Contact Lens Controls

19 August 2011

Health Products Regulation Group
Health Sciences Authority

SCOPE

1. What is a medical device?
2. Summary of regulatory controls for medical devices (including contact lens)
3. How to access SMDR?
4. How to Class A and B Transition List?
5. Import and supply of contact lens
6. Prohibitions and penalties under Health Products Act
7. Take-home message

WHAT IS A MEDICAL DEVICE?

Definition of medical device in Health Products Act

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its product owner to be used, whether alone or in combination, for humans for one or more of the specific purposes of —

(a)diagnosis, prevention, monitoring, treatment or alleviation of any disease;

(b)diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c)investigation, replacement, modification, or support of the anatomy or of a physiological process;

(d)supporting or sustaining life;

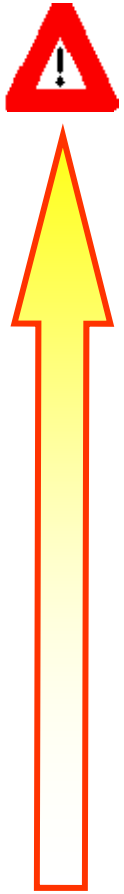
(e)control of conception;

(f)disinfection of medical devices; or

(g)providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Device risk-based classification



4 Categories based upon the degree of risk:

S'pore / GHTF	EU	Risk Level	Device Examples
D	III	High Risk	Absorbable sutures, implantable cardiac pacemaker, heart valves, heart stents
C	IIb	Medium-high Risk	Lung ventilator, orthopaedic implant, CT and X-Rays, baby incubators, blood bags, contact lens cleaning/disinfection solution
B	IIa	Medium-low Risk	Hypodermic needles, single-use catheters, digital thermometers, digital blood pressure monitors, MRI, contact lens
A	I	Low Risk	Wheelchairs, tongue depressor, bandage, walking aid, gauze dressings

NOTE
Risk classification rules are in 3rd Schedule of the Health Products (Medical Devices) Regulations 2010

HSA Guidances on risk classification
- GN-13: Guidance on risk classification of general medical devices, and
- GN-14: Guidance on risk classification for in-vitro diagnostic medical devices.

REGULATORY CONTROLS FOR MEDICAL DEVICES

Key Points of Medical Device Control

HEALTH PRODUCTS ACT

1. Controls on manufacture/ import/ supply of health products – manufacturer, importer, wholesaler (includes export)	**2. Controls on product itself**
3. Controls on post-market activity (e.g. Recalls, distribution records, advertisements)	

