IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
Singapore

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Key Regulatory Changes

1. Regulatory requirements for
   a. Class A and B medical devices
   b. Stand-alone mobile applications
2. Clarifying the scope of the medical device regulatory framework
3. Pre-Market Consultation and Priority Review Scheme

1. Regulatory requirements for Class A and B medical devices

Before 01 June 2018

Class A MDs **(sterile)** – Require product registration

Class A MDs **(non-sterile)**

- Product registration **not** required
- Declaration of all Class A non-sterile MDs under Class A exemption list (***public online database effective from August 2017***)

- Dealers of Class A MDs are required to ensure
  - The intended use/ claims for their devices are based on scientific evidence
  - Devices comply with the essential requirements for safety and performance

Before 01 June 2018

Class A MDs **(sterile)** – Require product registration

Class A MDs **(non-sterile)**
- Product registration not required
- Declaration of all Class A non-sterile MDs under Class A exemption list ***(public online database effective from August 2017***)

From 01 June 2018

Class A MDs

- **Sterile and Non-sterile** - Product registration not required

- Importers/ manufacturers are required to list all Class A MDs (sterile and non-sterile) on the public online Class A database as and when prior to import/supply in Singapore

- Dealers of Class A MDs are required to ensure
  - The intended use/ claims for their devices are based on scientific evidence
  - Devices comply with the essential requirements for safety and performance which includes
    - Ensuring compliance with appropriate sterilisation standards for the sterilisation process for their Class A sterile MDs

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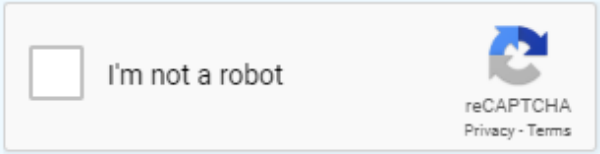
PUBLIC ENQUIRY - CLASS A MEDICAL DEVICE REGISTER

Class A Medical Device Search (Multiple criteria search is always AND condition)

Search Criteria	Search Entry	Search Mode
Dealer's Licence No :		Contains
Dealer's Name :		Contains
Product Owner Name :		Contains
Name as per Device Label :		Contains
Device Identifier		Contains
Intended Purpose :		Contains
Country of Manufacturer :		Contains
Sterility of Devices :	☐ Sterile ☐ Non-sterile	
Dealer's Type :	☐ Importer ☐ Manufacturer	

Note: To check both or either of the checkboxes to view the list of manufacturer and/or importer.



Disclaimer :

Information published on the Class A Medical Register is self-declared by the dealers and has not been verified by the Health Sciences Authority. The Health Sciences Authority does not claim, promise or warrant its accuracy or completeness. The Health Sciences Authority accepts no liability whatsoever arising from inaccurate or incorrect device information provided in the Class A Medical Device Register. The listing of medical devices in the Class A Medical Device Register should not be construed as an endorsement of any kind by the Health Sciences Authority.

Search

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PUBLIC ENQUIRY - CLASS A MEDICAL DEVICE REGISTER

Class A Medical Device Search (Multiple criteria search is always AND condition)

Search Criteria

Name as per Device Label Contains "bandage"

