HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 1 IMDRF/Industry Joint Workshop | 9 March 2026

Using alignment in product changes to strengthen reliance

Tracey Duffy

First Assistant Secretary, Medical Device and Product Quality Division

Therapeutic Goods Administration

OFFICIAL

Australia's experience

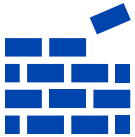
Australia has long supported regulatory reliance, particularly where **trusted regulators** have already assessed a device for market entry

The IMDRF Reliance Playbook makes clear that **reliance should apply across the full product lifecycle**

In practice, reliance becomes **harder to operationalise as products evolve**

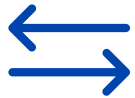
Post-market changes are often where **differences in thresholds and documentation expectations re-emerge**, and inconsistent international treatment of changes can limit how far reliance can be taken

Confidence as the Currency of Reliance



Confidence is strengthened when regulators share:

- A common understanding of what constitutes a **significant change**
- Comparable approaches to **risk categorisation**
- **Transparency** around decision rationales



Alignment does not require identical systems!

Done well, reliance can reduce duplication, support predictable outcomes, prevent supply disruption, and allow regulators to **focus effort where risk is highest**.

Australian Case Study: When Reliance Works

Step	Australian Approach	Outcome
Initial Approval	Hip implant with 10 angle variants, relied on overseas evidence	ARTG inclusion granted
Product Change	2 new angle variants developed	ARTG variation triggered
Evidence Review	TGA checks if overseas evidence covers changes	Review limited to IFU if evidence sufficient
Result	Risk-based reliance applied	Duplication avoided, confidence maintained

Where reliance is constrained

Regulatory Framework Differences
Variations in regulatory systems cause constraints on reliance despite trust between jurisdictions.

Impact on Product Classification
A product variant accepted overseas may require new classification and registration locally, adding complexity.

Need for Harmonization
Harmonizing definitions and requirements enables more consistent and effective reliance across borders.

Australian Example: A change accepted as a ‘variant’ and approved by a comparable overseas regulator may be considered a new ‘kind of device’ with a new UPI in Australia requiring a new ARTG application

Opportunities to improve reliance

Need for Clear Documentation
Clear and formal documentation is essential to prove that product changes have been assessed and approved by the conformity body.

Transparency in Assessments
Increasing transparency about product change assessments will improve regulatory confidence and consistency in reliance decisions.

Enhanced Regulatory Openness
Greater openness in regulatory decision-making supports the goals of the IMDRF Reliance Playbook and strengthens trust.

Thank You!

Therapeutic Goods Administration (TGA)
Australia

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HSA Health Sciences Authority

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CHANGE MANAGEMENT - MALAYSIA

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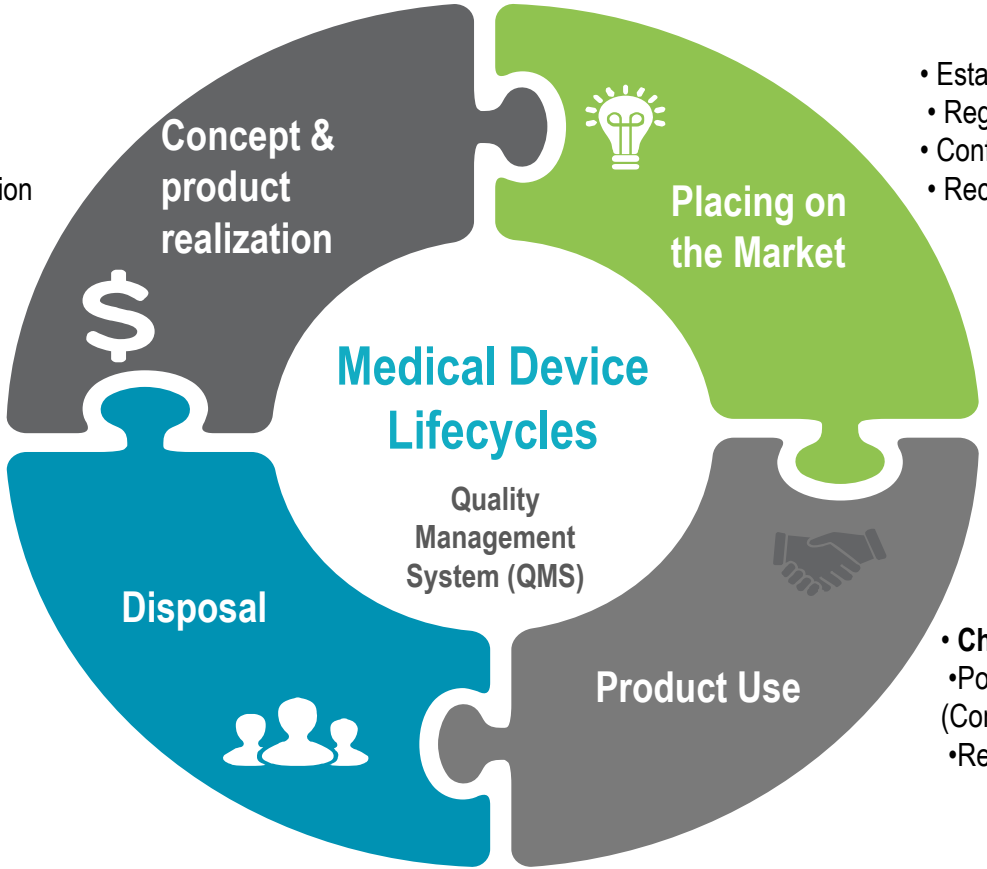
SENIOR DIRECTOR, PRE MARKET CONTROL DIVISION

