, information labelled in accordance with Section 10.4.5 of Annex I

22. URL for additional information, such as electronic instructions for use (optional)
23. if applicable, critical warnings or contra-indications
24. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

There are also additional data elements related to the device that must be provided as part of the registration of the device.

Please note

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

For example, a comparison of regulatory requirements between the U.S. FDA and EU Regulations can be found in the IMDRF consultation document N54:

Use of UDI data elements across different IMDRF jurisdictions.

In addition, the IMDRF has agreed on a set of data elements that should be entered into the UDI database.

The ARTG and AusUDID

We propose that ARTG entries for medical devices be linked to the relevant device information entered into AusUDID. When fully developed, the linkage will significantly improve the quality and reliability of data available.

This proposed approach has similarities with the requirements included in the EU Regulations which prescribe creation of Eudamed that will integrate different electronic systems, including UDI database. The objectives of the Eudamed are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, and to streamline and facilitate the flow of information between different participants of the supply chain.

Rules for specific device types

The UDI System has specific rules that apply to some categories of medical devices, including implantable devices, systems and procedure packs, configurable devices, software as a medical device and contact lenses. We propose to consult separately on these specific requirements.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Incident and adverse event reporting

Any reports of incidents or adverse events in particular must include the relevant Unique Device Identifier.

Also, any corrective action will be required to include a device's Unique Device Identifier. We propose to incorporate these requirements as conditions of ARTG inclusion.

Transitional arrangements

It is proposed that transitional arrangements in Australia—for the obligation to place the UDI carrier on the label of the device—will be consistent in each case with the respective transitional arrangements in Europe.

There will be staged implementation of the requirement to enter UDI-DI and other specified core data elements into AusUDID.

Article 123(3) of the EU Regulations provides that UDI carriers must be placed on the label of the device and on all higher levels of packaging for:

- implantable devices and Class III devices from 26 May 2021
- Class IIa and Class IIb devices from 26 May 2023
- Class I devices from 26 May 2025.

For reusable devices that must have the UDI carrier on the device itself, the requirement is imposed from two (2) years after the date referred to in the previous point for the relevant class of devices.

The implementation for IVD devices will be delayed by two (2) years from the requirements for other devices.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Class (and jurisdiction if applicable)	Relevant EU Regulation	Deadline for UDI-DI assignment and registration in Eudamed	Proposed timeframe for placement of UDI carrier on the device / label / packaging in Australia	Timeframe for direct marking for reusable devices in Australia
Class III and implantable	MDR Regulation (EU) 2017/745	26 May 2020	26 May 2021	26 May 2023
Class IIb/IIa			26 May 2023	26 May 2025
Class I			26 May 2025	26 May 2027
Class 4 IVD (Australia) **Class D (EU)**	IVDR Regulation (EU) 2017/746	26 May 2022	26 May 2023	N/A
Class 2 IVD and 3 IVD (Australia) **Class B IVD and Class C (EU)**			26 May 2025	
Class 1 IVD (Australia) **Class A IVD (EU)**			26 May 2027	

Fees and charges

The funding for maintenance of AusUDID will be based on the activity base costing and will be included in annual charges for medical devices and IVD medical devices.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- provide relevant material on the TGA website.

Consultation

Proposal to introduce a UDI system for medical devices in Australia

Feedback notes

Although we intend to harmonise with international UDI systems, it is important to note that legislative and regulatory frameworks are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. Therefore, because international regulation and legislation cannot always be replicated, your feedback is vital to ensuring that our proposed measures will best implement the UDI System in an Australian context.

What we invite you to do

In your submission, we ask you to consider the questions below and to provide comments related to any other matters outlined in this consultation paper.

Questions

- 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?
- 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 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?
- It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?
- 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 authorisation for the device?

