Medical Devices Industry Briefing: Regulatory Updates & Support Initiatives

20th May 2026

Medical Devices Cluster

Health Products Regulation Group

Health Sciences Authority

Overview

1. **Regulatory Updates:**
   a. GL-04 Regulatory Guidelines for Software Medical Devices
   b. Artificial Intelligence in Healthcare Guidelines (AIHGle 2.0)
   c. Provision of Audit Report for Medical Device Dealer License Applications
   d. Regulatory Reliance with Malaysia's Medical Device Authority
   e. Change in Risk Classification of COVID19 IVDs
   f. IVD Cluster Grouping Restructuring
   g. Registration Support Initiative to Encourage Registration of Unregistered Medical Devices accessed through SAR

Regulatory Updates:
GL-04 Regulatory Guidelines for Software Medical Devices

GL04- Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices – A Life Cycle Approach

One-Stop Reference
A comprehensive, reader-friendly guidance document that covers requirements throughout the software lifecycle.

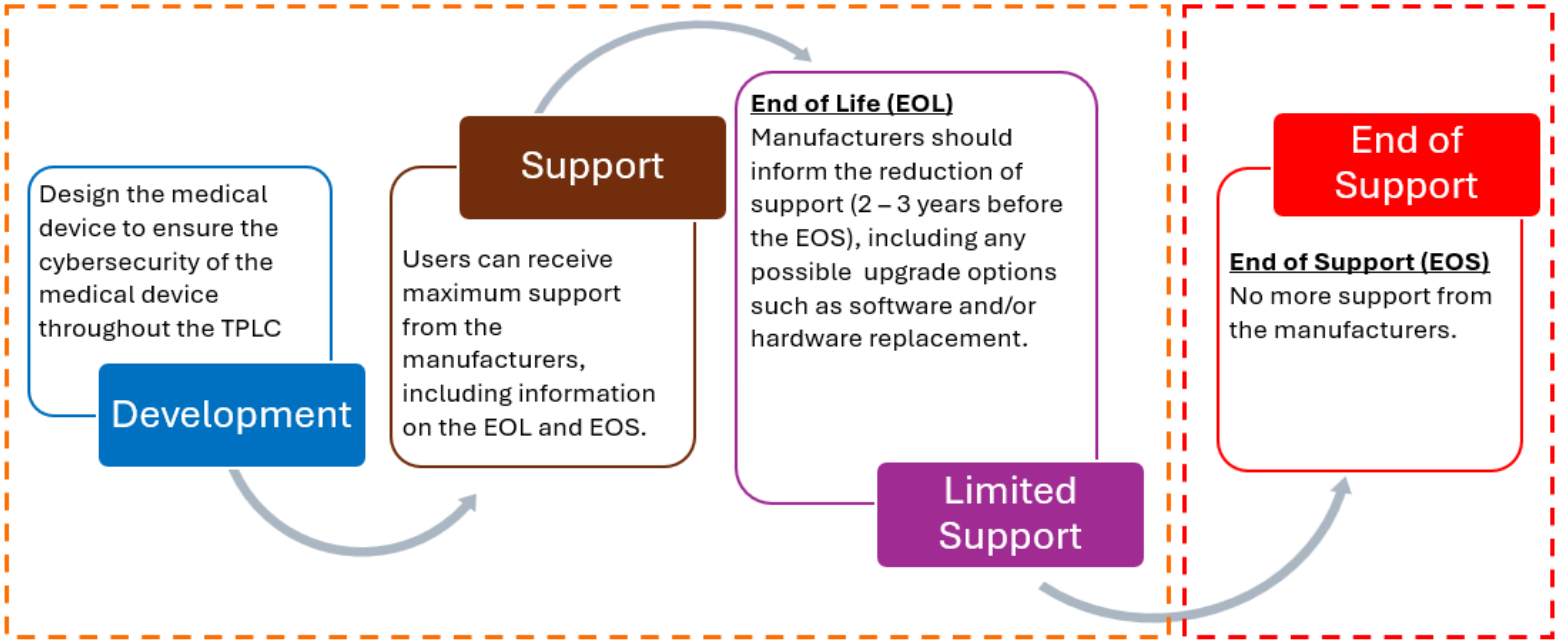
Aligned Definitions
Harmonizes key terms with international standards and IMDRF guidance, including Machine Learning, AI-enabled Medical Devices (AIMD), and Cybersecurity.

