IMDRF International Medical Device Regulators Forum

Medical Device Authority
Ministry of Health Malaysia

AFFILIATE MEMBER UPDATES: MEDICAL DEVICE AUTHORITY, MALAYSIA

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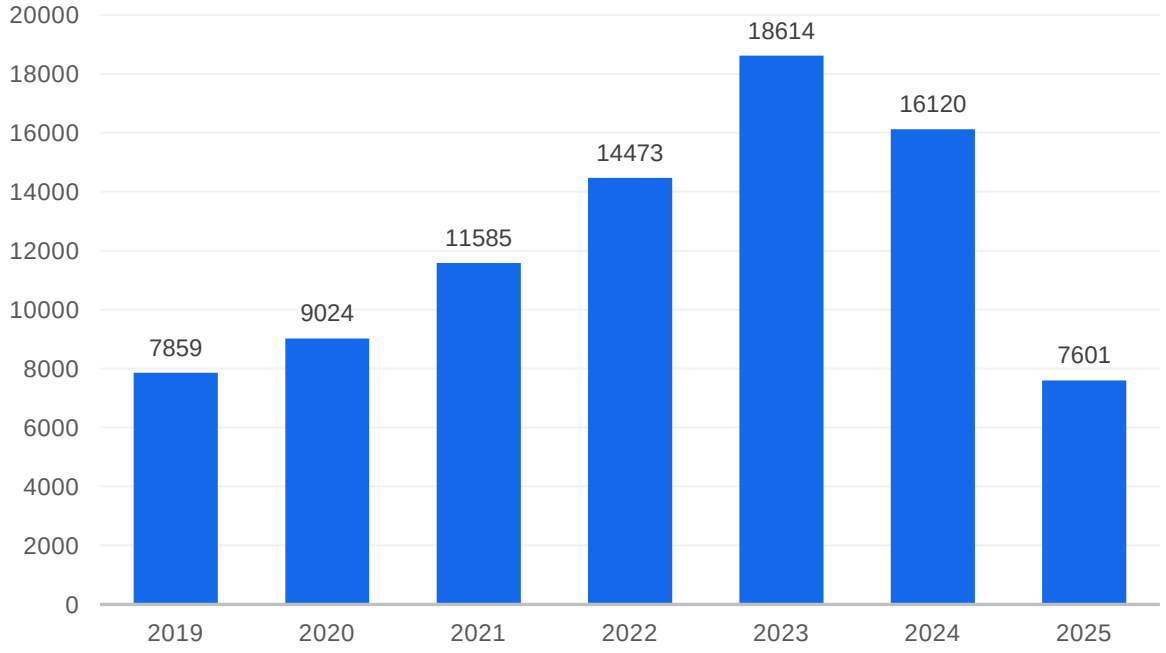
16 September 2025

Presentation Outline

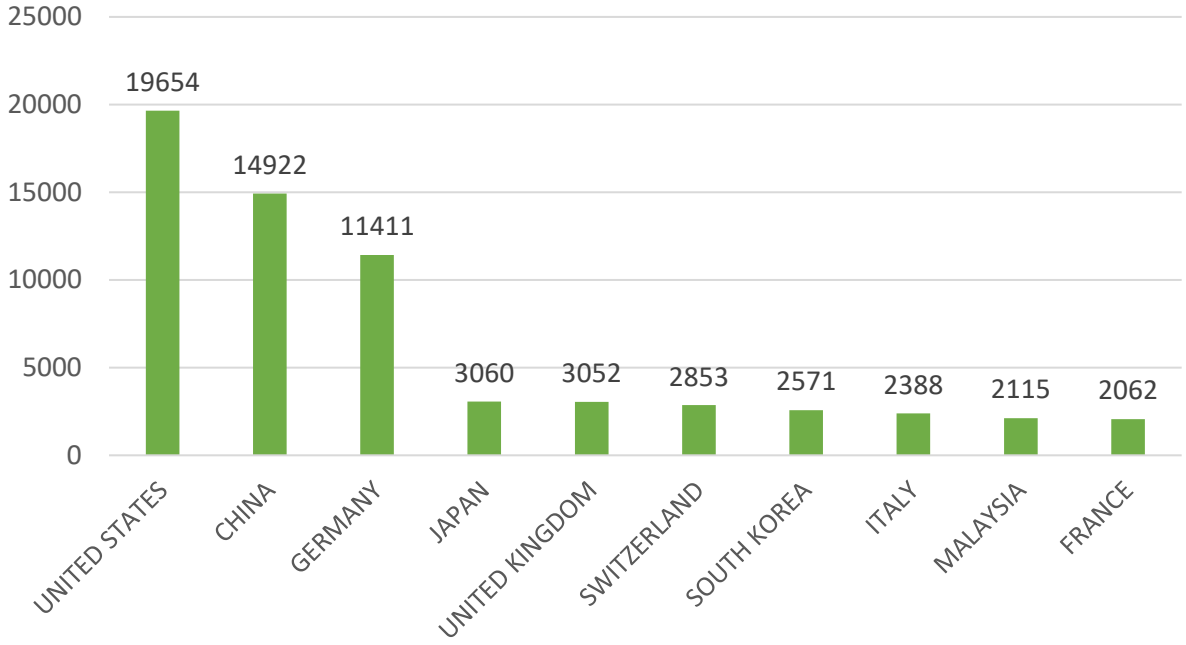
- Landscape Medical Device Registration in Malaysia
- Reliance Initiatives
- New Approach on Change Management