MEDICAL DEVICE AUTHORITY, MALAYSIA

What is Change Management

- Medical devices undergo changes as part of their product life cycle. Manufacturers make changes to existing products all the time
- Change management is a concept that ensures change is implemented in a controlled, systematic procedure, in compliance with quality and regulatory requirements
- Changes to a registered medical device is linked to the principles of safety and performance and the ability of the regulatory framework to manage the risk of the medical devices
- For any change made to a registered medical device, the manufacturer shall evaluate:
  - the device concerned;
  - the potential impact of the change on patients, practitioners, and/or users;
  - the implications of the change on the intended use or indications for use, risk classification, and device specifications.
- Following this evaluation, the manufacturer shall determine whether the change may reasonably be expected to influence the safety, performance, or effectiveness of the device, or its continued conformity with the Essential Principles and its overall risk–benefit profile throughout the device's lifecycle.
- Before making any decision whether a changed medical device can continue to be placed in the market the MDA ensure evidence of continued safety, performance and effectiveness of changes

- Essential Principles
- Verification&Validation
- Clinical Evidence
- Technical Documentation



- Establishment license
- Registration certificate
- Conformity Assessment
- Records

- Management of end of life

- **Change Management**
- Post market Vigilance (Complaints, FSCA, AE)
- Re-Registration

ROADMAP TO CHANGE MANAGEMENT FRAMEWORK

29th IMDRF 2026

2 Feb 2024

MDA Change Management Workshop by APACMed

10-11 July 2024

MDA-Industry Change Management Workshop by APACMed

4 Nov 2024

MDA-APACMed Meeting

11 Nov 2024

MDA-APACMed Workshop on Decision Tree CM Pre-work

29 Nov 2024

MDA-APACMed Workshop on Flowchart and List of Required Document to be submit

12 Dec 2024

MDA-APACMed Meeting during 28th GHWP Annual Meeting at Kuala Lumpur to Consolidate CM Information

21 March 2025

Application for Development of Change Management GD

April – Dec 2025

Discussion in CM Guidance Document Task Force to develop a draft GD

Okt 2023 – June 2026

Development of Medical Device Centralised Online Application System (MeDC@St 3.0) for the development of new system for Medical device registration and CM

3 Dec 2025

Final draft of 1st edition Change Management Guidance Document has been published for public comment

2 March 2026

Draft GD presented to Guidance Document Approval Committee (GDAC) for approval and publication

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Overall purpose	Establishes a structured, lifecycle-based **change management framework** for maintaining accuracy of registered device documentation	Provides guidance on **change notification** only, focused on categorizing and processing changes that are submitted to MDA
Structure	Includes a main flowchart plus seven detailed sub-flowcharts covering manufacturing, design, sterilization, software, materials, labelling, and registration information.	Textual guidance with tables of examples. No visual decision trees or separate flowcharts by change type.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Terminology / classification logic	Uses a **significant vs non-significant** change concept, with sub-categories for “notification required”, “notification not required”, and “notification optional”.	Uses **Category 1/2/3**: Category 1 – new registration required; Category 2 – evaluation before implementation; Category 3 – implementation upon submission.
Bundling of changes	Provides explicit rules for **single vs. multiple** applications, including when identical changes may be bundled across multiple certificates, with justification requirements.	Allows multiple Submission IDs per application (up to 50), but bundling principles are less developed and mainly explained via fee examples.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
UDI-DI impact	Introduces **UDI-DI trigger** criteria (e.g., proprietary name, clinical size, sterile state, single-use vs reusable, reprocessing attributes) that require a new UDI-DI.	UDI-DI is not addressed. No specific triggers or linkage to device identifier changes are described.
Re-registration linkage	Establishes a clear link between **Change Management and re-registration**. Updated CER/CPR, PMS, RM file, QMS, DoC, labeling, and technical documentation must be submitted via Change Management **before** MDA will accept a re-registration application.	No explicit connection between change notification and future re-registration. Updates can be addressed at renewal without going through a structured pre-step.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Software changes	Includes a dedicated software flowchart. Addresses versioning, functional changes and links to predetermined change control plans (PCCP) for software-based devices.	Software is handled as one of many change types under Category 2/3, with examples (e.g., performance-impacting software upgrades) but without a dedicated framework.
Sterilisation changes	Sterilization process and facility changes are covered in a specific flowchart, including validation expectations and assessment of impact on safety/performance.	Sterilization changes are captured under Category 2 with examples and document lists, but without a separate decision tree.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Material changes (general MDs & IVDs)	Separates material changes for **general devices** and **IVDs** into distinct flowcharts, clarifying when changes to biological or non-biological materials require notification.	Material changes are described in the Category 2 tables (general devices and IVDs), with examples and document requirements, but are not split into dedicated decision trees.
Labelling changes	Labelling changes are assessed via a dedicated flowchart to determine whether notification is required, optional, or not required, depending on impact on use, safety, and claims.	Labelling is covered under Category 2 and 3 (e.g., warnings, precautions, indications, IFU updates, EU MDR/IVDR-driven changes) with some examples of changes not requiring notification.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Registration information changes	Uses a flowchart to address changes to registration information (manufacturer/MAH details, device names, models, configurations, sets and systems, etc.).	Registration information changes (e.g., manufacturer address, device name, additions/reductions in a set) are described in Category 2/3 tables, but without a visual decision pathway.
Risk assessment logic	Builds decisions around whether the change affects safety, performance, intended purpose, clinical information or essential principles, and whether the impact is significant or not.	Refers to the impact on safety and performance, but largely through descriptive text and examples within the Category 1/2/3 framework rather than a formalized risk-based algorithm.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

