DENTAL LABORATORY REGULATORY REQUIREMENTS IN SINGAPORE

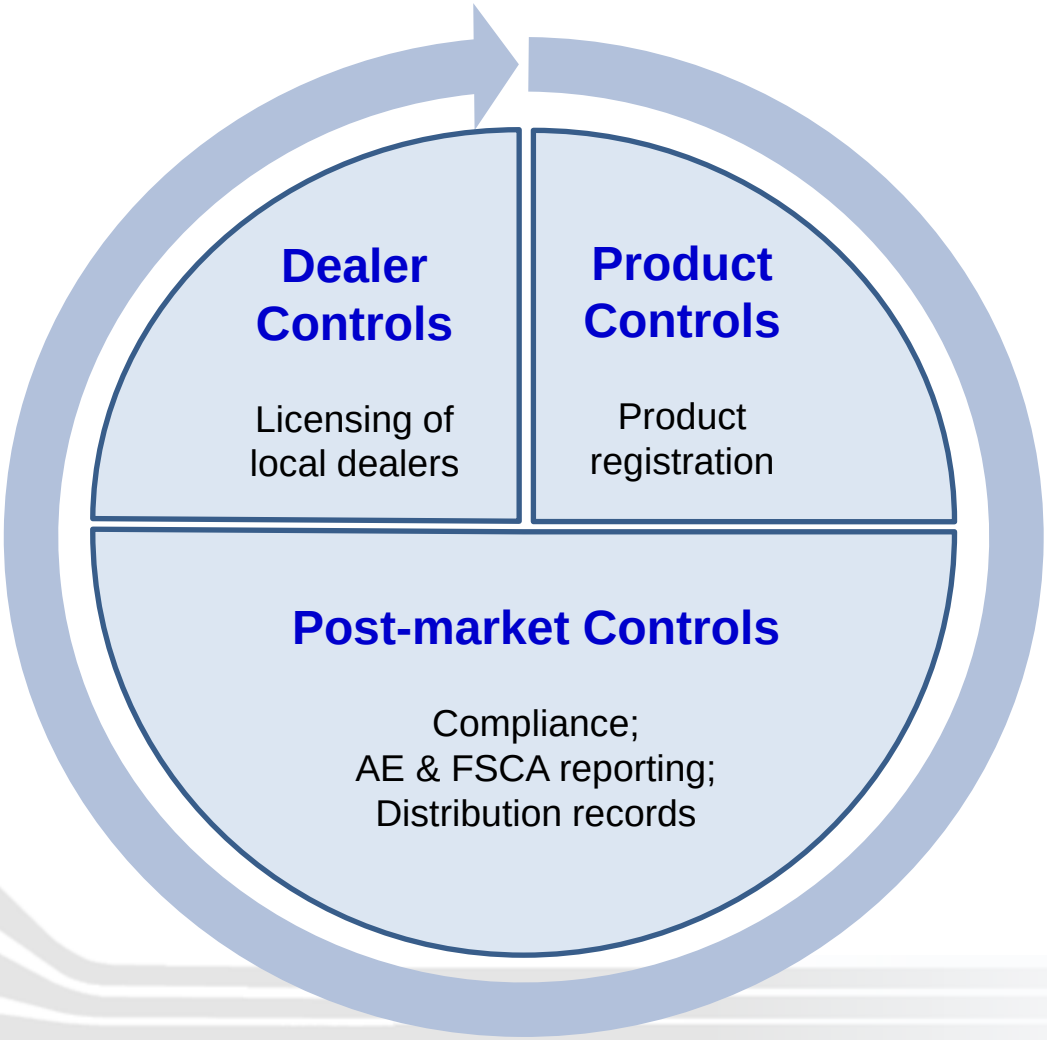
MEDICAL DEVICES CLUSTER

MAY 2022

OVERVIEW OF

MEDICAL DEVICE REGULATORY CONTROLS

MD Regulatory Controls



Pre-market

Post-market

Product Controls

- Medical devices (MDs), except Class A devices, are generally required to be registered with HSA before import and supply in Singapore
- Exceptions to registration include custom-made MDs
  - Custom-made MDs have unique design, attributes and/or specifications to fit an individual patient
  - Examples of custom-made dental MDs by risk classification*:

Class A *(lowest risk)*	Class B	Class C	Class D *(highest risk)*
• Dental aligners • Dentures	• Dental crowns • Dental bridges • Retainers • Inlays	• Dental implants intended for long term use	None

  - Dealers are required to notify HSA of the list of custom-made MDs that they deal with

* *See page 12 for more details on risk classification of dental implant components*

Dealers Controls

Dealer's Licensing

Local companies who **manufacture**^, import or supply MDs by wholesale are required to be licensed by HSA

Types of Dealer License – based on company's activities

Local manufacturing^	Importing	Wholesale (including export)
Manufacturer's License	Importer's License	Wholesaler's License

^ "***manufacture***", *in relation to a health product, means to make, fabricate, produce or process the health product and includes*
(a) any process carried out in the course of so making, fabricating, producing or processing the health product; and
(b) the packaging and labelling of the health product before it is supplied

Dealers Controls

- Dental laboratories that manufacture^ dental MDs, including custom-made MDs, are considered manufacturers

- Current requirements for a Manufacturer's License:
  - ISO 13485^^ certificate (Class B and above)

  OR

  - Declaration of conformity to a Quality Management System (Class A only)

