

Regulatory Updates

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Overview

Updates

1. UDI Implementation Progress
2. Change Management Program (CMP)

New Initiatives

3. Medical Device Cybersecurity Guidelines
4. HIV Self-Testing Initiative



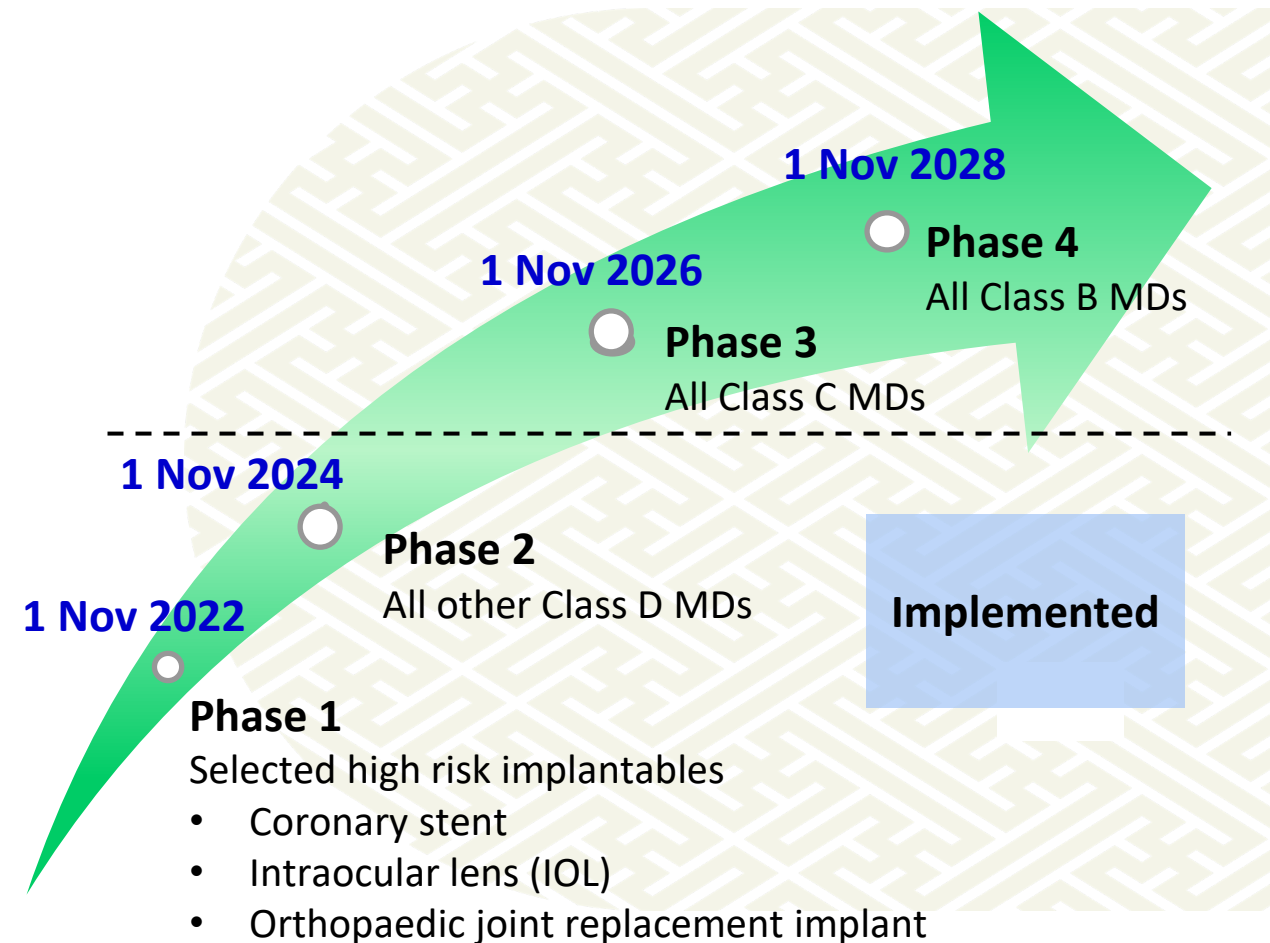


1. UDI Implementation

- Commenced on 1 Nov 2022
- Adopting a pragmatic approach by accepting UDI barcodes that manufacturers applied on their MD for the USA/EU.