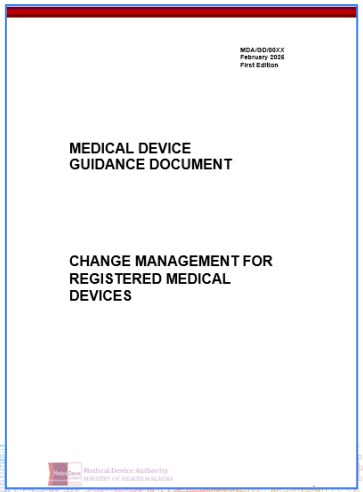
TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Non-significant changes with no notification	More clearly identifies changes that may be **documented internally only** (for example purely administrative or editorial updates) without submission to MDA, while still requiring QMS traceability.	Category 3 includes lower-impact changes, and some examples of changes that do not require notification, but there is no explicit “no notification” tier with lifecycle expectations.
Lifecycle and global alignment	Strong lifecycle emphasis. Requires Malaysian registrations to stay aligned with global technical documentation (CER/CPR, PMS, RM file, QMS, CAB certificates) via Change Management throughout the validity period.	Focused on how to process discrete change events. Lifecycle language is limited, and global documentation alignment is not tightly linked to the ongoing change process.

COMPARISON WITH THE CURRENT 4TH EDITION GUIDANCE

TOPIC	CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES (1ST DRAFT)	CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (4TH EDITION MDA/GD/0020)
Harmonization with other frameworks	More clearly aligned with international expectations (e.g. EU MDR-style lifecycle management and global UDI practices), using risk- and significance-based concepts.	Recognizes EU MDR/IVDR-driven changes mainly via specific labelling examples, but does not fully embed a lifecycle or UDI-based structure.

Malaysia Change Management Guidance Document

- Adopt and adapt GHWP guidance document (GHWP/WG2-WG1-WG3/F001:2023)
- Final draft of 1st edition Change Management Guidance Document has been published on 3rd of December 2025 for public comment
- The contents of the guidance document covers:
  - Introduction,
  - Scope,
  - Term and definitions,
  - General principles,
  - Categorisation and assessment of changes
    (which includes categorisation of changes, flowchart for categorisation of changes, reporting of changes, UDI-DI triggers, and non-significant changes not subject to change management)
  - Bundling of changes
    (Single or Multiple Type of Changes Under a Single Application, Single or Multiple Type of Changes Under Multiple Applications)
  - Updates to Registered Device Information Prior to Re-Registration
  - Predetermined Change Control Plan (PCCP) of SaMD
  - Replacement Reagent and Instrument Family Policy
  - Change Management Fees
  - Turn Around Time
  - Annexes (Flowchart General Type of changes,
    Flowchart Categorisation (significant/non-significant) based on Type Changes, and
    Table Examples of Changes with Required Supporting Documentation)



Malaysia Change Management Guidance Document

- The **Change Management (CM) process** applies to:
  1. Any changes to a registered medical device; or
  2. Updates arising from post-market issues, including reportable incidents and field corrective actions; or
  3. Updates to information or documents required in preparation for re-registration.
- **Categorisation of changes**:
  1. Significant change: Any change that could reasonably be expected to affect the safety and/or performance/effectiveness of a medical device or its conformity with the essential principles
  2. Non-significant change: Any change that has little or no potential to affect the safety and/or performance/effectiveness of the medical device
- **Type of changes**:

Type of Changes
Changes in Manufacturing Processes, Facility and/or Quality Management System (including QC) for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Changes in Design for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Changes to Sterilisation Facility and its Process
Changes to Software for Medical Devices
Changes in Materials for Medical Devices
Changes in Materials for In Vitro Diagnostic (IVD) Medical Devices
Changes to Labelling of Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Changes to Registered Medical Devices and In Vitro Diagnostic (IVD) Medical Devices registration information

Malaysia Change Management Guidance Document

- **Reporting of changes**

Type of Changes	Submission Approaches
Significant Change	Changes that require evaluation and approval by the MDA prior to implementation and before the device is placed on the market.
Non-Significant Change – Notification Required	Changes that may be implemented immediately upon submission of complete documentation through MeDC@St.
Non-Significant Change – Notification Optional	Changes that do not require submission; however, the manufacturer may submit a notification voluntarily.
Non-Significant Change	Changes that do not require submission but must be fully documented within the manufacturer's QMS and/or technical documentation.

- **Change to the Approved PCCP for SaMD**

Any subsequent change to the approved PCCP (that was submitted during the initial premarket review) within the allowable change boundaries must be submitted to the MDA through a change management application to ensure that the revised PCCP remains appropriate, scientifically justified, and consistent with the device's intended use and risk classification.

- **UDI-DI Triggers**

Specific changes or events in a medical device's characteristics, labelling, or packaging that necessitate the assignment of a new UDI-DI. When a change to a registered medical device results in the need for a new UDI-DI, the manufacturer shall determine whether a Change Management application or a new pre-market submission is required, in accordance with the applicable regulatory requirements.

Change Management (CM) Framework: Change to Registered Medical Device

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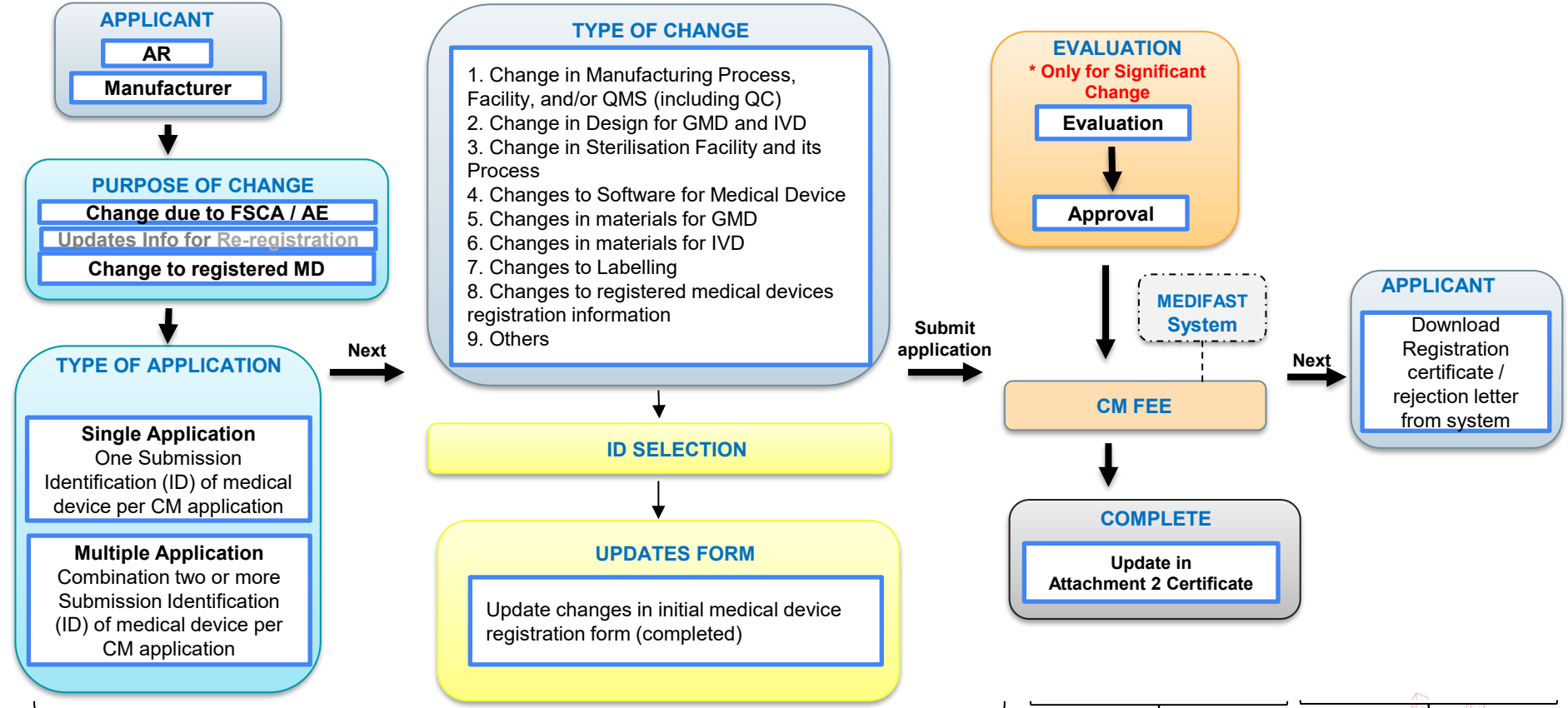