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*^^**ISO 13485**: Medical devices — Quality management systems — Requirements for regulatory purposes*

STANDALONE:

Operating outside PHMC^ licensed healthcare institutions and dental clinics, not licensed by MOH under the PHMCA^

UPCOMING REGULATORY APPROACH FOR

LOCAL STANDALONE DENTAL LABORATORIES

*^**Private Hospitals and Medical Clinics Act (PHMCA)** or **PHMC** Act covers the control, licensing and inspection of private hospitals, medical clinics, clinical laboratories and healthcare establishments in Singapore.*

Considerations

- Local dental laboratories have experience with manufacturing custom-made dental MDs

- Locally manufactured custom-made dental MDs
  - have had no serious safety incidents reported so far
  - are typically of lower risk class (risk class A and B)
  - are manufactured based on a prescription and fitted by registered dentists

Risk-calibrated regulatory approach
for local standalone dental laboratories manufacturing
Class A and/or Class B dental custom-made devices

Calibrated Regulatory Approach

1. Dealers Control (Manufacturing Activity)

Calibrated Approach For local standalone dental laboratories manufacturing **only** Class A and/or Class B dental custom-made MDs	**Standard Approach** For registrable MDs
Implementation of a Quality Management System • No certification required **One-time notification to HSA** • Local manufacturing site • Scope of manufacturing activities **No fees required**	**ISO 13485 certification** **Manufacturer's License application and annual renewal** **Licence fees apply**

- Standalone dental laboratories manufacturing higher risk MDs (Class C and/or Class D) will be subject to standard regulatory requirements

Calibrated Regulatory Approach

2. Product Control

Calibrated Approach For local standalone dental laboratories manufacturing **only** Class A and/or Class B dental custom-made MDs	**Standard Approach** For registrable MDs
Product notification of dental MD type (e.g. aligners, bridges) prior to supply **No fees required**	**Product registration prior to supply** **Registration fees apply**

3. Post-market Control

- All post-market obligations will apply, e.g.
  - Mandatory reporting of field safety corrective actions and adverse events
  - Maintenance of distribution records and complaints

Risk Classification of Dental Implant Components

Dental implant components are risk classified based on their

- degree of invasiveness, and
- duration of contact with the patient.

1. **Surgically-invasive, long-term**

   → Class C, Rule 8

   e.g. implant body, abutment

2. **Not surgically invasive, long-term (in oral cavity)**

   → Class B, Rule 5

   e.g. fixed dental prostheses: crowns, bridges, overdentures

For more information on risk classification rules, their definitions and examples, please refer to *GN-13 Guidance on the Risk Classification of General Medical Devices* available at https://www.hsa.gov.sg/medical-devices/guidance-documents

Frequently Asked Questions

What is a Quality Management System (QMS)?

A quality management system (QMS) documents the company's policies, procedures, forms, and work instructions, along with their sequence, interactions, and resources required for a company to consistently meet customer and company's requirements.

The purpose of a QMS is to ensure that, every time a process is performed, the same information, methods, skills and controls are used and applied in a consistent manner.

Quality management should adopt a risk-based approach, i.e. the time and effort spent on quality management should be relative to the risks involved. As a medical device manufacturer, your QMS should be consistent with the complexity of your device, manufacturing process, and facility.

Frequently Asked Questions

Is there a template I can adopt for my QMS?

Your QMS should be tailored to your company's unique requirements and there is no one-size-fits-all approach. However, the core elements that all QMSs have in common include:

- Quality policy and objectives, quality manual
- Organisational structure, processes, procedures, instructions, and records
- Document control and management
- Quality instruments, quality analysis
- Improvement opportunities

When establishing a QMS, your company should identify the processes which are essential to meet customer and company's requirements. The QMS design should be influenced by your company's objectives, needs, and the devices and services provided. Most QMS are designed around the plan-do-check-act (PDCA) cycle which allows for continuous improvement to both the product and the QMS.

Frequently Asked Questions

What is ISO13485?

ISO 13485 is an International Standard which covers the requirements of a QMS specifically for medical device-related services.

Does my manufacturing facility need to be ISO13485 certified?

If your facility only manufactures Class A and/or Class B dental custom-made MDs, no certification will be required. However, your QMS should be established in accordance to ISO13485.

If your facility manufactures higher risk MDs (Class C and/or Class D), or registrable MDs (e.g. non-custom made), the facility will need to be ISO13485 certified before you apply for a Manufacturer's Licence.

Useful Links

Controls on custom-made medical devices:

https://www.hsa.gov.sg/medical-devices/registration/special-access-routes/custom-made-devices

Medical Device Guidance Documents:

https://www.hsa.gov.sg/medical-devices/guidance-documents

- GN-02 Guidance on Licensing of Manufacturers, Importers and Wholesalers of Medical Devices.
- GN-13 Guidance on the Risk Classification of General Medical Devices
- Regulatory Guideline For 3D-Printed Medical Devices
  (*Product registration → Product Specific Regulatory guidelines*)
- GN-07 Guidance on Complaint Handling of Medical Devices
- GN-05 Guidance on Reporting of Adverse Events for Medical Devices
- GN-10 Guidance on Medical Device Field Safety Corrective Action
  (Safety Monitoring)

Queries

For clarifications regarding
dental laboratory requirements,
please email **HSA_MD_Info@hsa.gov.sg** with the
email subject "**Dental Laboratory**".