IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

10:10 – 10:25

Singapore

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IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority, Singapore

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28 March 2023

Revocation of Exemption implemented to manage COVID-19 pandemic

On 31 January 2020, an exemption order to enable **import, wholesale and supply** for **specified medical devices** to facilitate access during the pandemic was implemented:

- Exemption order was applicable to the following lower risk medical devices:
  - Surgical masks, medical masks;
  - Particulate respirators e.g. surgical N95 masks;
  - Thermometers for measuring body temperature; and
  - Any protective gear for medical professionals e.g. isolation gowns and gloves

As of 1 September 2022, the Exemption Order 2020 has been revoked.

- All standard regulatory controls would apply to medical devices that were previously exempted.
- Allowed for **retail supply** of these medical devices that were imported before 1 September 2022.

COVID-19 Tests - Transition from Special Access to Full Registration

Pandemic Special Access Route (PSAR)

Validity extended till **30 Jun 2023** for **21** essential COVID-19 tests
Authorisation lapsed on **31 Dec 2022** for **13** COVID-19 tests

Full Registration

29
Approved

This includes the following product categories:


COVID-19 Self-Test Kits


COVID-19 Diagnostic Tests

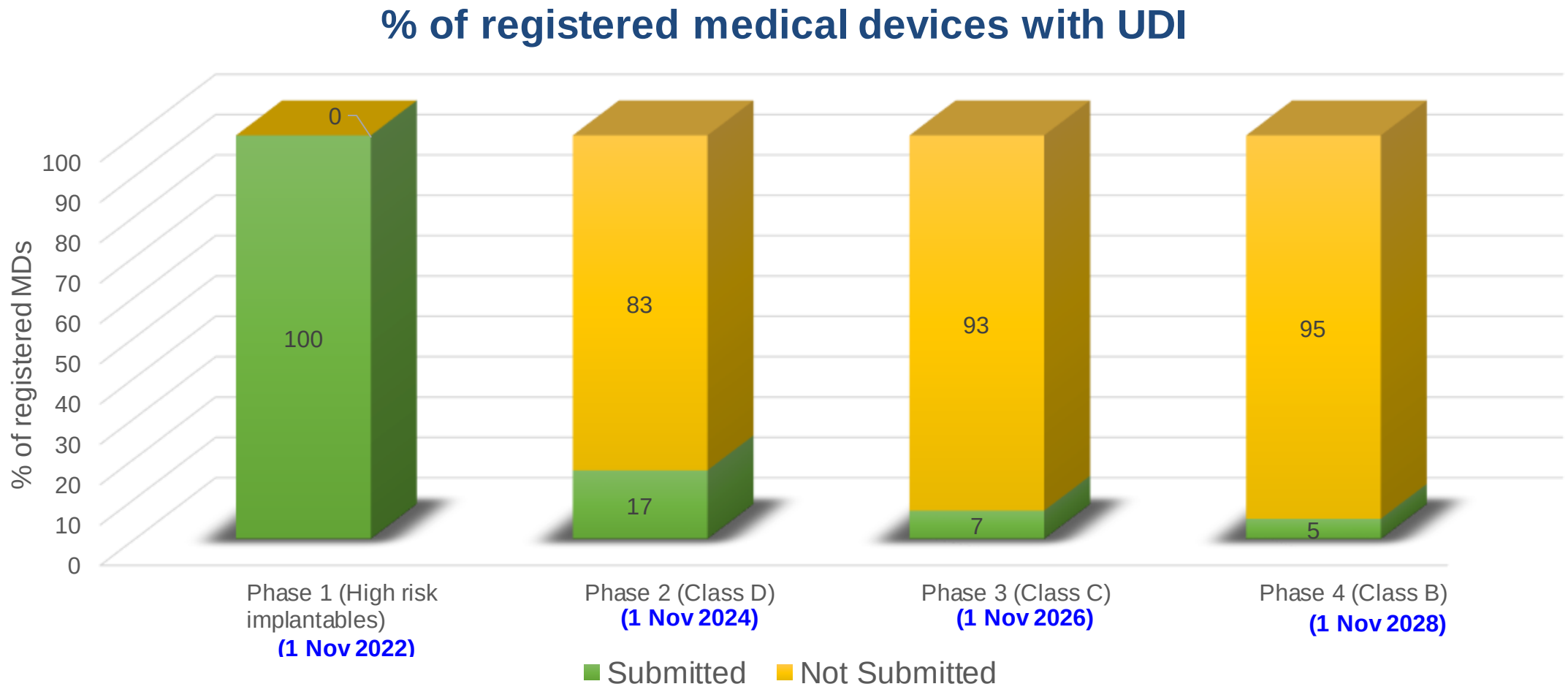
To facilitate transition to full registration, published a guide - Validation Requirements for Product Registration of COVID-19 Diagnostic Tests – Self-Tests on the key validation requirements for **full registration.**