Cybersecurity & Machine Learning
Provides clarity on the regulatory requirements for cybersecurity and machine learning.
Align MLMD requirement with IMDRF good machine learning practice document (IMDRF/AIML WG/N88 FINAL: 2025)

Change Management Program
Introduces a new section on the new streamlined pathway for software changes - Change Management Program (CMP).

Cybersecurity

Cybersecurity and the Total Product Life Cycle from Developer's Perspective



- Provides clarity on the need to maintain and update a comprehensive cybersecurity plan throughout the software lifecycle (both pre and post market)
- Emphasises on the importance of running on supported operating system (OS) and the plans when OS reaching end of support.
- Strengthens guidance on cybersecurity risk management, including threat modelling, vulnerability assessment, and timely response to emerging threats

Machine Learning-Enabled Medical Devices (MLMD)

Premarket Submission Requirements

Specifies required information in a clearer manner: ML model description, input/output features, training/test dataset details (source, size, labelling, curation), performance validation, and clinical workflow.

ML Specific Risk Management

Risk assessment will need to address ML specific risks such as overfitting, model drift and model degradation, with adequate risk controls in place.

Change Notification Alignment

Aligns the change notification flowchart for MLMD with GN-21 guidance.

Change Management Program (CMP)

- In line with making this guidance a one-stop reference for software medical devices, a new section on CMP has been added to ensure manufacturers are aware of this regulatory pathway when managing software changes.
  - CMP is a streamlined pathway allowing manufacturers to implement pre-approved software changes through their own QMS, with HSA monitoring post-market rather than reviewing each change upfront.

Faster Time to Market

Implement approved pre-specified updates immediately

Reduced Regulatory Burden

Elimination of multiple Change Notification submissions and associated fees

Clinical Benefit

Bug fixes, feature enhancements and performance improvements can be rolled out rapidly

Enables Innovation

Algorithm improvements and performance optimisation

Operational Benefits

Predictable update cycles and reduced regulatory workload

Artificial Intelligence in Healthcare Guidelines (AIHGle 2.0)