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Positive Impact on CM Application

- **Reduce regulatory costs**

MDA will implement a new approach for the Change Notification Framework that will reduce the regulatory cost. Changes to registered medical devices will be categorised as significant and non-significant changes according to the impact on the safety and performance of the medical device. Most of the change notification Category 2 and Category 3 will be categorised under non-significant change and do not require submission to the MDA. This approach will be significantly reduce the regulatory cost, and the changes can be implemented immediately for market access.

- **Patients' earlier access to new technologies and treatments**

Structured change management helps companies integrate new technologies and innovations into their product development and manufacturing processes more effectively, driving innovation and keeping them competitive

- **Eliminating or reducing differences between jurisdictions.**

Encourage harmonization initiatives between the regulatory authorities with a global approach.

- **Enhanced Regulatory Compliance**

By managing changes systematically, companies can more easily adapt to new healthcare regulations and keep their products compliant with legal requirements, reducing the risk of non-compliance

- **Increased Establishment Operational Efficiency**

Streamlined processes and the adoption of new technologies like Industry 4.0 can automate tasks, improve workflow, and boost productivity, making operations more cost-effective

Thank You!

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Bridging Regulatory Divergence: Strengthening Reliance for Product Lifecycle Changes

Alex Budiman

VP, Quality Management & Regulatory Affairs (Greater Asia)

Becton Dickinson and Company

GMTA/DITTA

Operationalizing the Product Lifecycle: The Volume of Change

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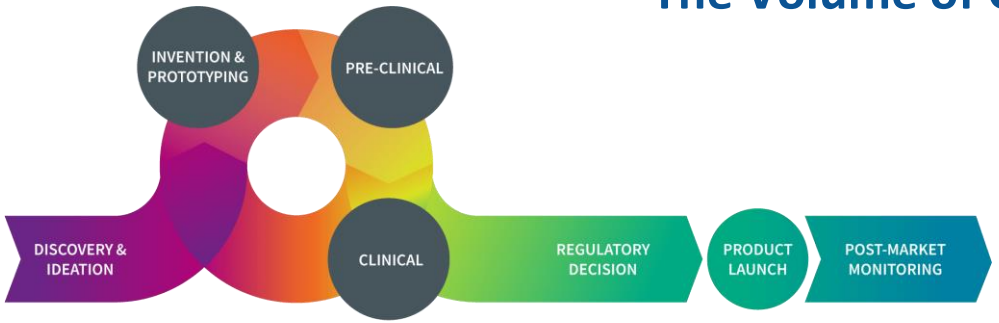
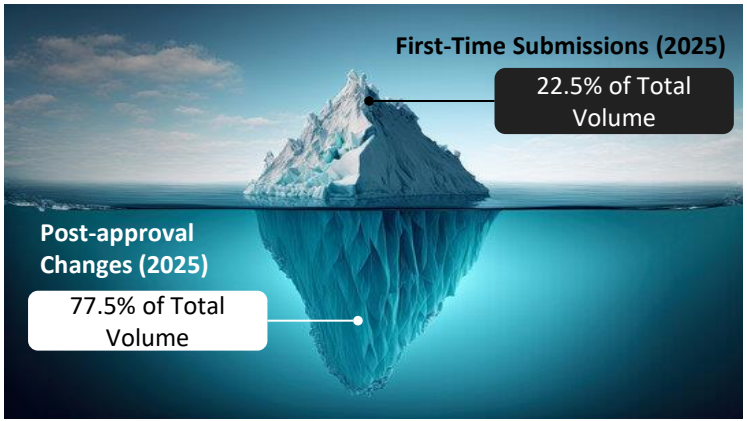


Medical Device Total Product Lifecycle[1]



2025 BD Greater Asia Submissions Overview[2]

Common Change Types

Manufacturing & Supply Chain
Supplier Changes
Site Transfers
Process Automation

Design & Materials
Material Changes
Component Obsolescence
Software Patches

Labeling & Quality
IFU Updates
Shelf-Life Extension
Standard Updates

All Post-approval Changes
High Volumes & Diverse

Regulatory Triage & Classification

Regulatory Actions

Technical File / Submission Dossier Update → Submission to Health Authority → Submission Types
- Notification / Filing
- Minor/Major Change Submission

→ Health Authority Reviews

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Note:
[1] MDIC, What is the TPL? Retrieved from Modeling Patient Engagement Throughout TPL - Medical Device Innovation Consortium
[2] BD (2026), BD Greater Asia Submissions Overview. Retrieved from BD RIM System.