Progress of UDI Implementation

- UDI implementation has commenced with Phase 1 on 1 November 2022
  - From 1 Nov 2022, selected high risk MDs, i.e, all coronary stents, orthopaedic joint replacement implants and Intraocular lens (IOLs) to be supplied in Singapore are required to be labelled with UDI and respective companies to submit UDI related information to HSA
  - Adopting a least burdensome approach to accept the UDI barcodes as is that manufacturers have applied on their MD labels for the USA and/or EU
  - For MDs not marketed in the USA and EU, companies are required to implement UDI for Singapore based on requirements published in HSA's guidelines
  - All MDs imported into Singapore are required to be UDI compliant from the compliance date stipulated for each phase (e.g. 1 November 2022 for Phase 1 MDs)
  - Additional 6 months from the compliance date is provided for companies to deplete the stocks that have been imported prior to the compliance date and are in their current supply chain

Progress of UDI implementation - Phases 1 to 4

- 100% of implants under Phase 1 have complied with UDI requirements
- HSA has been working with industry stakeholders to kickstart the subsequent phases of implementation on a voluntary basis. See status below:



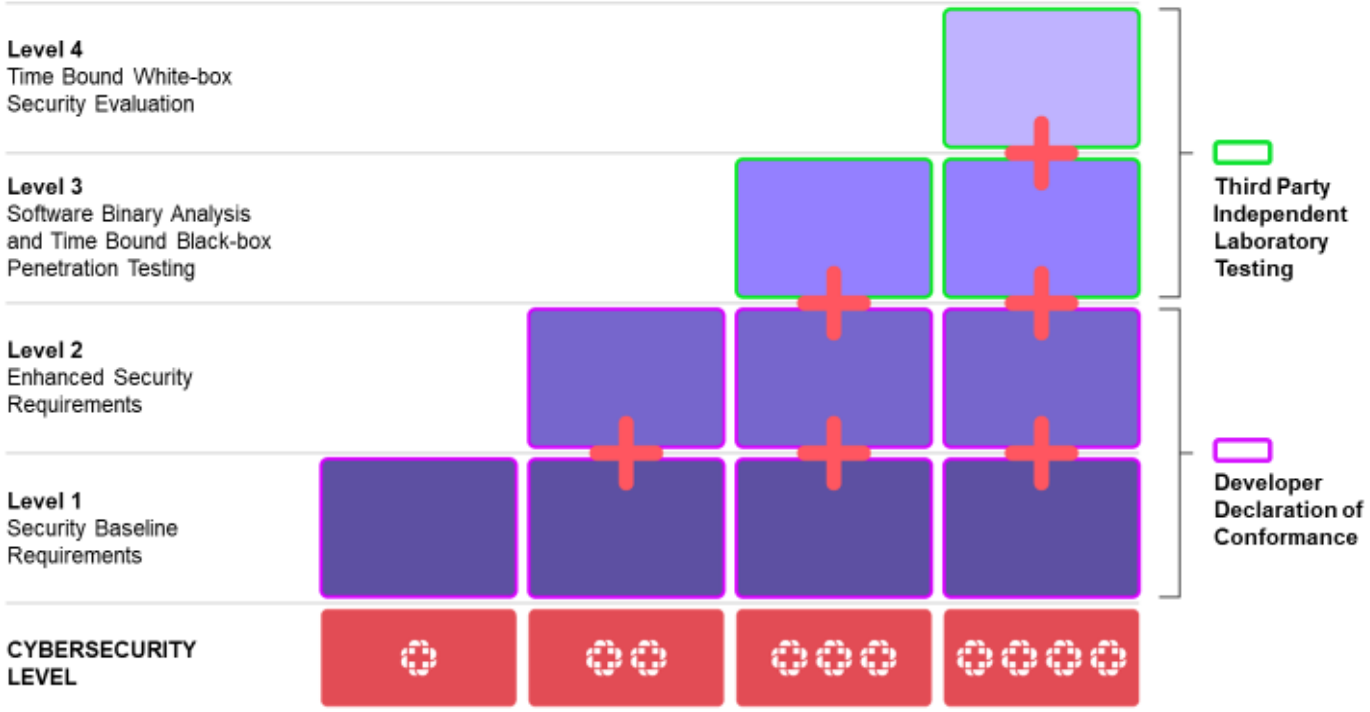
Cybersecurity Labelling Scheme for Medical Devices – CLS (MD)