2 Controls – Registration of product and Licensing of dealers

1

Product Registration

Registered medical device for supply in Singapore

S E P A R A T E

2

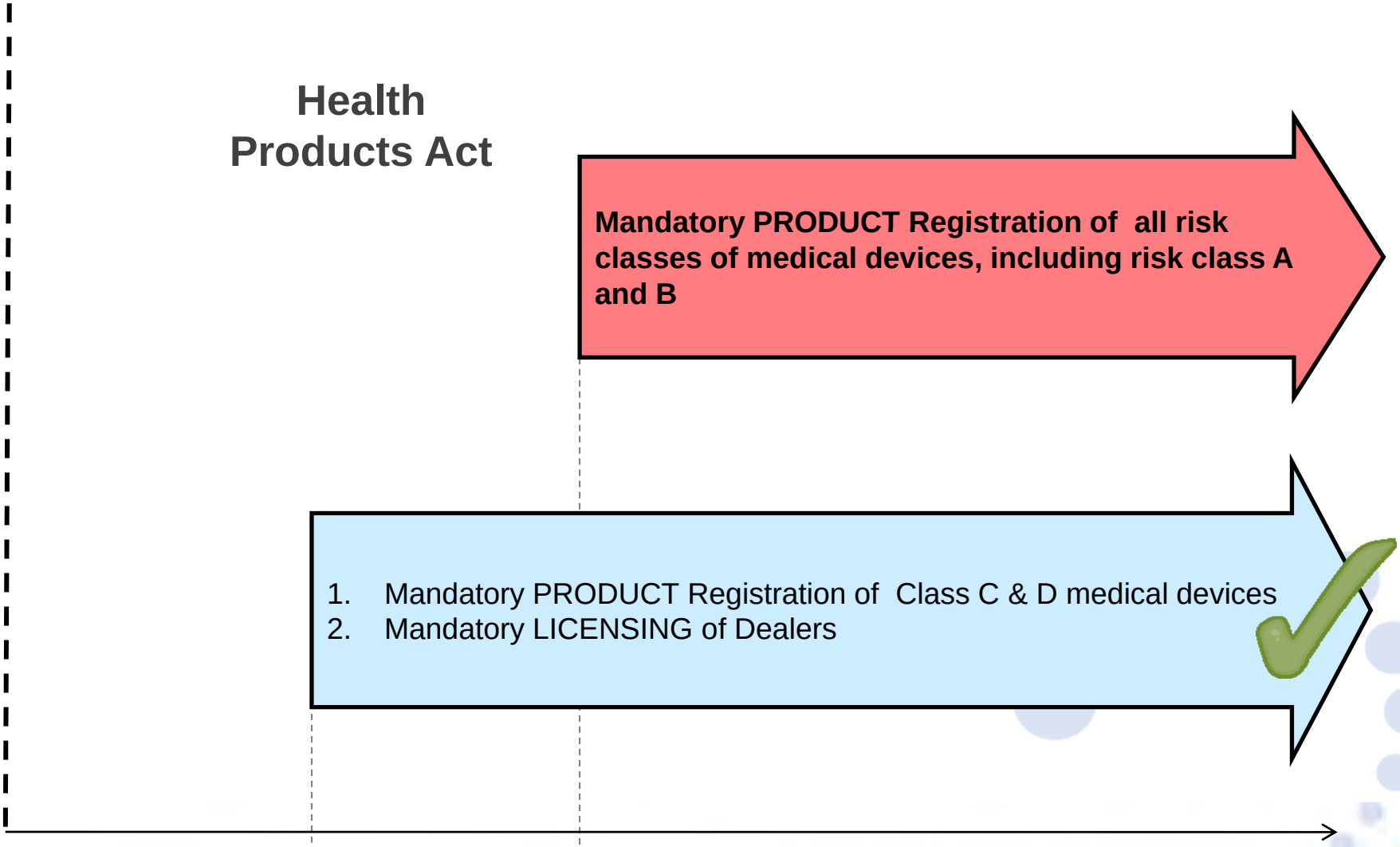
Dealer's Licensing

(i) Manufacturer's licence

(ii) Importer's licence

(iii) Wholesaler's licence

Medical Device Controls



Requirements of Dealer's Licence

Manufacturer's Licence	Importer's Licence	Wholesaler's Licence
ISO 13485 (for finished medical device manufacturing)	GDPMDS * OR ISO 13485 certificate or letter from certification body should state that scope of storage and distribution is included (for local manufacturers)	GDPMDS * OR ISO 13485 certificate or letter from certification body should state that scope of storage and distribution is included (for local manufacturers)

*Exceptions: GDPMDS is not required for

- Import for Re-Export only
- Import for Non-Clinical Use only

A declaration will be submitted in place of the certificate. Template is available: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html

CONTACT LENS

Contact Lens

Dealer's Licensing for powered contact lens

Since 10 Aug 2010, only **licensed dealers** are permitted to manufacture, import or wholesale medical devices, including powered contact lens.

Product Registration for powered contact lens

From 01 Jan 2012 , powered contact lens require **registration** with HSA prior to their supply.

Dealer's Licensing for non-powered contact lens

By end Q2 2012 (or as soon as 01 Jan 2012), only **licensed dealers** are permitted to manufacture, import or wholesale non-powered contact lens.

Product Registration for non-powered contact lens

By end Q2 2012 (or as soon as 01 Jan 2012), non-powered contact lens require **registration** with HSA prior to their supply.

Contact lens – Medical Device

From 01 Jan 2012, only the following powered contact lens can be legally supplied:

(i) Contact lens list on Singapore Medical Device Register (SMDR) :

(ii) Contact lens submitted (by 31 Aug 2011) but under processing:

- Listed on **Class A and B Transition list****
- Criteria apply
- Devices on Transition list can be imported and supplied in Singapore
- Transition list is subject to periodic review

By end Q2 2012 (or as soon as 01 Jan 2012), non-powered contact lens require **registration** with HSA prior to their supply.

HOW TO ACCESS SMDR?

How to access SMDR (1)

1. Go to the HSA website: http://www.hsa.gov.sg/

2. Select ‘Medical Devices’ under ‘For Industry’

3. Select “Singapore Medical Device Register”.

4. Select “Continue”

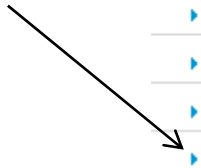
5. Select “Advanced Search” tab, and perform device search.

How to access SMDR (2)

Click Here

How to access SMDR (3)

Click Here



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- Cosmetic Products
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  - Regulatory Updates
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  - Fees and Charges
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  - Transition List
  - Authorisation Routes
  - TradeNet® Controls
  - Field Safety Corrective Action Reporting
  - Adverse Event Reporting
  - Medical Device Advisories
  - e-Services & Forms
  - Frequently Asked Questions

HEALTH PRODUCTS REGULATION

Medical Devices

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Medical devices are critical to the delivery of healthcare.

The term "Medical Devices", as defined in the Health Products Act 2007, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of disease or abnormal physical condition.

Medical devices vary in complexity from simple products such as tongue depressors, surgical sutures and contact lenses to more complex devices such as implantable defibrillators, prosthetic heart valves and diagnostic imaging systems

- Overview
  Learn more about what is a medical device and the principles of classification of medical devices
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  News updates, safety alerts on medical devices and guidance documents
- Regulatory Framework
  Provisions of the Contact Lens Practitioners Act, Radiation Protection Act, Medicines Act and Implementation of regulatory controls

e-Services & Forms

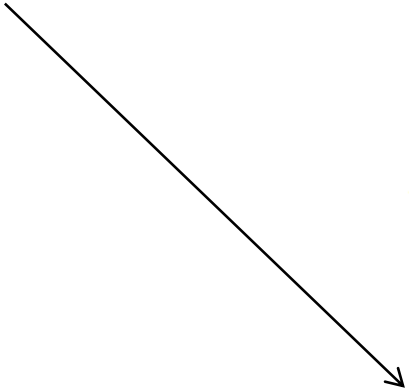
- Medical Device Information & Communication System (MEDICS)
- Applicant Feedback Form

- About Medical Device Branch

Contact Info

How to access SMDR (4)

Click Here



E-SERVICES & FORMS

Singapore Medical Device Register

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Disclaimer

Any reference to a commercial product, process, service, or company is not an endorsement or recommendation by the Medical Device Branch, Therapeutic Products Division, Health Sciences Authority, or any of its components. Manufacturers and/or its Registrants shall ensure that the medical device listed in the Singapore Medical Device Register (SMDR) meets the essential requirements for safety, quality and performance and keep objective evidence to establish that the medical device continues to meet those requirements.

Voluntary Product Registration Scheme (VPRS)

Any medical device registration application submitted to HSA before 31 March 2007 under the Voluntary Product Registration Scheme (VPRS) , were evaluated in accordance to VPRS requirements.

[Continue]

TradeNet® Declaration Procedures for Medical Devices that are listed on Singapore Medical Device Register (SMDR)