Search Results

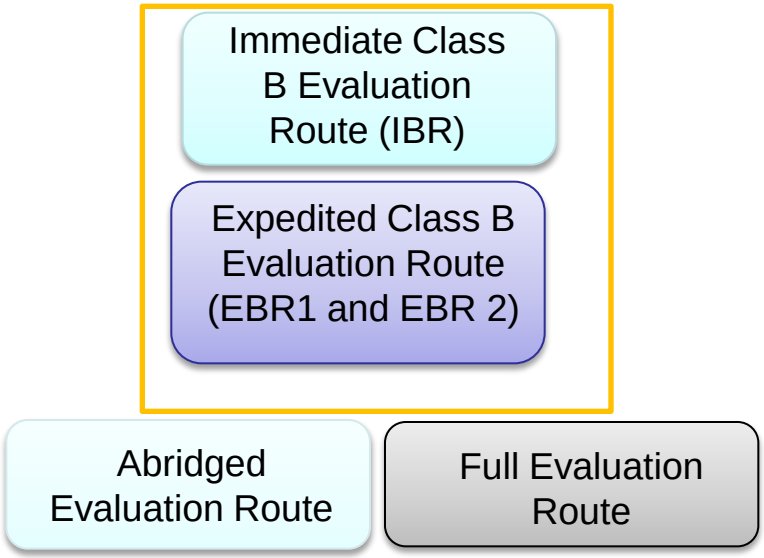
	Dealer's Licence No	Dealer's Name	Dealer's Type	Product Owner Name	Name as per Device Label	Intended Purpose	Device Identifier	Country of Manufacturer	Sterile/Non-sterile
1.	ES0001609	BENG KANG IMPORT & EXPORT	Importer	Zhiyuan Yiqihang	Da Bao Brands Bandage	genaral use for protect intact skin,	Bandage	Taiwan, Province Of China	Non-sterile
2.	ES0003551	MARKEN TIME CRITICAL EXPRESS LIMITED (SINGAPORE BRANCH)	Importer	Covidien	Curity Flexible Adhesive Bandage	First Aid Plasters which have a non-medicated pad that provides cushioning for injection site.	44101	United States	Non-sterile
3.	ES0001495	LUEN WAH MEDICAL COMPANY (SINGAPORE) PRIVATE LIMITED	Importer	BN Sandar & Son	Bandages Gauze 4" x 5 yds x 12's	It is used to cover and protect wounds. This is a single-use device.	Bandage, gauze	India	Non-sterile
4.	ES0002081	BIOCARE GLOBAL PTE. LTD.	Importer	Biocare Global Pte Ltd	Bandage, elastic	To cover wounds	B0200	Korea, Republic Of	Non-sterile
5.	ES0003176	MARINE PHARMA PTE. LTD.	Importer	N. Irfan Enterprises	Scissors, Lister Bandage 14cm	An instrument intended for cutting bandage	NIR0136E	Pakistan	Non-sterile
6.	ES0001711	HOSPITECH SINGAPORE PTE. LTD.	Importer	HOSPITECH Manufacturing Services SDN BHD	Crepe Bandage 10cmX4.5M	Clean cotton material for bandaging purpose	SH-030	Malaysia	Non-sterile
7.	ES0002769	SMITH PHARMACY PTE. LTD.	Importer	Yamakawa Trading Co Pte Ltd	SELF-ADHESIVE ELASTIC BANDAGE	BANDAGE WOUND DRESSING	860396	China	Non-sterile

DEALERS CONTROL – For solely Class A dealers

Dealer Licences	Current Pre-requisite	Proposed Pre-requisite
Manufacturer's licence	ISO13485 certification	Declaration of conformity to a Quality Management System (QMS) i.e. Third-party certification no longer required
Importer's/ Wholesaler's licence	Goods Distribution Practice for Medical Devices (GDPMDS) **OR** ISO13485 certification	

- Dealers of solely Class A MD are still required to be licensed by HSA
- As pre-requisite to their licences, dealers of solely Class A MD are required to establish and maintain an appropriate quality management system in their facilities
  - Third-party audit and certification is no longer required

Before 01 June 2018



Immediate market access for Class B MDs with no safety issues globally that have:

- ❑ 2 reference agencies approvals **and** 3 years marketing history

Before 01 June 2018

- Immediate Class B Evaluation Route (IBR)
- ~~Expanded Class B Evaluation Route (EBR 2)~~
- Abridged Evaluation Route
- Full Evaluation Route

From 01 June 2018

- Immediate Class B Evaluation Route (IBR) (Expanded scope)

75% of Class B

- Abridged Evaluation Route
- Full Evaluation Route

Immediate market access for Class B MDs with no safety issues globally that have:

- ❑ 2 reference agencies approvals **and** 3 years marketing history

Immediate market access for Class B MDs with no safety issues globally that have:

- ❑ 2 reference agencies approvals; **OR**
- ❑ 1 reference agencies **and** 3 years marketing history