AIM: Enable healthcare purchasers to make informed decisions towards buying more secure devices; thus elevating the usage of cyber secure medical devices.

Cybersecurity Labelling Scheme FOR MEDICAL DEVICES

- The CLS (MD) is a joint initiative developed by the Ministry of Health (MOH), Cybersecurity Agency of Singapore(CSA), Integrated Health Information Systems (IHiS) and the Health Sciences Authority (HSA)
- To improve the visibility of cybersecurity status of medical devices (MDs) in Singapore to enable users to make informed choices in buying/procuring their MDs
- To encourage the embedding of a higher tier of cybersecurity measures into MDs, which will be beneficial for **patient health, safety and privacy**

CLS-MD Framework



Levels	Descriptions
1 +	Manufacturers to meet the existing mandatory HSA requirements that are internationally aligned
2 ++	Manufacturers need to meet the enhanced security requirements titrated from MDS2, Post-market policies and existing CLS standards.
3 +++	The software of the medical device (i.e., firmware, mobile applications if available) undergo automated binary analysers to ensure no known critical software weakness, vulnerabilities or malware. **&** The device will also undergo a timebound black-box(1) penetration testing to provide basic level of resistance against common cybersecurity attacks.
4 ++++	The device undergoes a timebound white-box(2) security evaluation to provide higher level of resistance against cybersecurity attacks.

(1) *Black-box penetration test: Evaluator performs testing using only limited information (i.e. only user guidance manuals that is provided with the device).*
(2) *White-box security evaluation: Evaluator is provided with information on the design/implementation of certain security functionalities (i.e. cryptographic functions). With more information, evaluator would be able to devise targeted tests and better assess the security functionalities of the device.*

CLS-MD Scheme

- Applicable to medical devices which can be **connected** to other devices, systems and services and/or have the ability to collect, store, process or transfer personally identifiable information (PII) and clinical data.
- CLS(MD) comprises four cybersecurity levels (1 to 4).
- Currently, connected medical devices are required to meet HSA's cybersecurity requirements, which is **equivalent to the CLS (MD) level 1** requirements, before they are distributed and used locally.
- Obtaining the higher CLS(MD) levels (i.e. 2 to 4) will be voluntary and may involve independent third-party testing
- Labelled devices will be listed in the CLS(MD) product list on the CSA website

Consultation on the CLS (MD) Scheme

Public Consultation commenced in January 2023 and closed on 10 March 2023; Feedback collation and review in progress

Do write to certification@csa.gov.sg should you have queries relating to CLS-MD scheme

Guidance Documents – Key Updates

- Finalised version of the guidelines - Regulatory Guidelines for Laboratory Developed Tests (LDTs) has been published on our website post consultation period
  - Effective 1 March 2023

- Updated guidance on Medical Device Special Access Routes was published
  - Greater oversight on import and use of unregistered medical devices in healthcare facilities for essential clinical needs
  - Additional oversight from MOH on the clinical use of unregistered Class D (highest risk) MDs in public healthcare institutions

- Enhanced the current processes for applications related to changes to registered medical devices and updates to the Guidance Document on Change Notification

- Guidance documents and Guidelines can be accessed online at:

https://www.hsa.gov.sg/medical-devices/guidance-documents

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Thank you/Questions

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