The Challenge:
Divergence Change Submission Pathways for Identical Changes

Component Raw Material Change
Change that does not affect device safety, performance and efficacy

Jurisdiction A
(Risk-Based Approach)

Change Classification:
Minor Change

Submission Pathway | Review Process
Notification/Annual Report | “File and Use”/admin check

Rapid Implementation (~30 days):
Supply Continuity

Jurisdiction B
(One-Size-Fits-All Approach)

Change Classification:
Major Change

Submission Pathway | Review Process
Change submission/application | Full Technical Review

Significant Delay (9 – 12 Months):
Supply Risk, Dual Inventory

Impact: Fragmented global implementation creates inefficiency and delays

The Path Forward:
Strengthening Reliance to Enhance Resilience and Access

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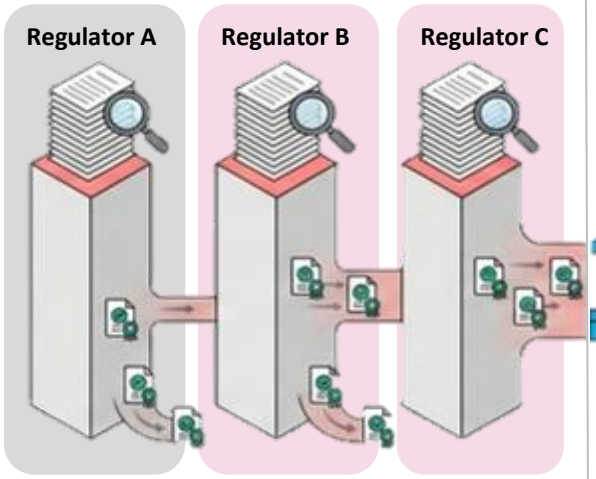
Current State:
Repetitive, Siloed Reviews

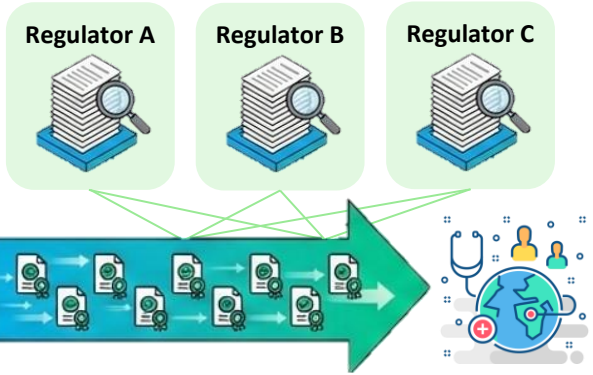


High Admin Burden, Duplicative Effort

The Way Forward:
Reliance

- Trusted Peer Reviews
- Shared Technical Data
- Consistent Standards

Future State:
Strengthened Reliance Across Product Changes



- Focus on High-Risk / Novel
- Supply Chain Resilience
- Faster Patient Access

Outcome: Enhanced Global Safety & Timely Access for Patients

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Thank You!

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Using Alignment In Product Changes To Strengthen Reliance