Landscape Medical Device Registration in Malaysia (2019 – 2025)

Total of Application Received by MDA

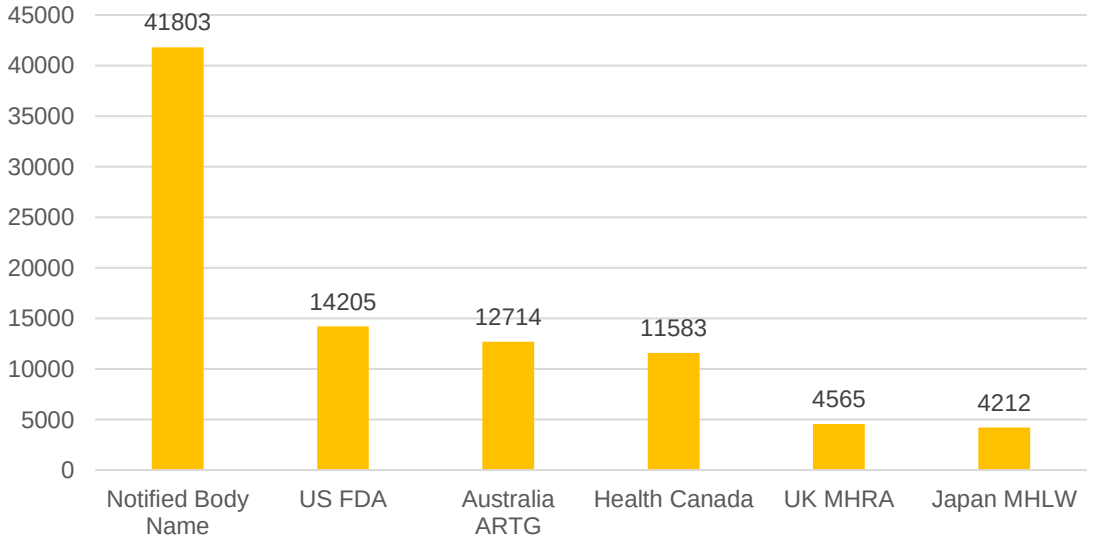


Total of Application Received By Country

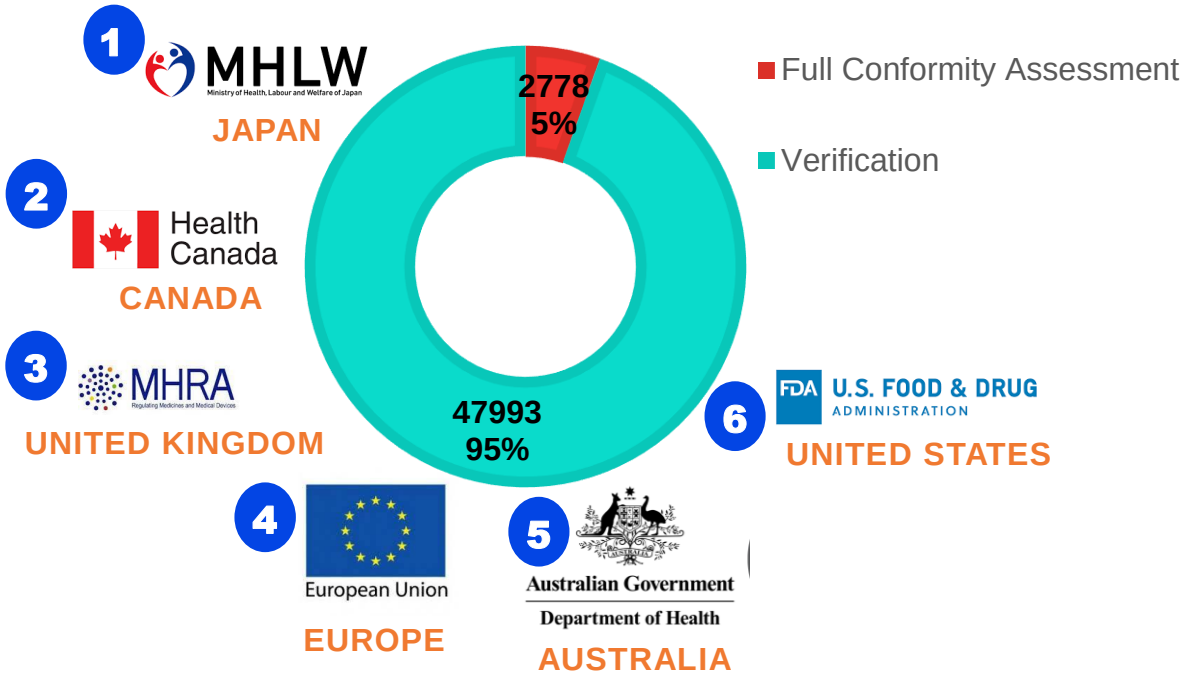


Landscape Medical Device Registration in Malaysia (cont'd)

Type of Approval/ Certification Received

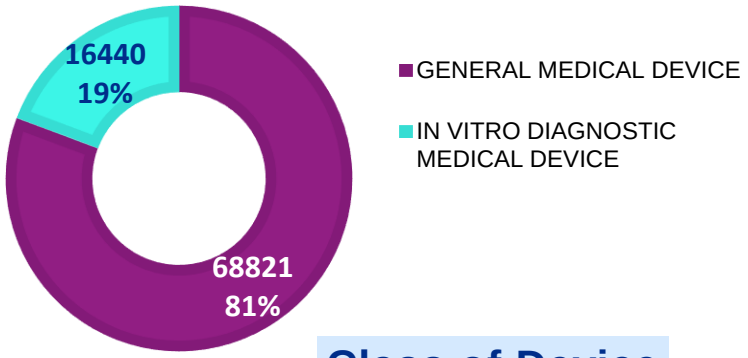


Verification vs Full Conformity Assessment

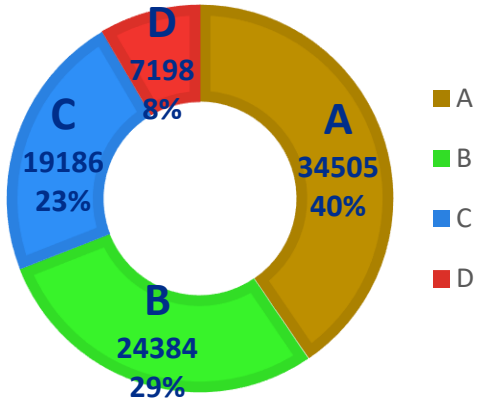


Landscape Medical Device Registration in Malaysia (cont'd)