Consultation

Proposal to introduce a UDI system for medical devices in Australia

- 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?
- What core data elements and other relevant information should be entered into AusUDID?
- How should we link the ARTG and the UDI database? What information should they share?
- Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?
- What impacts (including unintended impacts) do you anticipate for you and other stakeholders?
- Are there any other issues and questions we need to consider when implementing this change?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

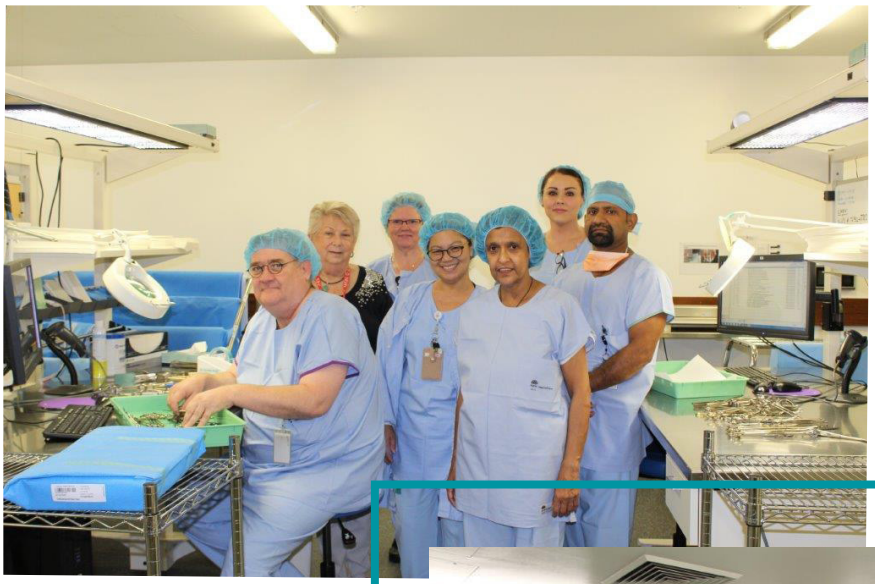
Please submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au.

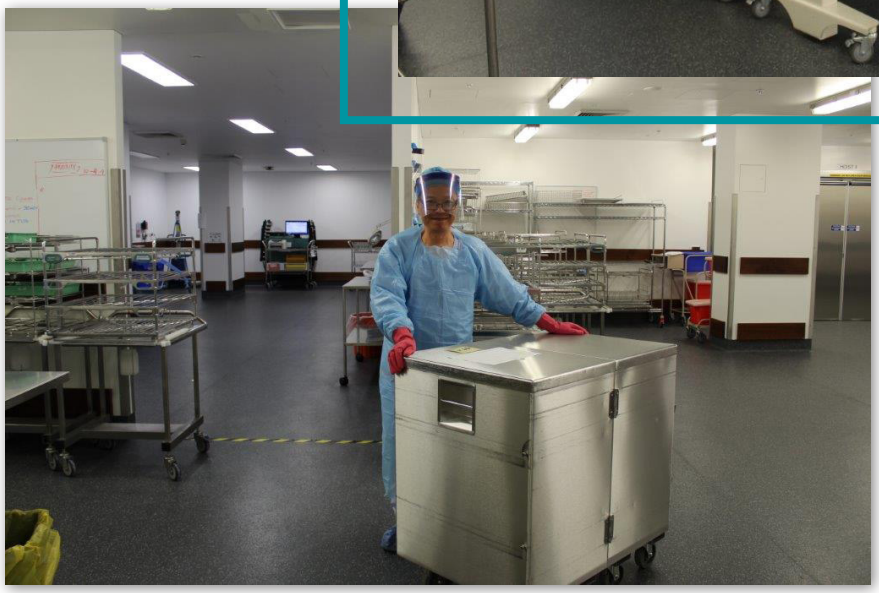
This consultation closes on 18 February 2019.