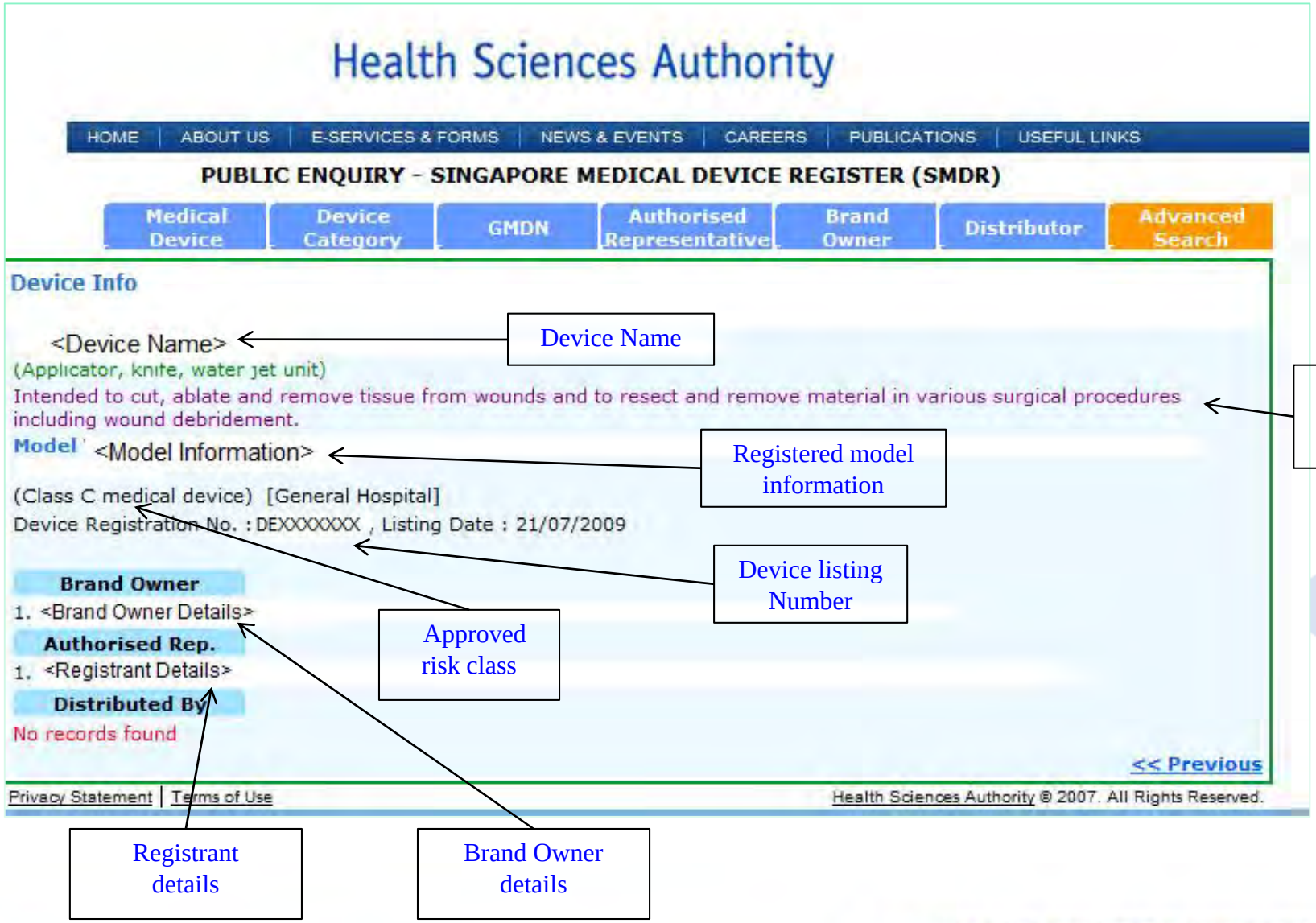
HS Codes that are controlled solely by Medical Device Branch

This document provides the procedure to facilitate Import Permit applications via TradeNet® for medical devices listed on the Singapore Medical Device Register (SMDR) which use HS Codes that are controlled solely by MDB. Please refer to MDB Circular.

How to access SMDR (5)