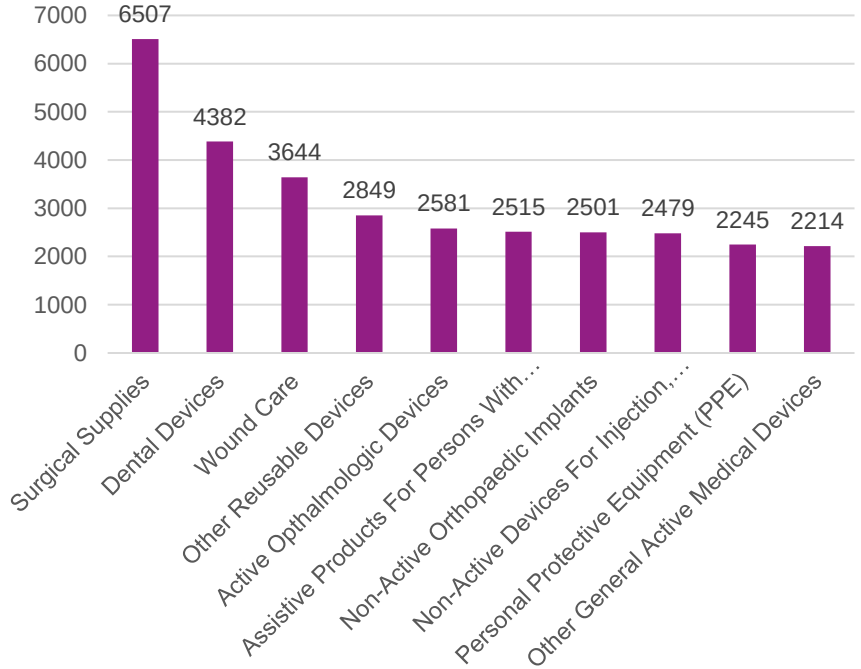
Medical Device Category



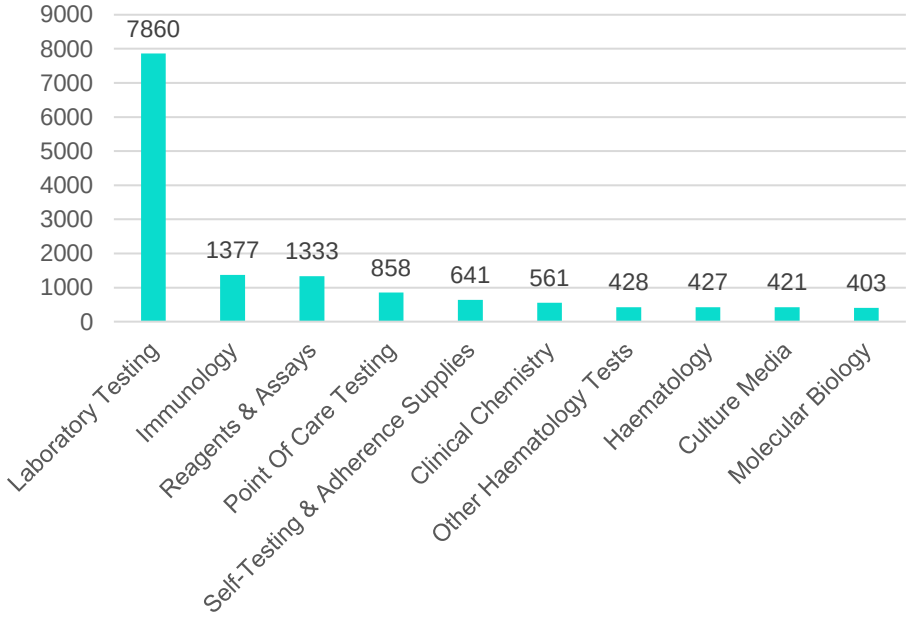