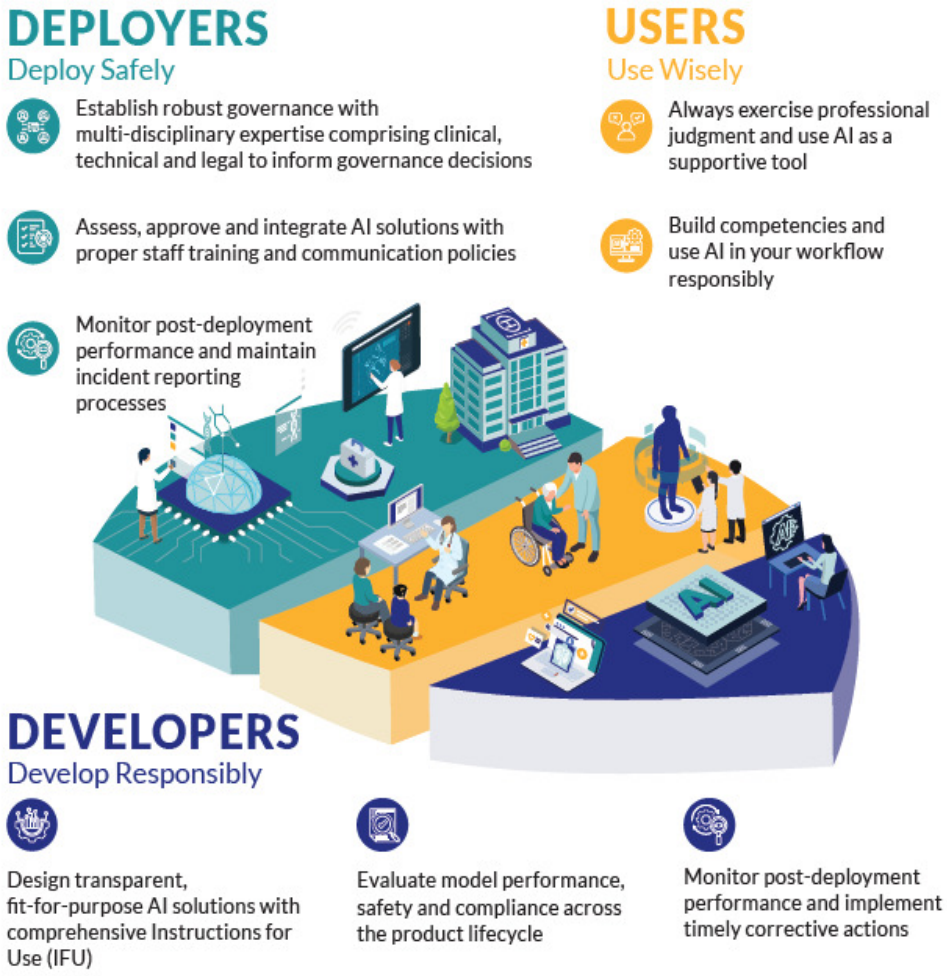
AIHGle 2.0

AIHGle 2.0 – Artificial Intelligence in Healthcare Guidelines

- Published on 10 March 2026
- **Aim**: Ensure patient safety & public trust while improving healthcare efficiency, accessibility, quality & affordability
- Practical guidance for **developers, deployers & users**
- Complements existing HSA Software Medical Device Regulatory framework

Key Updates vs 2021 Version

- Clearer accountability across the ecosystem
- Stronger transparency & explainability requirements
- Enhanced risk-based tools for validation, monitoring, model drift & generative AI
- New Deployers' Toolkit & infographic
- Living document to support responsible innovation
- General considerations for Gen AI technology



Enhanced Regulatory Oversight Through Audit Data Collection

Enhanced Regulatory Oversight Through Audit Data Collection

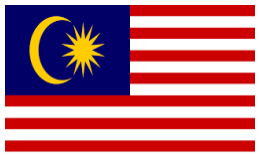
Strengthened detection of systemic issues and early safety signals through audit and postmarket surveillance data

Proactive risk management combining audit findings with post-market surveillance insights for faster regulatory response

From 1 April 2026, latest audit reports to be submitted alongside with QMS certificates (i.e. GDPMDS, MDSAP, ISO 13485) for MD dealer licence applications

Regulatory Reliance with Malaysia's Medical Device Authority (MDA)

Medical Device Regulatory Reliance with Malaysia's MDA



MALAYSIA

Verification Route for MDs registered on **Singapore Medical Devices Register (SMDR)**

Reciprocal Regulatory Reliance

SINGAPORE

Abridged Route for MDs registered on **Malaysia Medical Device Authority Register (MDAR)**

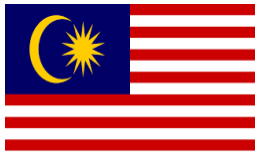
Applicable Devices:

- Class B, C and D medical devices only
- Must have completed **full conformity assessment** by MDA-recognised CAB and registered with MDA
- Labelled use **must be identical to intended use** for marketing in Singapore

Exclusions:

- Medical devices incorporating registrable therapeutic/medicinal products
- Borderline products classified differently by MDA and HSA

Medical Device Regulatory Reliance with Malaysia's MDA



MALAYSIA

Verification Route for MDs

SINGAPORE

Abridged Route for MDs

Application Process

Step 1: Opt-in via SHARE System

- Select "Regulatory reliance Program: Malaysia Medical Device Authority (MDA)" under Evaluation Route Determinants
- Abridged evaluation TAT automatically applies

Step 2: Document Submission

- Medical Device Registration Certificate from MDA
- **Certificate of Conformity issued by CAB**
- All required registration documents per GN-15 Annex 5 and Annex 7 (Abridged evaluation route)

Change in risk classification of COVID-19 IVDs

Risk classification of COVID-19 IVDs

- During the pandemic, COVID-19 IVDs were classified as **Class D** due to SARS-CoV-2 being a transmissible agent causing life-threatening disease with high propagation risk.
- With COVID-19's **transition to endemic status,** the virus now presents moderate rather than high public health risk. Whilst propagation risk has significantly decreased, serious illness remains possible.
- Seniors aged 60 years and above, pregnant women, and persons who are immunocompromised or have concurrent medical conditions such as obesity, diabetes, heart, or lung disease are at greater risk of severe disease or complications when infected.