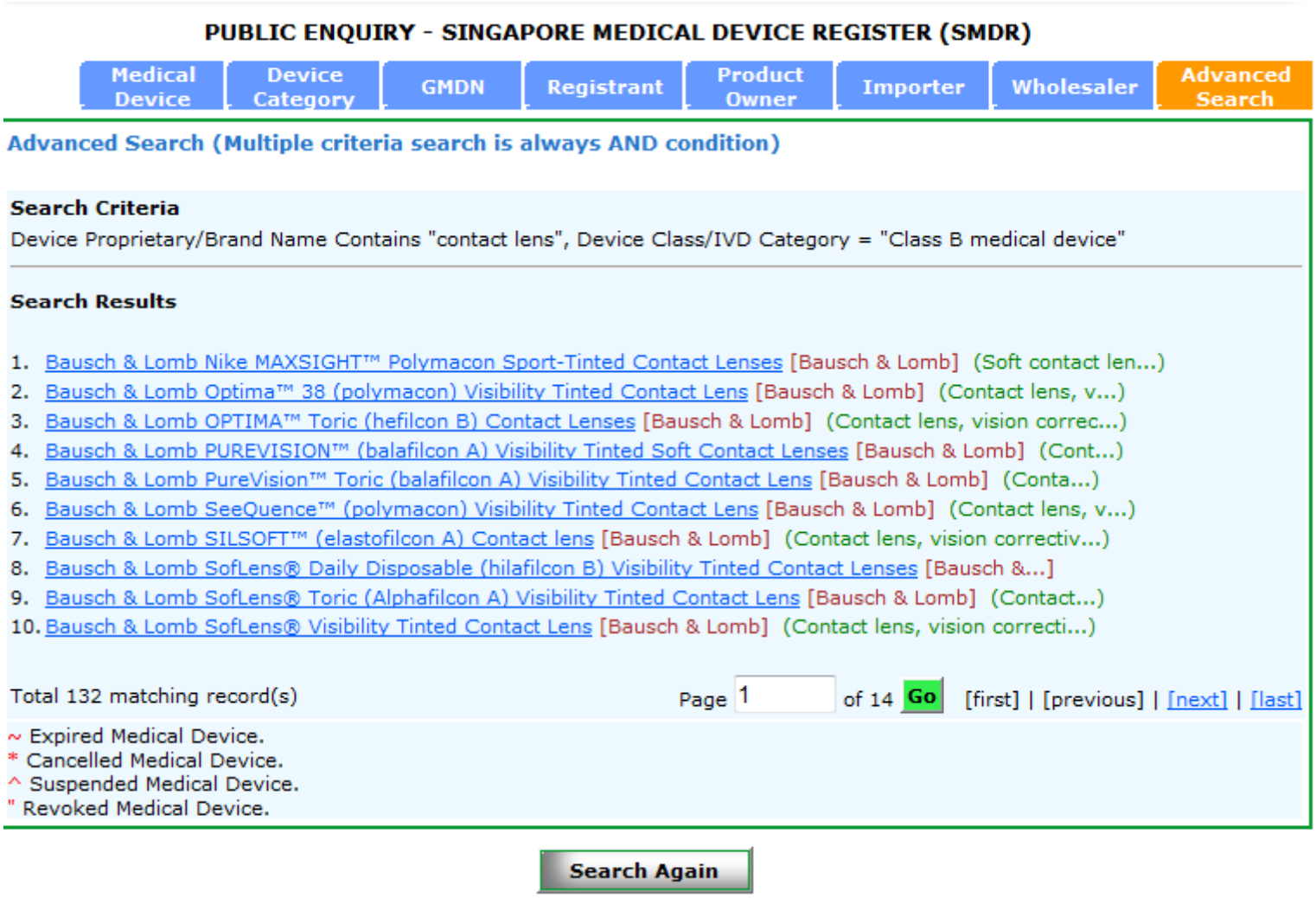
For searches based on device listing number

How to access SMDR (6)



Registered contact lens on SMDR

As of 01 Aug 2011, 132 registered contact lens on SMDR



PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device | Device Category | GMDN | Registrant | Product Owner | Importer | Wholesaler | Advanced Search

Advanced Search (Multiple criteria search is always AND condition)

Search Criteria

Device Proprietary/Brand Name Contains "contact lens", Device Class/IVD Category = "Class B medical device"

Search Results

1. Bausch & Lomb Nike MAXSIGHT™ Polymacon Sport-Tinted Contact Lenses [Bausch & Lomb] (Soft contact len...)
2. Bausch & Lomb Optima™ 38 (polymacon) Visibility Tinted Contact Lens [Bausch & Lomb] (Contact lens, v...)
3. Bausch & Lomb OPTIMA™ Toric (hefilcon B) Contact Lenses [Bausch & Lomb] (Contact lens, vision correc...)
4. Bausch & Lomb PUREVISION™ (balafilcon A) Visibility Tinted Soft Contact Lenses [Bausch & Lomb] (Cont...)
5. Bausch & Lomb PureVision™ Toric (balafilcon A) Visibility Tinted Contact Lens [Bausch & Lomb] (Conta...)
6. Bausch & Lomb SeeQuence™ (polymacon) Visibility Tinted Contact Lens [Bausch & Lomb] (Contact lens, v...)
7. Bausch & Lomb SILSOFT™ (elastofilcon A) Contact lens [Bausch & Lomb] (Contact lens, vision correctiv...)
8. Bausch & Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lenses [Bausch &...]
9. Bausch & Lomb SofLens® Toric (Alphafilcon A) Visibility Tinted Contact Lens [Bausch & Lomb] (Contact...)
10. Bausch & Lomb SofLens® Visibility Tinted Contact Lens [Bausch & Lomb] (Contact lens, vision correcti...)

Total 132 matching record(s) Page 1 of 14 Go [first] | [previous] | [next] | [last]

~ Expired Medical Device.
* Cancelled Medical Device.
^ Suspended Medical Device.
" Revoked Medical Device.

Search Again

HOW TO ACCESS CLASS A & B TRANSITION LIST?

