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?
“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:

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

**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
REGULATORY CONTROLS FOR MEDICAL DEVICES
## Key Points of Medical Device Control

### HEALTH PRODUCTS ACT

<table>
<thead>
<tr>
<th>1. Controls on manufacture/import/supply of health products</th>
<th>2. Controls on product itself</th>
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</thead>
<tbody>
<tr>
<td>– manufacturer, importer, wholesaler (includes export)</td>
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<table>
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<tr>
<th>3. Controls on post-market activity</th>
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<tr>
<td>(e.g. Recalls, distribution records, advertisements)</td>
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</tr>
</tbody>
</table>
2 Controls – Registration of product and Licensing of dealers

1

Product Registration

Registered medical device for supply in Singapore

2

Dealer’s Licensing

(i) Manufacturer’s licence
(ii) Importer’s licence
(iii) