QD-722-3-23 V3

OVERVIEW OF HK REGULATION

2026-06



ISO 13485 CERTIFIED

bsi. ISO 13485 Medical Devices Quality Management

MD 653109

Vee

CONTENT

- Regulatory Body
- System & Scope
- Local Responsible Person
- Listing Process
- Classification of Medical Device
- Validity of Listing
- Labelling of Device
- Vee Care Background

REGULATORY BODY

- Medical Device Division (MDD) of Department of Health in Hong Kong
  - Phased Implementation of Medical Device Administrative Control System (MDACS)



SYSTEM & SCOPE

- Medical Device Administrative Control System (MDACS)
  - Voluntary system
  - To be eventually superseded by a statutory system
  - Scope
    - Listing System
      - Medical Devices (Classes II, III and IV)
      - In Vitro Diagnostic (IVD) Medical Devices (Class B-D)
      - Local Manufacturers
      - Importers
      - Distributors
    - Recognition of Conformity Assessment Bodies (CABs)
    - Adverse Incident Reporting System
      - Must be reported by the Local Responsible Person (LRP) in HK

LOCAL RESPONSIBLE PERSON

- A manufacturer who wishes to apply for inclusion of a device into the Listing of Medical Devices in HK, must, before the application can be made, designate an LRP
- MDACS requires that the applications for listing of medical devices are made by LRPs
- Importance of LRP
  - To serve as communication hub among users, manufacturer, importer and government
  - To ensure the safe and efficacious use of the medical devices
  - To provide quality services to the users

LOCAL RESPONSIBLE PERSON

- Who can be an LRP?
  - A company incorporated in Hong Kong; or
  - a legal / natural person with business registration in Hong Kong

And who is

  - Itself the manufacturer of the device; or
  - Supported by the manufacturer (the manufacturer has to designate the LRP in writing)

LOCAL RESPONSIBLE PERSON

❑ Relationship between MFR and LRP

Type of Manufacturer	Itself	Designate
Local Manufacturer	✓	✓
Overseas Manufacturer with branch in HK	✓ (HK Branch)	✓
Overseas Manufacturer without branch in HK	✗	✓

LOCAL RESPONSIBLE PERSON

❑ Roles of an LRP

Commercial & Regulatory Hub

- Applicant for MDACS device listing
- Maintaining valid listings and reporting changes
- Facilitating collaboration with importers and distributors to align on pre and post-market requirements
- Maintaining distribution and supply records
- Making records available

Safety & Vigilance

- Tracking listed medical devices in Hong Kong
- Managing product recalls and field safety corrective actions with MDD
- Managing reportable adverse incidents with MDD
- Coordinating implementation of MDD safety decisions

Quality & Communication

- Handling user and customer complaints
- Acting as primary contact with MDD
- Communicating safety information to local stakeholders

LISTING PROCESS



LISTING DOCUMENTS

Submission Requirements	LRP	Manufacturer
LRP's BR	✓	
LRP Documentation Procedure	✓	
New LRP Letter		✓
Sample of Special Listing Information (HK labelling requirements)	✓	
Position to Display Special Listing Information • Outer packaging of every device or sales unit OR; • On documents supplied with the device and delivered to the end-user facilities (IFU, delivery note, etc.)		✓
IFU		✓
Device Labelling		✓
QMS Certificate of Manufacturer/Manufacturing Sites/Subcontractors - (ISO 13485, GB/T 42061, Medical Device Manufacturing Licence, MDSAP, KGMP)		✓
Simple Flowchart of Manufacturing Process		✓
Function of components and accessories (MDS-01 & MDS 02)		✓

LISTING DOCUMENTS

Submission Requirements	LRP	Manufacturer
Marketing Approval Certificate – (EU, US 510K, Health Canada, Australia TGA, China NMPA, Japan, South Korea, Singapore)		✓
EU DOC, if EU approval, CFG if US approval		✓
History of recalls / adverse events		✓
Risk and safety analysis – according to ISO14971		✓
Type Test Reports		✓
Clinical Evaluation Report		✓
Essential Principles Conformity Checklist or MDCCL		✓
Essential Principles Declaration of Conformity Letter	✓	
Information on device procured by the Hospital Authority (HA) [if any] • HA Purchase Order Number • Purchase Order Date • Name of Supplier		✓