How to access Transition List (1)

Click Here

How to access Transition List (2)

Click Here

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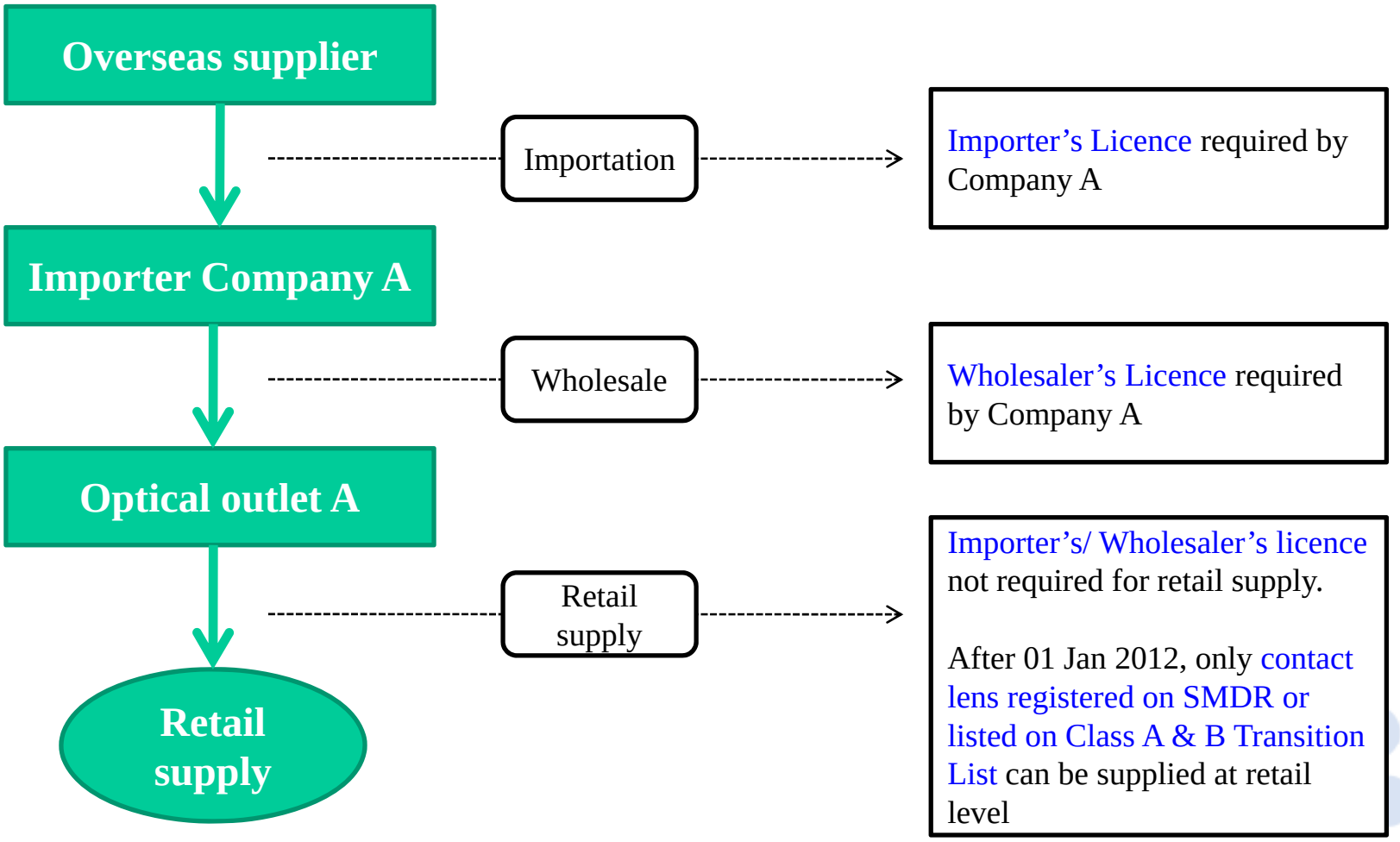
IMPORT AND SUPPLY OF CONTACT LENS