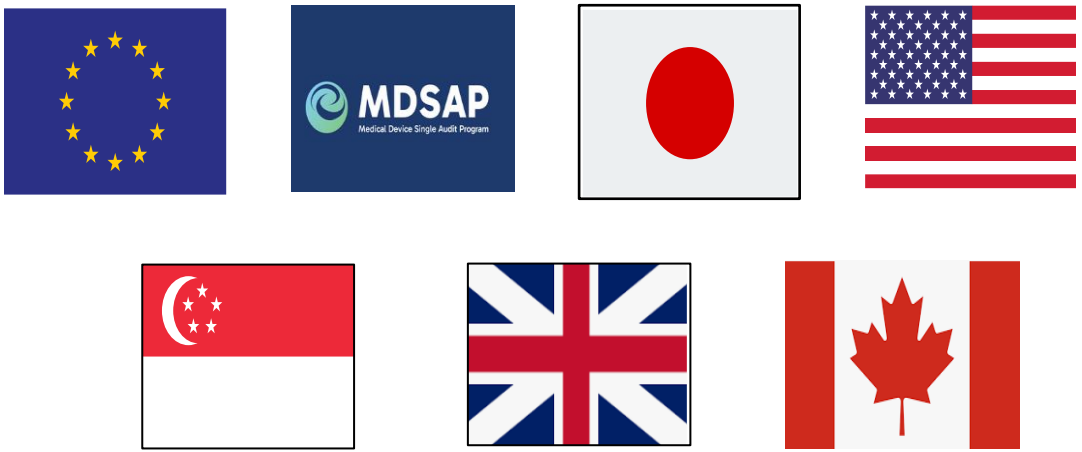
Jasjit Baveja

Director, Regulatory and Industry Policy

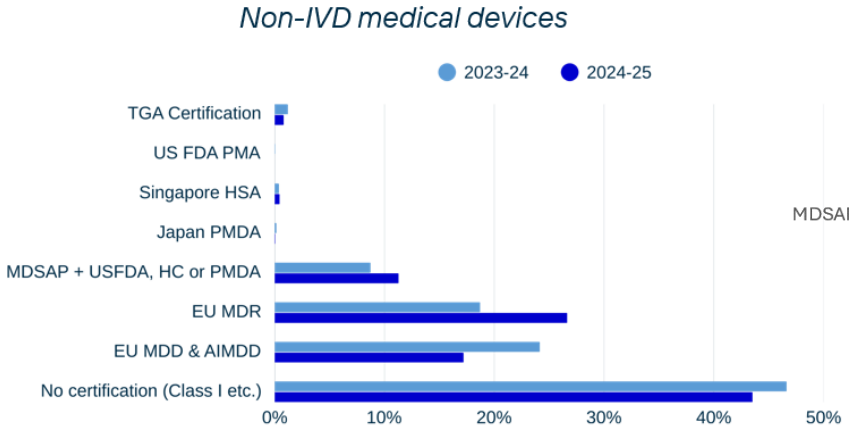
Medical Technology Association of Australia