For MDs not marketed in these regions, device to comply with HSA's UDI guidelines

- Risk calibrated and phased approach. Not mandatory for Class A MDs

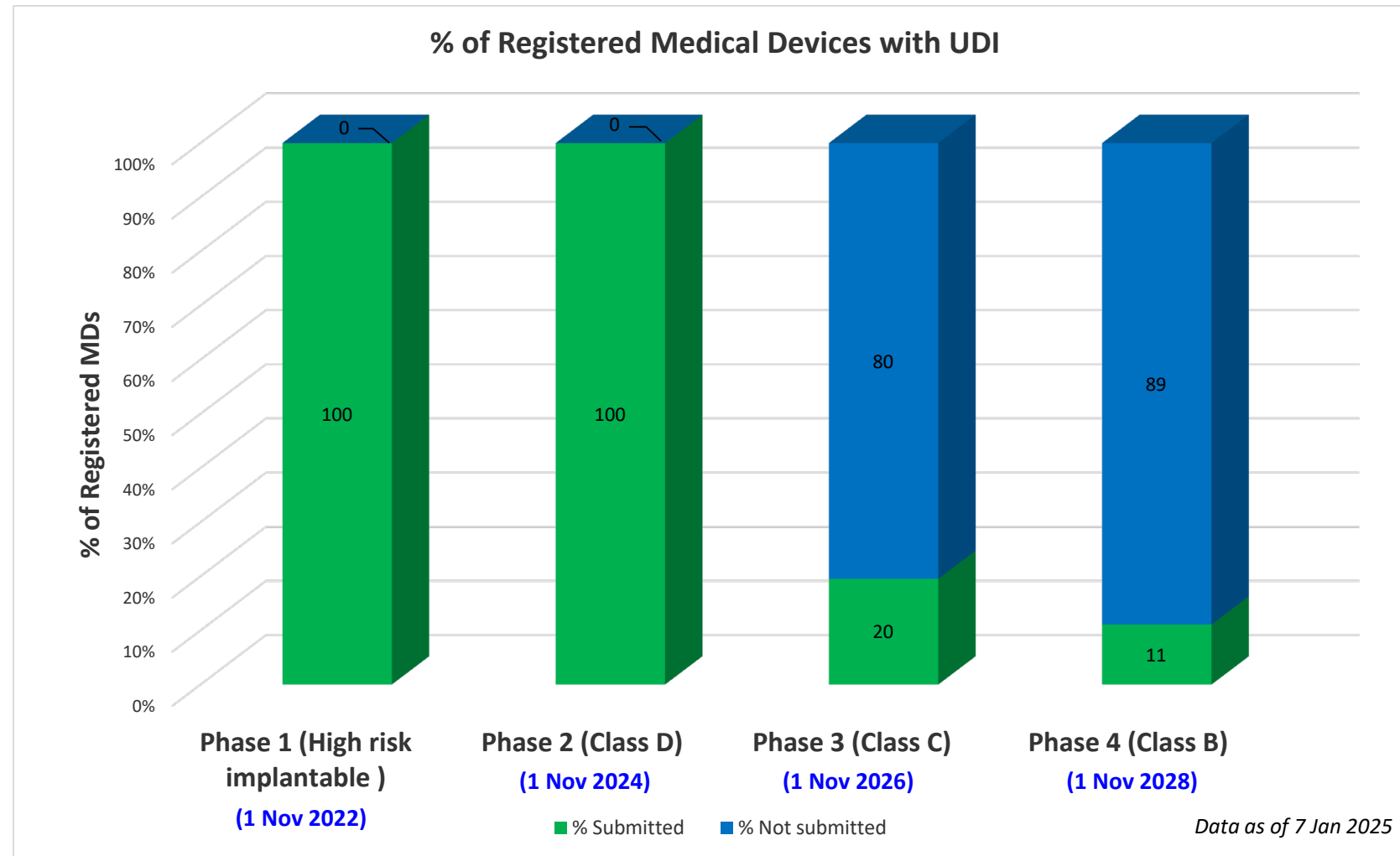




Progress Status

- ✓ Phase 1 (**Completed**)
- ✓ Phase 2 (**Completed**)
- Phase 3 (In Progress)
- Phase 4 (Planned)

Companies to kickstart subsequent phases of implementation on a voluntary basis





2. Change Management Program (CMP)

- A new optional regulatory pathway to facilitate timely implementation of “pre-specified” SaMD software changes post-registration, based on manufacturer’s demonstrated robust quality management practices
- Allows concurrent review of device application and CMP by HSA
- Enables manufacturers to implement approved pre-specified changes without submitting change applications to HSA, requiring only annual declarations of implementation