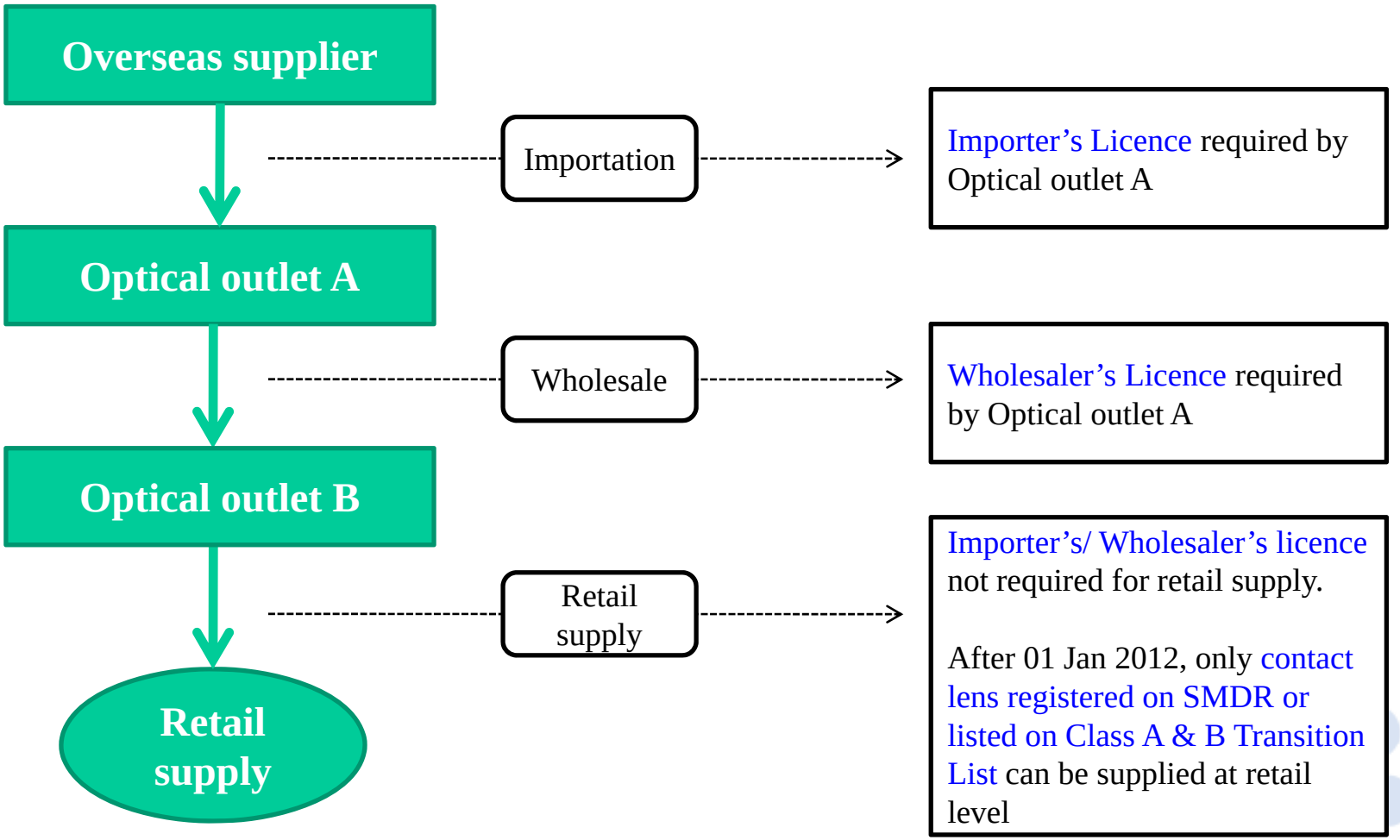
Scenario 1



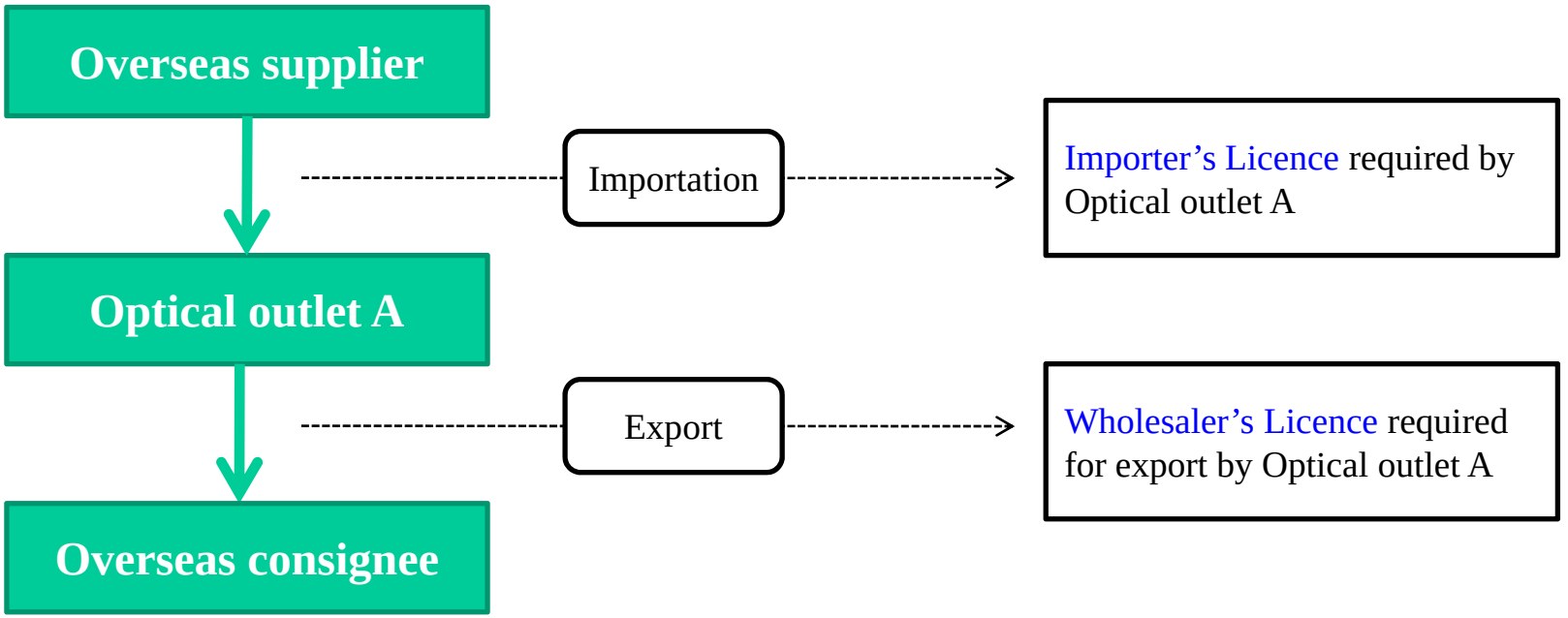
Important Note

1. **Registered medical devices can only be imported by importers authorised by Registrant (listed on SMDR)**
2. **Optometrists and their optical outlets should only purchase contact lens from authorised importers, as the authenticity of supply from parallel importers cannot be ascertained.**

Scenario 2



Scenario 3



Note

1.Direct purchase from internet source is also an import and requires importer's licence.

2.Imports of contact lens through parcel post are no longer permitted even if for personal use.

Optometrist and Opticians Act

- The Optometrists & Opticians(O&O) Act (administered by the Ministry of Health) was passed in Parliament in July 2007 to regulate the practice of Optometry and Opticianry in Singapore

- Under the O&O Act, only Optometrists and Opticians (Contact Lens Practice) can supply, prepare and dispense contact lenses, including non-powered cosmetic lenses.

PROHIBITIONS AND PENALTIES

Supply of unregistered medical device

Under section 15 of the Health Products Act, it is an offence to supply an unregistered medical device.

<u>Penalties</u>

A fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

Manufacture and Import of unregistered medical device

Under section 12 and 13 of the Health Products Act, it is an offence to Manufacture or import an unregistered medical device.

Penalties

A fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