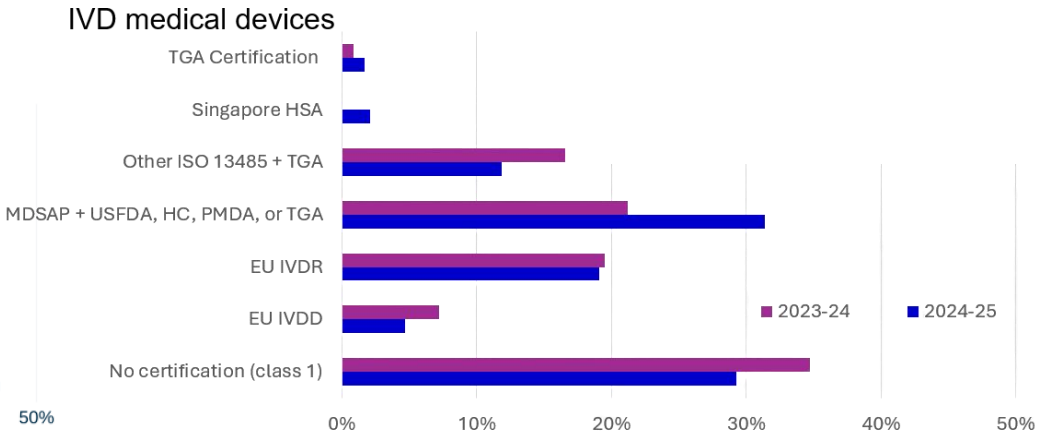
Recognition Based Reliance Frameworks

1. Recognising decisions made by a list of reference regulators
2. Mutual Recognition Agreement (MRA)

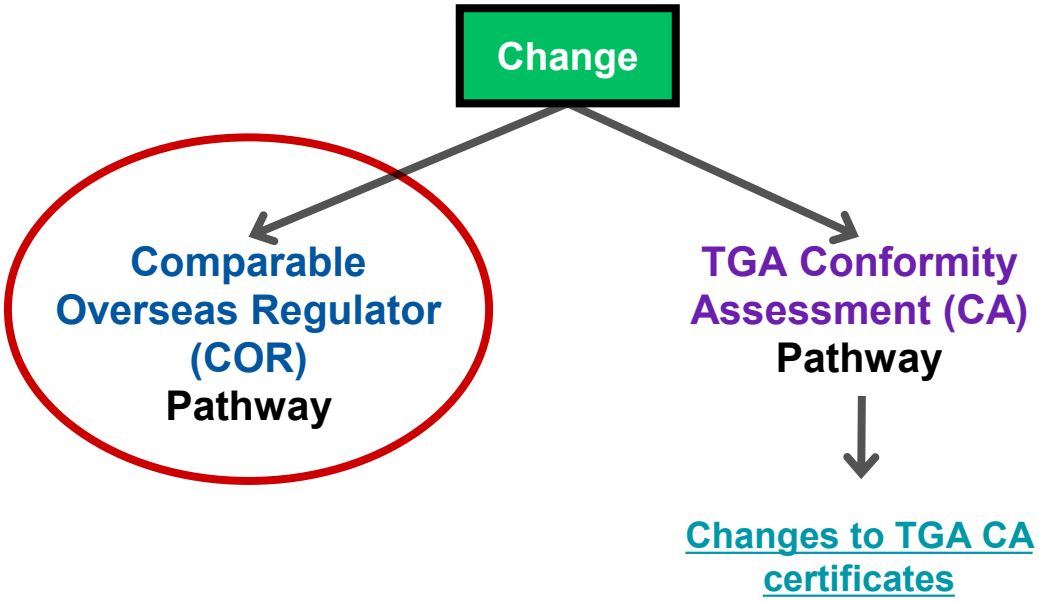


Reliance on Comparable Overseas Regulators – Pre-market





Management of Product Changes – Comparator Overseas Approval

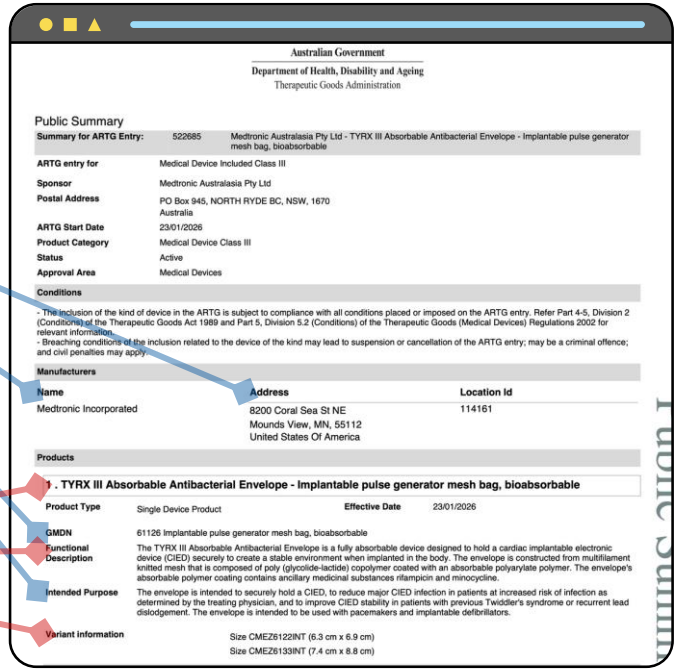


Management of Product Changes – Comparator Overseas Approval

All Products
- Manufacturer name and address
- GMDN Code
- Intended purpose

Change Request/Notification Triggered

Classification Dependent Changes
- Class III MD: Unique Product Identifier (Product Name), Product Variant Range, Total Number of Devices, Functional Description
- Class 4, Class 3, Self Testing and PoC IVDs: Product Name



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	522685	Medtronic Australasia Pty Ltd - TYRX III Absorbable Antibacterial Envelope - Implantable pulse generator mesh bag, bioabsorbable
ARTG entry for	Medical Device Included Class III	
Sponsor	Medtronic Australasia Pty Ltd	
Postal Address	PO Box 945, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	23/01/2026	
Product Category	Medical Device Class III	
Status	Active	
Approval Area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Location Id
Medtronic Incorporated	8200 Coral Sea St NE Mounds View, MN, 55112 United States Of America	114161

Products

1 . TYRX III Absorbable Antibacterial Envelope - Implantable pulse generator mesh bag, bioabsorbable

Product Type	Single Device Product	**Effective Date**	23/01/2026
GMDN	61126 Implantable pulse generator mesh bag, bioabsorbable		
Functional Description	The TYRX III Absorbable Antibacterial Envelope is a fully absorbable device designed to hold a cardiac implantable electronic device (CIED) securely to create a stable environment when implanted in the body. The envelope is constructed from multifilament knitted mesh that is composed of poly (glycolide-lactide) copolymer coated with an absorbable polyarylate polymer. The envelope's absorbable polymer coating contains ancillary medicinal substances rifampicin and minocycline.		
Intended Purpose	The envelope is intended to securely hold a CIED, to reduce major CIED infection in patients at increased risk of infection as determined by the treating physician, and to improve CIED stability in patients with previous Twiddler's syndrome or recurrent lead dislodgement. The envelope is intended to be used with pacemakers and implantable defibrillators.		
Variant Information	Size CMEZ6122INT (6.3 cm x 6.9 cm) Size CMEZ6133INT (7.4 cm x 8.8 cm)		

ARTG Listing Example

Management of Product Changes – Comparator Overseas Approval

Administrative Changes

- Manufacturer name or address
- GMDN

Typically approved with minimal review

Technical & Clinical Changes

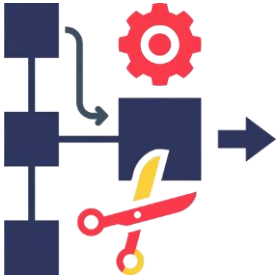
- Indication expansions
- Product variants
- Design features
- Software versions
- MR safety status

May trigger additional TGA assessment

Device Change Request Working Group

TGA/Industry working group to review change management process through COR pathway

Working towards better clarity on documentation requirements and improved timelines



Simplify and streamline process

Thank You!