Class of Device



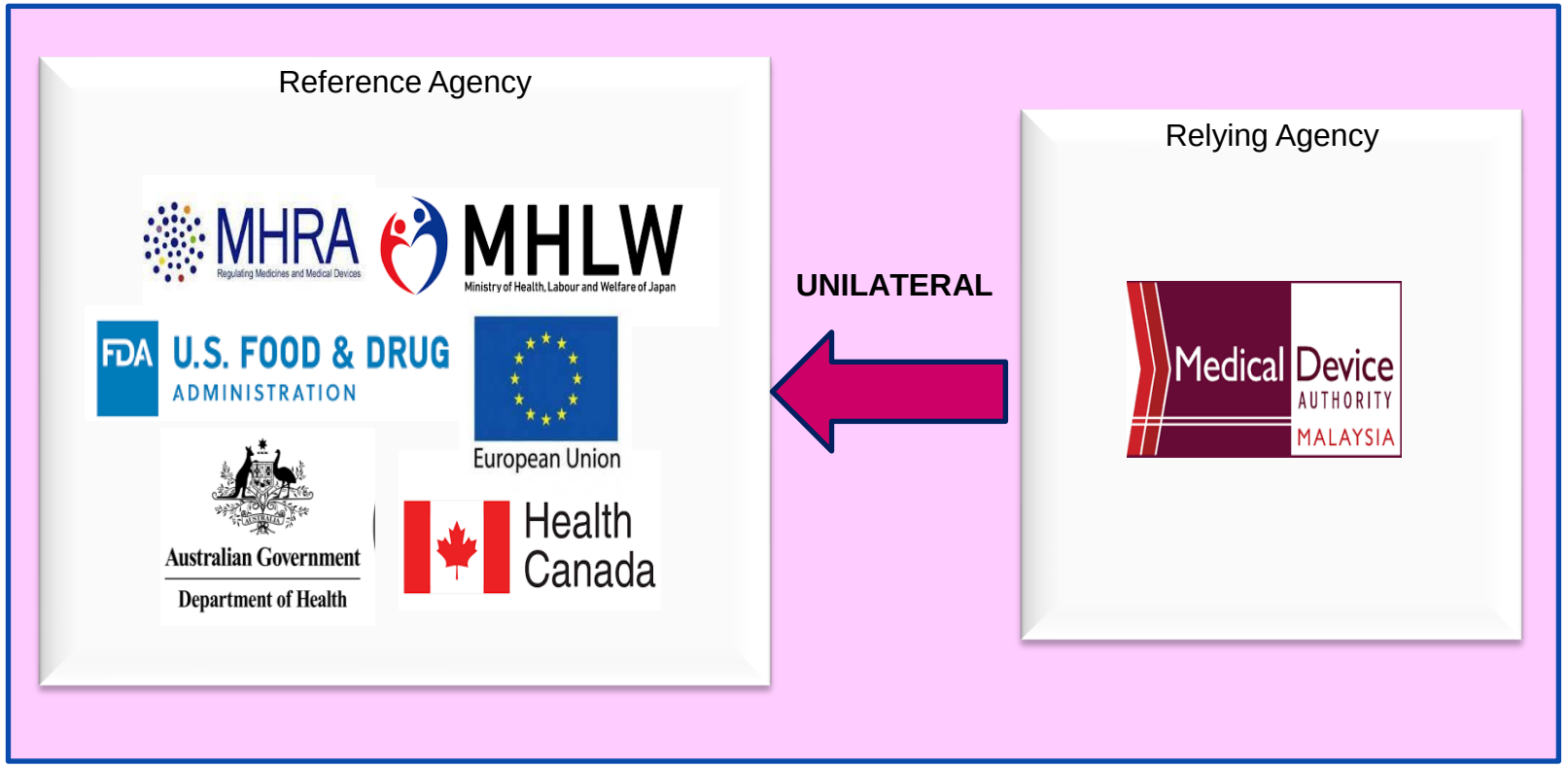
Type of General Medical Device



