Guidance documents for medical devices

Here is the list of guidance documents with relevant forms and templates to help you meet the regulatory requirements for dealing in medical devices.

Product Registration

Product Registration

Product Registration Guidelines

- GN-15-R13 Guidance on Medical Device Product Registration (2026 Mar) PUB
  - GN-15-R13 ANNEX 1 Letter of Authorisation Template (2026 Mar)
  - GN-15-R13 ANNEX 2 Marketing History Declaration Template (2026 Mar)
  - GN-15-R13 ANNEX 3 Safety Declaration Template (2026 Mar)

Unique Device Identification (UDI) Submission Guidelines

- GN-36-R2 Guidance on Medical Device UDI System (2022 July) PUB 2248 KB
  - FAQ (Medical Device UDI System)_Updated 18 July 2022 480 KB
  - UDI-DI Submission video for Registered Medical Devices15398 KB

IVD Analysers

- GN-34 R2 Guidance for IVD Analysers (2025 Oct) PUB
  - Annex 2 to GN-34 (2025 Oct)

Medical Devices Product Classification

- GL-06-R2 Medical Devices Product Classification Guide (2023 Oct) PUB 2076 KB

Product Specific Regulatory Guidelines

- Telehealth Products R2.1 1226 KB
  - FAQ Telehealth Products R2.0 401 KB

- Aesthetic-Related Guidelines_2018 461 KB
- NGS (IVDs) 588 KB
- GL-04-R4 Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach (2025 Dec) PUB
- GL-07-R2 Guidelines Risk Classification SAMD-CDSS (2025 Jul) PUB
- Regulatory Guideline For 3D-Printed Medical Devices 601 KB
  - FAQ (3DP Medical Devices) 2021 804 KB
- GL-08-R2 Regulatory Guidelines for Laboratory Developed Tests (LDTs) (2025 Sep) PUB
  - GL-08-R2 Annex 1 LDT Objective checklist Template (2025 Sep)

Product Registration Dossier Requirements

- GN-17 R4 Guidance on Preparation of a Product Registration Submission for GMD using the ASEAN CSDT (2025 Oct) PUB
  - E-Submission Guide for GMD for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS R4 (2025 OCT) PUB
  - Annex 2 for GN-17 and GN18 List of Configurations (2025 Oct)
- GN-18 R4 Guidance on Preparation of a Product Registration Submission for IVD MD using the ASEAN CSDT (2025 Oct) PUB
  - E-Submission Guide for IVD MD for ASEAN CSDT and IMDRF ToC based Submissions R4 (2025 OCT) PUB
  - Annex 2 for GN-17 and GN18 List of Configurations (2025 Oct)

Medical Devices Risk Classification

- GN-13-R2.1 Guidance on the Risk Classification of General Medical Devices (18Sep-pub) 755 KB
- GN-14-R3 Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices (updated on 24 July 2023) 320 KB

Grouping of Medical Devices

- GN-12-1-R2.1 Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria (Updated on November 2017) 616 KB
- GN-12-2-R2 Guidance on Grouping-Specific (2022 Jan) PUB 446 KB

Labelling of Medical Devices

- GN-23-R2 Guidance on Labelling for Medical Devices(2022 Sep) PUB 292 KB

Clinical Evaluation

- GN-20-R2 Guidance on Clinical Evaluation(2022 Nov)_PUB 443 KB

Declaration of Conformity

- GN-11-R1.3_Guidance on the Declaration of Conformity(2022 Nov)_PUB 266 KB
  - GN-11 Declaration of Conformity Template(2022 Nov) 32 KB

Essential Principles for Safety and Performance

- GN-16-R4 Guidance on Essential Principles for Safety and Performance of Medical Devices(2023 Sep) PUB331 KB
  - Annex 2 GN-16 R4 Essential Principles Checklist Template (June 2018 version)172 KB
  - Annex 3 GN-16 R4 Essential Principles Checklist Template (Dec 2017 version)128 KB

Change Management program

- GN-37-R1 Guidance on Change Management Program (CMP) for SaMD, including machine-learning enabled SaMD