**https://data.who.int/dashboards/covid19/*

Based on WHO COVID-19 dashboard, 586 COVID-19 deaths and 1,400 new COVID-19 hospitalisations were reported in the last 28 days up to 26 Apr 2026 at the global level.*

Change in risk classification of COVID-19 IVDs

- HSA will reclassify COVID-19 IVDs from **Class D to Class C to** ensure regulatory oversight remains appropriate to current risk levels **with effect from 2 June 2026**.
- HSA's classification adopts a cautious, stepwise approach while maintaining appropriate controls for devices that may still pose significant individual health risks, particularly for vulnerable populations.
- Requirements will now be aligned with other Class C infectious disease IVDs, ensuring continued safety and efficacy standards while reducing regulatory burden proportionate to the current endemic status of COVID-19.

IVD Cluster Grouping Restructuring

IVD Cluster Grouping

- **Original Purpose** of “IVD Cluster” grouping in GN-12-1:
  - Designed to facilitate mass registration during the initial implementation of Singapore’s medical device regulatory controls
  - Served as a pragmatic "catch-all" for Class A and B IVDs for regulatory transition
  - Enabled smooth transition to Singapore's medical device regulatory framework

IVD Cluster Grouping

- Today, "IVD Cluster" grouping is no longer **fit for purpose** and losing relevance:
  - **Administrative Burden**
    - 47 complex categories create inefficient, resource-intensive reviews
    - Low industry utilization
  - **Regulatory Overlaps**
    - Significant duplication with specific IHC/FISH groupings in GN-12-2 (E.g. cancer markers, bacterial markers, pathogen markers)
  - **Obsolete Provisions**
    - Class A IVDs no longer require product registration

IVD Cluster Grouping Restructuring

What's Changing

- HSA will obsolete the “IVD Cluster” grouping in GN-12-1 **with effect from 2 June 2026.**
- Specific grouping criteria in GN-12-2, where it adds clear regulatory value, such as for IHC and FISH grouping will be retained and expanded on in GN-12-2.

Industry Input Opportunity

- HSA will gather industry feedback to add potentially new specific categories in GN-12-2
- Industry feedback form will be made available on HSA website for relevant stakeholders to provide feedback **by 31 July 2026.**
- GN-12-2 will be updated for industry consultation with new specific categories

Registration Support Initiative to Encourage Registration of Unregistered Medical Devices accessed through SAR

Special Access Route

- Medical device (MD) registration is fundamental to patient safety, requiring HSA evaluation to ensure devices meet rigorous safety, quality, and efficacy standards before market access
- Registration of MDs provides regulatory certainty and confidence in device performance while maintaining Singapore's medical device regulatory standards aligned with international best practices
- HSA allows the import and supply of unregistered MDs, in **exceptional circumstances** (e.g. for **unmet clinical needs**, to deliver a better clinical outcome for patients), under the Special Access Route (SAR)
- Over the years, HSA has strengthened SAR oversight measures and disallows continual repeated SAR requests, encouraging companies to submit their unregistered devices for registration

Industry Challenges

HSA recognizes that companies are hesitant to submit registration, particularly for:

- Medical devices **supplied at low volumes and low prices,** citing registration costs do not justify the applicable evaluation fees for the registration of the device with HSA
- **old and established medical devices with a long history of clinical use (legacy medical devices**) due to high cost and heavy administrative burden of preparing dossiers