CLASSIFICATION OF MEDICAL DEVICE

- Factors Influencing Device Classification
  - Invasive Device

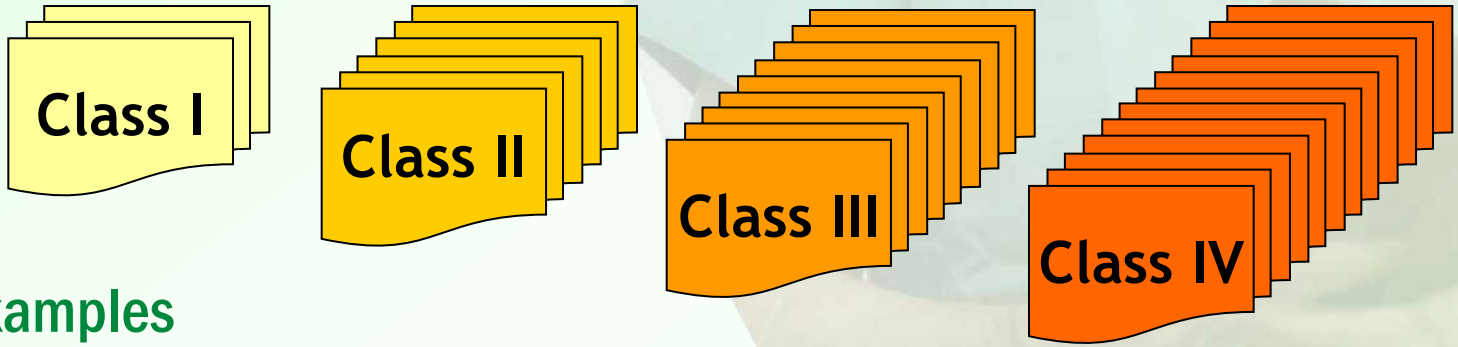
    Device, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body
  - Active Medical Device

    Device whose operation depends on a source of electrical energy or any source of power
  - Transient use (<60mins) / Short Term Use (>60mins & <=30 days) / Long Term Use (>30 days)
  - Intended Use

CLASSIFICATION OF MEDICAL DEVICE



Adopted the classification rules promulgated by the GHTF



Examples

tongue depressor, bandage, dressing

suction pump, gastroscope, transdermal stimulator

lung ventilator, orthopaedic implant, X-ray machine, medical laser

prosthetic heart valve, implantable cardiac pacemaker, heparin-coated catheter

Listing Available for Class II/III/IV

VALIDITY OF LISTING

- Validity of Listing
  - An approval for listing a device will be valid for 5 years
  - The LRP must submit an application for continuation of the listing to the MDD between 12 weeks to 1 year (inclusive) before the expiry of this five-year validity period

Required Labelling Documents

Required Labelling Documents:

Instructions for use

- shall be written in terms and languages readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

Device Labelling

- Legal manufacturer's name and contact information
- Other necessary information / instructions where applicable, e.g. indicate if the device is sterile, single-use only, etc.

Special Listing Information**

SPECIAL LISTING INFORMATION

- The Special Listing Information of a medical device comprises (i) and (ii) below:
- (i) The "device's Listing Number", and in case the device's instructions for use are available only in English or only in Chinese, a supplementary statement to inform the user of this fact. The information shall be displayed in the applicable format shown in the next page.
- (ii) The "LRP information " including the name, address, and contact telephone / fax numbers in both English and Chinese wherever applicable.

SPECIAL LISTING INFORMATION

HKMD No. xxxxxx

(a)

HKMD No. xxxxxx
Instructions for use in English not available

(b)

HKMD No. xxxxxx
沒有中文版使用說明

(c)

Note:
"xxxxxx" stands for the device's Listing Number

- If the instructions for use are available
  - in both English and Chinese, the format in figure (a) shall be applied
  - Only in Chinese, the format in figure (b) shall be applied
  - Only in English, the format in figure (c) shall be applied
- Whenever (a), (b) or (c) is applied, it shall be with a "printed rectangular border " as shown.
- All the characters shall be of a uniform font size of not less than 2mm high. In (c) the Chinese characters shall be in kaishu (楷書).

SPECIAL LISTING INFORMATION - SAMPLE

HKMD No. XXXXXX
沒有中文版使用說明

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VEE CARE BACKGROUND

- ISO 13485–certified medical device regulatory consultancy
- Offices and regulatory teams in Taipei and Hong Kong — local Greater China presence
- Extensive submission experience with good understanding on regulatory requirements
- Leading local license holder / Authorized Representative in Taiwan and HK — over 100 licenses in each market (current clients include Huawei, Apple, Penumbra, IBA, Masimo, etc.)
- End-to-end services: registration strategy, dossier prep, submissions, and post-market support

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MD 醫療器械科 Medical Device Division

FDA 食品藥物管理署 Food and Drug Administration

澳門特別行政區衛生局 Serviços de Saúde



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