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# Cybersecurity Labelling Scheme for Medical Devices

BY CYBER SECURITY AGENCY OF SINGAPORE

## ***Updates to Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)] Sandbox***

As announced at the Singapore International Cyber Week 2023 in Oct 2023, the Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)] Sandbox is currently open for applications.

Manufacturers are invited to participate in the Sandbox by putting their medical devices through the different level of assessments and processes, such as the declaration of conformity against the baseline/enhanced security requirements, software binary analysis, penetration testing, and security evaluation. Participating manufacturers will enjoy a first-mover advantage in getting a CLS(MD) label at the launch of the scheme when the application meets the respective scheme level requirements and can also provide feedback on the scheme requirements and application processes. The feedback will be useful for the team to refine the requirements and/or operational workflow of the scheme.

Since the launch of sandbox in Oct 2023, the CLS(MD) scheme have received more than 20 applications, with the majority in CLS(MD) Levels 1 and 2. We have since completed preliminary review of the 13 Level 1 applications and comments sent out to the company applicants to address them.

The Sandbox is planned to run for nine months and will complete on 20 July 2024. Considering the duration needed to assess and complete each application (especially Levels 3 and 4), we would like to take this opportunity to strongly encourage all interested applicants to submit your applications soonest, particularly so if you want to submit for CLS(MD) Levels 3 and 4. We greatly value your support and active participation and applications. More details on the CLS(MD) Sandbox can be found at <https://www.csa.gov.sg/cls-md-sandbox>. For further enquiries, you can email to us at [cls\\_md@csa.gov.sg](mailto:cls_md@csa.gov.sg).

**Background: Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)]**

The Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)] is a joint effort from the Ministry of Health (MOH), Cyber Security Agency of Singapore (CSA), Health Sciences Authority (HSA), and Synapse to raise cyber hygiene levels in medical devices.

Under the CLS(MD) voluntary scheme, medical devices are rated according to 4 levels of cybersecurity assessments. The CLS(MD) label aims to improve visibility by providing an indication of the level of cybersecurity provisions and features available in medical devices helping and empowering healthcare organisations and users make informed purchasing decisions.

The scope of CLS(MD) applies to medical devices as described in the First Schedule of the Health Products Act (Cap122D, 2008 Rev Ed) which have any of the following characteristics:

- Handle personal identifiable information and clinical data and has the ability to collect, store, process, or transfer such data; or
- Connect to other devices, systems, and services - Has the ability to communicate using wired and / or wireless communication protocols through a network of connections.

Best regards,

Ministry of Health (MOH), Cyber Security Agency of Singapore (CSA), Health Sciences Authority (HSA), Synapse

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