In Vitro Diagnostic Medical Device



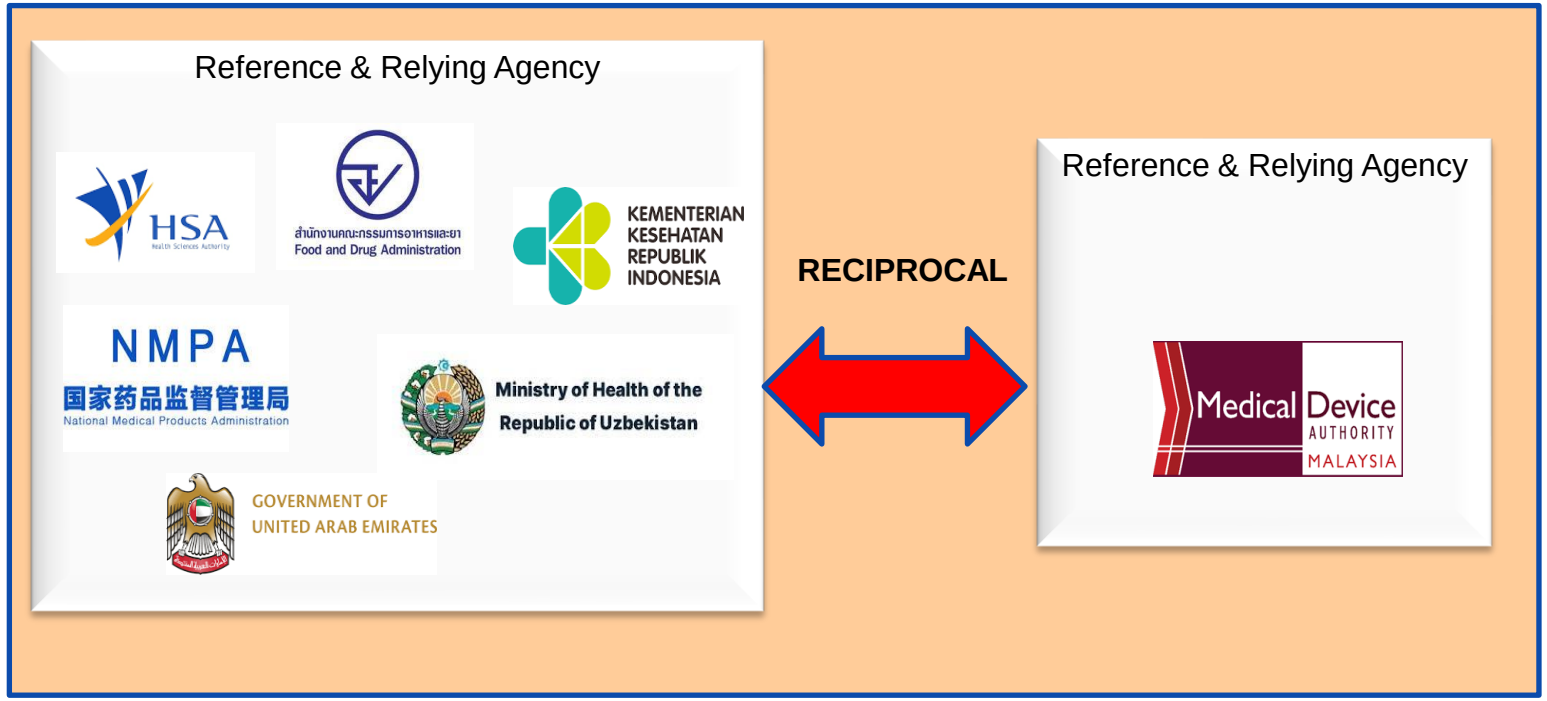
Reliance Initiatives (Current) : Unilateral