2. Faster access to Standalone Mobile Applications that are medical devices

- Final Telehealth Guidelines published in 2017

HSA Telehealth Guidelines:
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

Standalone Mobile Applications

- Standalone mobile application refers to a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices
  - Typically these include algorithm based calculators of parameters for use in clinical practice or for use in diagnosis or managing a disease or condition
  - Designed based on formulae with established scientific evidence and clinical utility

- Such Standalone Class B or Class C mobile medical device application if reviewed and approved by at least one of HSA's reference regulatory agencies, will qualify for Immediate Registration Route
  - Immediate Class B Registration Route for Class B Standalone Mobile Applications with one reference regulatory agency approval*
  - New Immediate Class C Registration Route for Class C Standalone Mobile Applications with one reference regulatory agency approval*

** The reference regulatory agency approval must be within the list of approval types listed in our GN-15 Guidance document on medical device registration to qualify for current abridged, expedited and immediate registration routes.*

Immediate Registration Route – Standalone Mobile Applications

- The eligibility criteria for the Immediate Registration Route at the point of submission are:
  - Approval by at least one of HSA's reference regulatory agencies for intended use identical to that submitting for registration in Singapore
    - *[HSA's independent reference regulatory agencies are i) Health Canada, ii) Japan's Ministry of Health, Labour and Welfare, iii) United States Food and Drug Administration, iv) Australian Therapeutic Goods Administration v) European Union Notified Bodies and the corresponding approvals indicated in GN-15.]*
  - No safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, defined as
    - No reported deaths;
    - No reported serious deterioration in the state of health of any person; and
    - No open field safety corrective actions (including recalls) at the point of submission.

III. Clarifying the Scope of the Medical Devices Regulatory controls

Devices for wellness purposes

- Telehealth products are involved in the provision of healthcare services over physically separate environments via infocomm technologies
- The intended use of the Telehealth product as determined by the manufacturer will determine whether it will be regulated as a medical device
- If the Telehealth product is intended to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, it is a Telehealth medical device and is subject to HSA's regulatory control.

HSA Telehealth Guidelines:
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

Devices for wellness purposes

- If the Telehealth product is **not intended** by the manufacturer to be used for the aforementioned medical purposes (e.g. intended for fitness tracking), **but is able to perform such function/purpose** (e.g. monitoring heart rate), such products are required to be **labelled** to clearly inform the users of the product's appropriate use (i.e. **not for medical purpose**) → Devices for "Wellness purposes"

- This information should be presented clearly to the users, where practicable (e.g. Packaging, Instructions for use (IFU) or splash screen/loading screen in a mobile application). This is necessary to ensure that users do not misconstrue any health-related information accessed through these devices as medical advice.

HSA Telehealth Guidelines:
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

- Wellness device includes devices or software intended by its manufacturer to be used
  - solely to enable or encourage the user to adopt or maintain a healthy lifestyle; or for the user's general well-being; but
  - not to be used for any medical purpose
  - e.g. Fit bit watches, heart rate measuring devices for fitness purposes

- Wellness device refers to devices that are not intended for medical purpose i.e. intended for wellness purposes.
  - Includes the category of Telehealth products not intended for medical purpose

- Wellness devices not to be subject to medical device regulatory controls if
  - The device is labelled as not for medical purpose and is supplied with the clarification statement on the device presentation and advertisements

  - Clarification statement refers to the following text or equivalent
    - *This device or software is intended for use only for general well-being purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose (such as the detection, diagnosis, monitoring, management or treatment of any medical condition or disease). Any health-related information provided by this device or software should not be treated as medical advice. Please consult a physician for any medical advice required.*

Devices for modification of appearance or anatomy

Background

•Devices could be intended by the manufacturer for medical purposes and/or for modification of appearance or anatomy* of an individual

•As long as the intended purpose of a device includes one or more medical purposes, the device is subject to the medical device regulatory controls

•Need for clarity on the scope of medical device regulatory controls for devices intended for modification of appearance or anatomy* only (e.g. treatment of wrinkles, Improving skin texture, body contouring)

Key Review Considerations

•Post-market surveillance data globally and locally related to these devices

•Other regulatory oversight in place locally:

- Professional bodies (e.g. Singapore Medical Council (SMC)) governs the use of devices which are intended for use by doctors only
  - *Guidelines on Aesthetic Practices for Doctors (Allowed aesthetic procedures, premises and training requirements to conduct aesthetic procedures)*
- NEA has licensing requirements for individuals or facilities handling ionizing/non-ionizing radiation emitting equipment
  - *Radiation Protection Act (Use of ionizing and non-ionizing radiation)*

Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"

Risk-based approach

- For devices intended for modification of appearance or anatomy* only, HSA to focus our regulatory oversight on **high risk** devices under this category
  - High risk devices with known or reported serious adverse events globally
  - High risk devices that pose **comparable risks** to other regulated medical devices (e.g. foreseeable hazards)

Device Types	Known Serious Adverse Events - **Examples**
Gluteal implants, breast implants	Rupture, capsular contracture (scar tissues that forms around the implant and squeeze the implant)
Collagen/ hyaluronic dermal fillers, lip fillers	Injection site necrosis, nodules, allergic reaction

Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"

List of high risk devices intended for modification of appearance or anatomy* only that will be regulated as medical devices

i. any implant for the modification or fixation of any body part
(e.g. breast implant, gluteal implant)

ii. any injectable dermal filler or mucous membrane filler
(e.g. soft tissue fillers, wrinkle fillers)

iii. any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means
(e.g. liposuction devices)

NOTE: *Above list may be expanded in the future when new risks are identified (e.g. New technology, New application/use for existing technology, New risks surface from wide-spread use)*

****Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"***

Devices for modification of appearance or anatomy

- Devices intended for modification of appearance or anatomy* that also have medical claims are already regulated as medical devices
  - Hence the devices in the positive list are currently subject to medical device regulatory controls

- Devices intended solely for modification of appearance or anatomy that are not within the high risk list of devices (e.g. cryolipolysis equipment, laser devices for skin tightening) → not regulated as MD
  - Some of these devices will still be subject to other local regulatory controls (e.g. NEA controls) where applicable
  - No impediment to market access

Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"

VI. Premarket Consultation and Priority review scheme

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Pre-Market Consultation (PMC) Scheme

1 Medical Device Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

2 Medical Device Pre-submission Consultation

Channel for stakeholders to **seek feedback on their device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

Medical devices* to be registered via FULL Evaluation Route → **Route 2**

Qualification Criteria

1 Falls under 1 of the 5 healthcare focus area

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

2 Designed & validated to meet unmet clinical needs

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

OR

Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

→ **Route 1**

**** Devices incorporating registrable medicinal products are not eligible for the Priority Review Scheme.***

Risk Class	TAT for Registration Routes (in working days)				
	R7 ► **Immediate** ◄	**Expedited**	**Abridged**	**Full**	**Full (Priority Review Scheme)**
Class B	Immediate Registration upon Submission		100	160	120
Class C	R7 ► Immediate registration upon submission (for Class C standalone medical mobile application only) ◄	120	160	220	165
Class D		180	220	310	235
Class D (devices incorporating medicinal products)			220	310	

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Faster Access to Lower Risk Medical Devices

Approval Timeline

	Current	From 1 June 2018
Class A Sterile Devices	30 working days	0 working days

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Faster Access to Lower Risk Medical Devices

Approval Timeline

Current	From 1 June 2018
Expedited Route	Immediate Route
60 working days	0 working days

Class B Devices with:

1. No safety issues globally
2. Two independent regulatory agencies' approval
   or
   One reference agency's approval and 3 years of marketing history

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Clearer Regulatory Controls

	Regulated	Not Regulated
Telehealth Products	• For medical purpose	• Not for medical purpose • Wellness devices *To include a clarification statement that the product is not for medical purpose

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Clearer Regulatory Controls

Devices for Modification of Appearance or Anatomy

Regulated as Medical Device

Positive list of high risk devices:

- **Implants**
- **Injectable dermal or mucous membrane fillers**
- **Invasive devices for fat removal or fat degradation purpose**

***List may be expanded in future**

Thank you