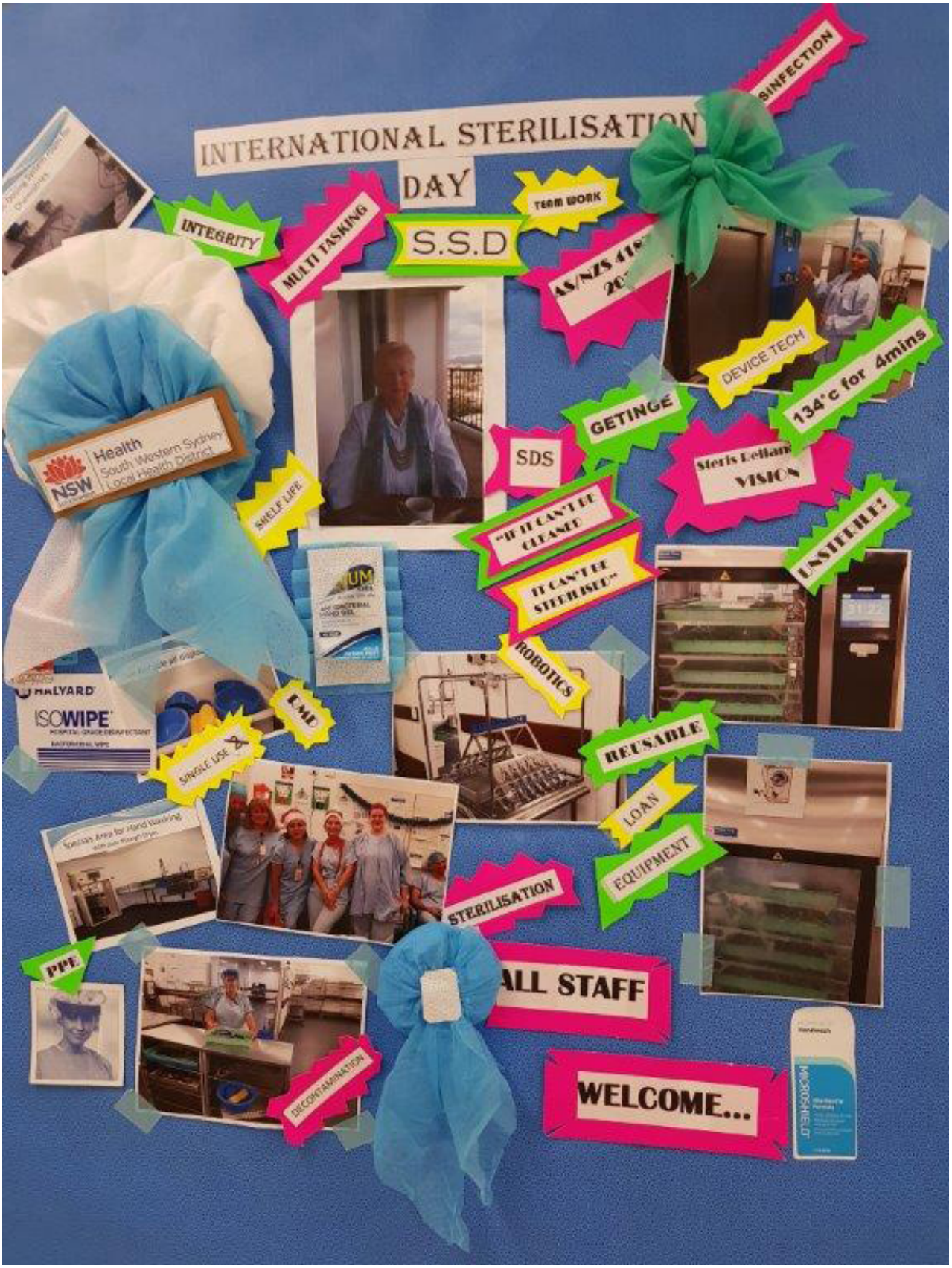
Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