Contravention of licence conditions

Under section 24(5) of the Health Products Act, HSA is given the authority to issue licence conditions.

<u>Implications</u>

Failure to comply with licence conditions opens the licence holder to the following possibilities:

- Suspension or cancellation of licence under section 27 of the Health Products Act, and
- Prosecution under regulation 32 of the Health Products (Medical Devices) Regulations 2010

Import of counterfeit medical devices

Under section 13 of the Health Products Act, it is an offence to import a counterfeit medical device.

Penalties

A fine not exceeding $100,000 or to imprisonment for a term not exceeding 3 years or to both.

Supply of counterfeit medical devices

Under section 16 of the Health Products Act, it is an offence to supply or procure or arrange for the supply of a counterfeit medical device.

Penalties

Fine not exceeding $100,000 or to imprisonment for a term not exceeding 3 years or to both

TAKE-HOME MESSAGE

Take-Home Message

1. No imports of medical devices, including contact lens, without importer's licence from HSA
2. After 01 Jan 2012, ensure medical devices are registered with HSA prior to supply from your retail optical outlet
3. Avoid purchases from non-authorised importers as they may be sources of counterfeit MD. If not sure, check with original supplier.
4. Sale/transfer of contact lens between optical outlets is wholesale supply and would require wholesaler's licence.