Reference:

Circular Letter of MDA No1 Year 2025 – Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

Reliance Initiatives (Current) : Reciprocal



Reference:

1. *Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase I)*
2. *Malaysia And Singapore Sign Memorandum Of Understanding And Launch Medical Device Regulatory Reliance Pilot To Fast Track Medical Device Market Access*

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Medical Device Regulatory Reliance Programme in Malaysia (MDSAP)

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Change Management (CM) - Malaysia

- A streamlined regulatory approach that enables faster implementation of changes to registered medical devices—especially pre-approved software updates for Software as a Medical Device (SaMD)—based on the manufacturer's proven quality management systems.
- This new framework allows manufacturers to make certain "pre-specified" changes to SaMD after registration without needing to submit a full change notification each time. Instead, they rely on their robust quality management practices—such as ISO 13485 and IEC 62304 compliance—to ensure safety and effectiveness throughout the product's lifecycle
- The framework draws upon the GHWP Guidance Document on Change Management and has been customized to align with Malaysia's regulatory requirements and implementation context.

Type of Changes

1. Change in Manufacturing Process, Facility, and/or QMS (including QC)
2. Change in Design for GMD and IVD
3. Change in Sterilization Facility and its Process
4. Changes to Software for Medical Device
5. Changes in materials for GMD
6. Changes in materials for IVD
7. Changes to Labelling
8. Changes to registered medical devices registration information
9. Others

Change Management (Improvement from current practice)

No	Area	Current	Future
1	Title	Change Notification	Change Management
2	Classification of Change Category	Three Category: Category 1 – New registration application Category 2 – Major Change Category 3 – Minor Change	Two Category: Significant Change – affect safety and/or performance of MD Non-Significant Change - not affect safety and/or performance of MD **Auto generated by the system based on the changes made to the related section in the form*
3	Reporting of Changes	All category of change shall be reported to MDA	Significant changes – Reported to MDA for review & approval before implementation of change Non-Significant Change – Not reported to MDA. Change to be recorded in QMS / Technical documentation of medical device Non-Significant Change (required notification) – Notification to MDA. Can be implemented immediately upon submission
4	MDA Approval	For all types of change	Only for Significant change
5	Form and Documents	Changes not reflected in the initial registration form Summary table of change - manually upload in the system Change Declaration of Safety and Performance - manually upload in the system	Changes updated in the initial medical device registration form Summary table of change – Info retrieved from the system Change Declaration of Safety and Performance - provided in the system
6	Bundling of Changes -Multiple device ID	Multiple submission id only limited to - Change in manufacturer name and address Change in manufacturing site name and address Change in sterilisation site name and address Change in QMS information	Additional Multiple submission id for: Change in brand / proprietary name Change in labelling- e.g.EU MDR symbol, AR info
7	FSCA Related Changes	Cannot identify FSCA related change application	Can Identify FSCA related change application in system

Positive Impact of the New Approach on CM

- **Reduce in regulatory cost**

MDA will implement new approach for Change Notification Framework that will reduce in the regulatory cost. Changes to registered medical device will be categorised as significant and non-significant change 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 required submission to the MDA. This approached will be significantly reduced in 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 initiative between the regulatory authorities which in line with GHWP guidance

- **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

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Thank you/Questions

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