2. Change Management Program (CMP)

- **Guidance on Change Management Program (CMP) for SaMD, including machine-learning enabled SaMD**

This document has completed consultation. Finalized document published in Dec 2024 can be accessed at

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

- Future plan – CMP will progressively extend to other device categories, e.g. software in medical device (SiMD) and IVD





3. New Guidance Document – Best Practices for Medical Device Cybersecurity

- **Target audience:** MD manufacturers (MDMs) & healthcare providers (HCPs)
- This guidelines outline cybersecurity best practices for the development, deployment, and maintenance throughout a MD lifecycle
 - **Pre-market Stage:** covers key concepts e.g. Security by Design, Risk management strategies, Types of security testing, Information for user, Software Bill of Materials (SBOM) use cases and additional consideration for AI-MDs
 - **Post-market Stage:** Provides clarity on the roles of MDMs and HCPs at various stages, i) Support ii) Limited support [between End-of-Life (EOL) and End-of-support (EOS)] and iii) EOS



3. New Guidance Document – Best Practices for Medical Device Cybersecurity

- The principles and approach presented in this document are aligned with the relevant IMDRF documents from the Cybersecurity working group
- Draft guidance will be published for public consultation in Mar 2025



4. HIV Self-Testing Initiative

- Starting **Jan 2025**, HIV self-test kits will be available at selected retail pharmacies nationwide, expanding access beyond clinical settings.
- Shift from clinic-only to wider community access
- Aims to improve community access to HIV testing and encourage early detection, regular screening

Better access to HIV screening with self-test kits at selected pharmacies

ment or offer emotional support, he said.

“I would like to emphasise that self-testing is an additional tool, and it is not a replacement of our broader HIV testing efforts. Visiting a clinic or engaging with community-based testing programmes should remain the preferred method, and these pathways will continue to be available,” he added. He said the Government will work closely with community partners to ensure the kits are used effectively.

MOH said on Nov 30 that the result of a single rapid diagnostic test such as the HIV self-testing kit is not sufficient to make a diagnosis of HIV infection. Individuals who test positive should receive further confirmatory testing from a healthcare provider and be referred for treatment.

If the test result is negative but the individual has had a recent unprotected sexual exposure or is at a higher risk of HIV infection, it may take up to three months to develop antibodies to HIV that will be detected on the testing kits. Repeat HIV testing is advisable.

MOH and the Health Promotion Board recommend that every adult should get tested at least once in their lifetime, regardless of risk factors. Individuals who engage in high-risk sexual behaviours should go for regular HIV testing every three to six months.

“HIV can be treated effectively with modern HIV medicine or antiretroviral therapy. With early and effective treatment, people living with HIV can lead lives no different from others,” said the ministry.

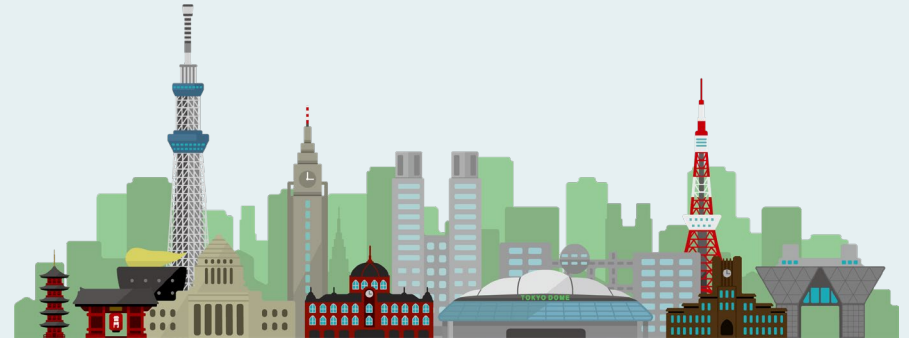
209 new HIV cases in Singapore in 2023, with total number of infections at 9,540

Shermaine Ang

HIV self-testing kits will be available for sale at selected Guardian and Watsons pharmacies by the end of January 2025, as part of efforts by the Ministry of Health (MOH) to encourage regular test-

\$21.85. The kits will have an oral swab for detecting the body's natural antibodies, and results can be obtained after at least 20 minutes.

Dr Janil said the 95-95-95 targets set by the Joint United Nations Programme on HIV/Aids aim to have 95 per cent of people living with HIV know their diagnosis, 95 per



Thank you