LIVERPOOL WORLD SSD





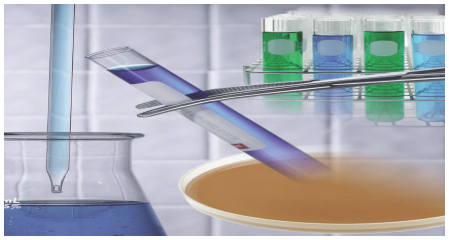


Thanks to Joyce Kenyon and the Liverpool Team

Expression of interest for The Sterilizing Industry

APPLYING FOR A RESEARCH GRANT

Sterilizing Research Advisory Council of Australia



Federation Sterilizing Research Advisory Council of Australia invite all financial members of SRACA to apply for a research grant of up to $1400.00

This package includes;

- Information
- Guidelines
- Application form

You can request your package from your State Secretary, or download from your State or Federal website.

Purpose

To provide financial assistance, to promote research and develop skills to ensure the sterilizing industry is contributing to quality patient care.

Value

Maximum $1,400.00

1. Selection criteria

- Financial assistance will be considered for projects which would be relevant and beneficial to both the applicant and those involved in the field of sterilization.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

2. Eligibility

- Highly developed written and oral skills
- State SRACA membership number and proof you are a current active member.
- Be a full member of a state SRACA and have been a member of a state SRACA for a minimum of two years immediately prior to submitting an application.
- Be currently employed in the field of sterilization and have been employed in the field of sterilization for a minimum of two years immediately prior to submitting an application
- Has attended SRACA meetings and educational activities during the two years immediately prior to submitting an application.
- Be actively involved in his/her state SRACA. Active involvement is considered to include but is not limited to:
  - Willingness to serve on SRACA committee or sub-committee
  - Promotion of SRACA activities
- Applicants shall submit information about any application for funding from an alternative source/s for the same purpose.
- Only one research grant will be awarded annually.

3. Application Guidelines

- Application forms are available from both FSRACA and SRACA State secretaries
- Applicants should submit a completed type written application form
- Comprehensive Curriculum Vitae, which show details of work and education qualifications.
- Full details of the project, including the objectives, the methodology of the research, the outcome and how the research can enhance sterilization and the estimated or actual budget.
- The proposed project must have commenced within 12 months from receipt of the research grant.
- Within four weeks of completing the research project the recipient will need to submit a type written report outlining the project

- The recipient of a FSRACA grant shall:
  Be prepared to speak on the funded project at FSRACA and/or SRACA meetings, conferences or workshops
- The report may be published in the "Sterilization in Australia" Journal or in an appropriate national professional Journal at the discretion of the editor.
- The recipient will submit progress reports to FSRACA if requested to do so.
- Papers and reports shall not be returned to the grant recipient by FSRACA committee.
- Projects involving human bioethics shall show proof of permission by the people and/or organization's concerned.
- The grant may fund all or part of the project
- The grant will be available only once to any individual.

4. Selection

- Completed application forms together with al l supporting documentation shall be submitted to the Secretary of the state SRACA of which the applicant is a member, by 31 December each year.
- The state SRACA committee will determine whether eligibility requirements (as set out in this document) have been met.
- All applications will be forwarded by SRACA to the FSRACA Secretary together with a State committee recommendation.
- The applications shall be assessed at a meeting of the FSRACA committee.
- The decision of FSRACA committee shall be final and binding on all matters.
- Confidentiality of the selection process shall be upheld by all those involved.
- The names of successful applicants, together with an outline of project and funds granted, will be published in the minutes of FSRACA meeting.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

5. Publication

- Grant recipients shall retain copyright of all papers/reports submitted to FSRACA

6. Financial Considerations

- Applicant shall submit a statement of proposed expenditure for the proposed project.
- FSRACA committee reserves the right to cancel the grant and request return of any monies granted should the recipient fail to pursue the purpose for which the grant was awarded.