Dealer's licensing

Dealer's licensing

Manufacturers, Importers and Wholesalers Licensing

- GN-02-R8 Guidance on Licensing of Manufacturers Importers and Wholesalers of MD (2026 Apr) PUB
  - GN-02-R8 Annex 1 Declaration for dealing with MD that are solely for export or re-export purposes (2026 Apr)
  - GN-02-R8 Annex 5 Declaration of Conformity to a QMS (2026 Apr)

Documents for Licensing

- GN-03-R3 Guidance on Preparation of a Site Master File for Licensing 71 KB
  - SMF Example for GN-03 Guidance on Preparation of a Site Master File for Licensing 84 KB

Class A Medical Devices

- GN-22 R8 Guidance for Dealers on Class A Medical Devices (Jul 2025) PUB

Good Distribution Practice for Medical Devices (GDPMDS)

- GN-33 R2 Guidance on the Application of Singapore Standard GDPMDS (2023 Sep) PUB 464 KB
- GN-06-R3 Guidance on Distribution Records(2022 Nov)_PUB 245 KB

Change Notification and Amendments

Change Notification and Amendments

Change of Registered Medical Device

- GN-21-R6 Guidance on Change Notification for Registered MD (2025 Jul) PUB
  - Annex 2 to GN-21 R6 Guidance on Change Notification for Registered MD (2025 Jul)

Change of Registrant

- GN-24-R2 Guidance on the Change of Registrant (2025 Jul) PUB
  - ANNEX 1 GN-24-R2 Letter of Request Template (2025 Jul)
  - ANNEX 2 GN-24-R2 Relinquishing Company Form (2025 Jul)

Cancellation of Medical Device

- GN-25-R1 Guidance on the Cancellation of Medical Device Listing 327 KB

Special Access Routes

Special Access Routes

- GN-35-R5 Guidance on Special Access Routes (2025 Sep) PUB
  - SAR Device List 54 KB
  - Request form for unregistered medical device for use on patients by QP and Licensed HCF(2025 Sep) by qualified practitioner and healthcare facility (for GN-26 and GN-27 application)
  - MOH CLINICAL JUSTIFICATION REVIEW FORM FOR CLASS D MEDICAL DEVICE
  - GN-30 Product Owner Authorisation Template (2025 Sep) from product owner (for GN-30 application)
- SAR webinar slides_24mar22 616 KB

Import of Unregistered Medical Devices for Exhibition

- GN-32-R6 Guidance for Importation of Unregistered MD for Exhibition (2025 Jul) PUB

Custom-made Medical Devices

- List of Custom-made Medical Devices_August 2014 12 KB

Advertisement and Sales Promotion

Advertisement and Sales Promotion

- GN-08-R2 Guidance on Medical Device Advertisements and Sales Promotion 215 KB
- Guidance for HCSA Licensees and Telemedicine Service Providers on Advertisement Controls of Health Products
  - FAQs on Guidance for HCSA Licensees and Telemedicine Service Providers on Advertisement Controls of Health Products

Safety Monitoring

Safety Monitoring

Adverse Events Reporting

- GN-05-R3 Guidance on the Reporting of Adverse Events (2023 Sep) PUB 274 KB

Field Safety Corrective Action (FSCA)

- GN-10-R4 Guidance on Medical Device Field Safety Corrective Action (2025 Jul) PUB
  - GN-10-R4 Annex 1 (2025 Jul)

Recall of Medical Devices

- GN-04-R2.2 Guidance on Medical Device Recall 339 KB

Complaint Handling

- GN-07-R3 Guidance on Complaint Handling (2023 Sep) PUB 237 KB

Dear Healthcare Professional Letter (DHCPL)

- GN-09-R4 Guidance on the Component Elements of a DHCPL (2025 Jul) PUB

- GN-09 R4 Annex 1 (2025 Jul) DOC

Technical Reference Documents

Technical Reference Documents

- TR-01 R3 Contents of a Product Registration Submission for GMD using the ASEAN CSDT (2024 Mar) PUB PDF 340 KB
- TR-02 R3 Contents of a Product Registration Submission for IVD MD using the ASEAN CSDT (2024 Mar) PUB PDF 382 KB

Archived Regulatory Guidances

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- Archived Regulatory Guidances

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