Registration Support

- To address these challenges and to encourage registration of unregistered MDs brought in for use via SAR that meet criteria of
  - essential/life-saving MDs for rare clinical situations
  - legacy MDs with no registered alternatives
- HSA will provide registration support through **waiver of evaluation fees** while ensuring appropriate standards of quality, safety and efficacy for patient health and safety

Registration Support Initiative

- HSA's goal is to uphold patient health and safety through the assurance of device quality, performance and safety.
- Unregistered medical devices that fulfill the qualification criteria (A or B) will qualify for a waiver on their product registration evaluation fees. Only the application fee of $560 will be charged.
  - **A: Essential life-saving MDs for rare clinical situations**
  - **B: Legacy MDs with no registered alternatives**

Pre-requisite:

Unregistered medical devices must be proposed by healthcare institutions (HCIs) and ***endorsed by Chairman, Medical Board (CMB) for public HCIs*** *or* ***Academy of Medicine Singapore (AMS) for private HCIs.***

Qualification Criteria A

Essential/life-saving MDs for rare clinical situations

All criteria must be fulfilled

Criteria	Evidence to be provided	Provided by
Medical devices that are higher risk (i.e. Class C or Class D MDs); and	• Risk classification based on GN13	Company ✓
Medical devices that are **essential and/or life-saving** in nature and are used in **rare clinical situations** (i.e. limited use circumstance); and	• Clinical justification/elaboration to be provided by requesting doctor and supported by CMB/AMS	Healthcare Institution
Medical devices that are not novel/ not based on new technology and have an **established history of use for at least > 5 years**; and	• Year of first introduction globally • Brief explanation on why the device is not novel / not based on new technology	Company ✓
Medical devices that are **supplied at low prices**, which companies view as not justifying the high registration cost to HSA	• Justification that the medical device is supplied at prices which, considering the expected quantity of supply of the device within 1 year after approval of registration, a reasonable supplier would not view as justifying the applicable evaluation fees for the registration of the device with HSA	Company ✓

Qualification Criteria B

Legacy Medical Device

All criteria must be fulfilled

Criteria	Evidence to be provided	Provided by
Medical devices have at least three years of local clinical use in Singapore through SAR (with at least 2 consecutive SAR GN-26 or GN-27 applications); and	• Past 3 SAR licence numbers	Company ✓
Medical devices that have an **established history of use for at least > 10 years;** and	• Year of first introduction globally	Company ✓
Legacy device necessity with no registered alternatives available in Singapore	• Clinical justification/ elaboration to be provided by requesting doctor and supported by CMB/AMS	Healthcare Institution

Submission Details

Registration Support Initiative to Encourage Registration of Unregistered Medical Devices accessed through SAR

1. Company Name
Company Name as per ACRA

2. Contact Person

3. Email Address

- Company to submit request via FormSG.
- Information provided should correspond to the forms filled by Healthcare Institution.

6. Qualification Criteria
Please select your qualification criteria.

A: Essential life-saving devices for rare clinical situations

B: Legacy medical devices without registered alternatives

7. Requested Device Information
- For system: To state overall system name (ABC Generator System), without consumables
- For implant: To state overall implant name (DEF Stent), without listing all sizes
- For test kits: To state overall test kit name (GHI test kit)

Device name	Identifier

+ Add another row

1 out of max 10 rows

8. Clinical Justification
Please ensure that the clinical justification is consistent with the Request Form signed by the QP/CMB/AMS.

9. Requesting Doctor and Facility
Fill in the details of qualified practitioners in the table below.

Name of Qualified Practitioner	Designation	Department	Name of Ho

10. Endorsement by CMB/AMS
Fill in the details of CMB/AMS in the table below.

Full Name	Designation

11. Attachment I: Clinical Justification and Endorsement Form
- For multiple forms, kindly merge them into one file or upload them as a ZIP file.

Choose file or drag and drop here

Supporting Documentation

Clinical Justification and Endorsement Form *(Healthcare Institution)*

Qualification Criteria:
☐ A: Essential life-saving devices for rare clinical situations
☐ B: Legacy medical devices without registered alternatives

Name of unregistered medical devices requested:
- *For system: To state overall system name (ABC Generator System), without consumables*
- *For implant: To state overall implant name (DEF Stent), without listing all sizes*
- *For test kits: To state overall test kit name (GHI test kit)*

Unregistered medical devices fulfilled Qualification Criteria A:

Unregistered medical devices fulfilled Qualification Criteria B:

Clinical Justification:
For Qualification Criteria A: Please ensure all pointers are addressed.
- *Clinical elaboration on how the medical devices are essential and/or life-saving in nature, detailing the consequences of device unavailability on patient outcome and*
- *Describe the rare clinical circumstances requiring use of device (i.e. limited use circumstance).*

For Qualification Criteria B:
- *Clinical elaboration on legacy device necessity and*
- *Confirming absence of registered alternatives*

Should space be insufficient, Clinical Justification may be furnished in a separate document signed, stamped and dated by the requesting Qualified Practitioner.

LIST OF UNREGISTERED MEDICAL DEVICES
Qualification Criteria A: Essential/life-saving MDs for rare clinical situations

S/N	Name as per device label	Identifier

LIST OF UNREGISTERED MEDICAL DEVICES
Qualification Criteria B: Legacy Medical Device

S/N	Name as per device label	Identifier

Section B: Endorsement by Chairman Medical Board/Academy of Medicine Singapore

• Name of Qualified Practitioner:	
• MCR or DCR Number:	
• Department:	
• Designation:	
• Email:	

☐ I support the unregistered medical devices listed above as meeting the qualification criteria.

Date

Signature of CMB/AMS

Supporting Documentation

Supporting Evidence *(Company)*

For Qualification Criteria A only

Medical devices that are supplied at low prices and not justifying the high registration cost to HSA:
Justification that the medical device is supplied at prices which, considering the expected quantity of supply of the device within 1 year after approval of registration, a reasonable supplier would not view as justifying the applicable evaluation fees for the registration of the device with HSA

General guideline:
The information provided on the unregistered medical devices should correspond with the details filled in by the hospitals/clinics.

LIST OF UNREGISTERED MEDICAL DEVICES
Qualification Criteria A: Essential/life-saving MDs for rare clinical situations

S/N	Name as per device label	Identifier	Risk classification *(only Class C/D)*	Risk classification rule, as per GN-13	Year of first introduction globally

LIST OF UNREGISTERED MEDICAL DEVICES
Qualification Criteria B: Legacy Medical Device

S/N	Name as per device label	Identifier	Year of first introduction	Past SAR Licence Numbers *To be separated by comma*

- List of Unregistered Medical Devices must correspond with the details submitted by the healthcare institutions.
- Additional information are to be provided by company.

Timelines

- **Annual Device Identification (June 1 – August 31)**
  - Submit requests to participate in registration support initiative yearly
  - Include clinical justification/elaboration form signed and endorsed by CMB/AMS together with other supporting documents (will be published on HSA website at later date)
- **Notification to Industry (by October 31)**
  - HSA notifies qualifying companies of fee waiver eligibility
  - Companies submit registration within 1 year of notification (**by 30 October the following year**) attaching notification email from HSA on eligibility for fee waiver

Timelines

After Application Submission

- **Registration Processing** (No committed TAT)
  - HSA processes applications
  - **Published turn-around-times (TAT) would not apply**
  - Supporting documentary requirements will apply as per GN15, based on risk classification and evaluation route
  - Continued SAR supply permitted during evaluation
- **Post Registration**
  - Upon listing on the public SMDR, annual retention fees applies
  - Post-market obligations applies

Next Steps

Actions:

- Review SAR device portfolios against qualification criteria
- Engage QPs/ healthcare institutions early for **clinical endorsement**
- Prepare supporting documentation for annual submission
- Submit requests to participate in registration support initiative with supporting documents **by 31 Aug**

Key Dates:

Submission Period: June 1 - August 31, 2026

Notification by HSA: By October 31, 2026

To qualify for waiver, premarket registration application to be submitted: By October 30, 2027

Contact: HSA_MD_SA@hsa.gov.sg

Thank you