7. Alternative Funding

- FSRACA financial grants are conditioned upon the applicant informing FSRACA at any time should funding received exceed the total cost of the project.
- FSRACA committee reserves the right to request the return of monies over and above full funding.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

Application form

Title Ms, Miss, Mrs, Mr., Dr (Please circle your title)

Surname _____

Given Names _____

Address _____

_____ **Post code**_____

Email address: _____

Phone number. _____

Current occupation and years of experience _____

_____

Amount of Funding requested $_____

I have/have not made application to alternative sources for funding YES/NO

If YES from whom and what support has been requested/granted: _____

_____

If funding is granted I _____ **agree to abide by the terms and Conditions of FSRACA "Guidelines for Financial Grants"**

SIGNATURE: _____ DATE_____

OFFICE USE ONLY

Received by _____State SRACA Secretary on _____

State SRACA comments regarding eligibility (as per financial grant guidelines)

_____

_____ _____

SIGNED: _____POSITION:_____DATE:_____

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

Received by FSRACA Secretary on _____ DATE:_____

Presented to FSRACA meeting on _____ DATE: _____

FSRACA Action: _____

_____ _____

SIGNED: _____ POSITION:_____ DATE:_____

Attachments

- Current SRACA Membership
- Curriculum Vitae
- 2 x Professional Referees
- Proposed Project
- Budget Plan

Applicant_____

1= Criteria not met

5= Criteria fully met

Criteria Rating Comment

1. Documentary evidence. (Circle correct answer)

- Current membership and active member State group YES/NO
- Two relevant references supplied YES/NO
- Curriculum Vitae supplied YES/NO
- Project details YES/NO
- Budget Plan YES/NO

2. Essential Qualifications supplied YES/NO

3. Communication skills

• Written 1,2, 3,4,5

• Oral 1,2,3,4,5

Summary

_____

_____

_____

_____

_____

_____

Approved/not approved (Circle the correct answer)

Amount granted $_____

Signature_____Date_____

2019 NSW SRACA Calendar of Events

AGM

- 6th May 2019

General Meeting

- 19th September 2019
- 4th December 2019

State Conference

- 18/19/20 September 2019

Executive Committee Meetings

- 18th February 2019
- 4th March 2019
- 1st April 2019
- 6th May 2019
- 3rd June 2019
- 1st July 2019
- 5th August 2019
- 2nd September 2019
- 14th October 2019
- 4th November 2019

WORLD CSSD DAY

- 10th April 2019

January 2019

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

February 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28		

March 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

April 2019

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

May 2019

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

June 2019

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

July 2019

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

August 2019

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

September 2019

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

October 2019

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

November 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

December 2019

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Please note dates and venues are subject to change due to venue availability

S.R.A.C.A (N.S.W.) INC.

Membership Application/Renewal

Renewals Due 1st July Annually

Sterilizing Research & Advisory Council of Australia (NSW)

ABN: 85 914 815 703

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st July each year and is valid till 30th June the following year

TITLE_____SURNAME_____GIVEN NAME_____

HOSPITAL/COMPANY_____

POSTAL ADDRESS_____

POSTCODE_____STATE_____PHONE NO_____

EMAIL_____

Please tick Membership Type

FULL Membership renewal includes Electronic Journal **$50.00**	$50	☐
NEW Membership includes Electronic Journal & Joining fee **$55.00**	$50 + $5 Joining fee (Admin)	☐
ASSOCIATE Membership includes Electronic Journal **$50.00**	$50	☐

(NOTE: New Membership MUST be approved at Executive Meeting prior to be accepted after application made)

TOTAL PAYMENT ENCLOSED $_____

TOTAL PAYMENT BANK DEPOSIT $_____

Make cheques payable to:

S.R.A.C.A. (NSW) Inc.

Return with form to

S.R.A.C.A. (NSW) Inc

PO Box M71

MEMBERSHIPS CAN BE DONE VIA EFT or ONLINE

S.R.A.C.A. (NSW) Inc.

BSB: 032096

Account: 871850

Reference: Company/Member Name

Please send or Email Application Form after payment made


STERILIZING RESEARCH & ADVISORY COUNCIL
OF AUSTRALIA