



IMDRF International Medical
Device Regulators Forum

Regulatory Updates Health Sciences Authority Singapore

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IMDRF

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Launched Online Systems for e-submissions

- A new online system for submission of recalls and field safety corrective actions (FSCA) for medical devices has been launched
 - Enhance ease of reporting and efficiency of follow-ups
- A new module in our online portal for Special Access applications has been launched
 - Submission of applications and approvals are processed online
- Relevant updated guidance documents and training videos have been published on our website



Guidance Documents – Updates

- **Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach**
 - Final Document post consultation has been published on our website in April 2020
 - Consultation included online consultation and focus group discussions with local industry groups
- This document covers the regulatory considerations and requirements applicable throughout the lifecycle of the software medical device
 - Intended as a one stop reference document for developers/manufacturers of software medical devices
- This document can be accessed online at:
<https://www.hsa.gov.sg/docs/default-source/announcements/regulatory-updates/regulatory-guidelines-for-software-medical-devices--a-lifecycle-approach.pdf>



Guidance Documents – Updates

- **Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach: [Key Contents](#)**
 - Quality Management System (QMS) for Software Medical Devices
 - Pre-market registration requirements for Software Medical Devices
 - Software Medical Device Manufacturers and Distributors controls
 - Managing Changes to Registered Software Medical Devices
 - Post-market Management for Software Medical Devices
 - Cybersecurity Requirements
 - Cybersecurity considerations including Verification and Validation, Risk management and on-going surveillance and monitoring
 - Artificial Intelligence Medical Devices (AI-MDs)
 - Regulatory Requirements for AI-MDs including pre-market, post-market and change management requirements
 - Additional considerations for AI-MDs with continuous learning algorithms



Guidance Documents – Updates

- A significant percentage of the registered medical devices distributed in Singapore are from Europe. With the MDR and IVDR implementation, many of these registered medical devices are impacted by the new or updated requirements
 - Changes to the registered medical devices here could include simple labelling updates to more complex changes such as updates to performance characteristics or specifications
 - An interim guideline on the regulatory approach to manage changes to registered medical devices has been drafted
 - Categorising changes based on their significance and the regulatory submission requirements
 - Under consultation with local industry stakeholders
 - To be finalised by Q4 2020



Regulatory Initiatives related to COVID-19: A summary

- Fit for purpose regulatory pathways for COVID-19 diagnostic tests, ventilators, decontamination devices for respirators and other essential medical devices
 - Provisional Authorisation process has been implemented to review these medical devices
<https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation>
- Regulatory flexibility in facilitating access to essential medical devices including respiratory devices, 3D printed medical devices, medical masks, surgical respirators and protective gears
 - Guidelines have been published to facilitate compliance with regulatory requirements and also support local innovation
<https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-regulatory-position-on-respiratory-devices-supply-for-management-of-covid-19-patients>
[https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-3-d-printing-of-essential-medical-devices-and-accessories-for-use-in-covid-19-\(coronavirus-disease-2019\)-situation](https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-3-d-printing-of-essential-medical-devices-and-accessories-for-use-in-covid-19-(coronavirus-disease-2019)-situation)
[https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-medical-devices-for-decontamination-of-single-use-respirators-during-the-covid-19-\(coronavirus-disease-2019\)-situation](https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-medical-devices-for-decontamination-of-single-use-respirators-during-the-covid-19-(coronavirus-disease-2019)-situation)
- A virtual remote audit process has been implemented to audit compliance to ISO 13485 requirements and specific product standards prior to licensing new manufacturing facilities for medical masks and respirators

Thank you!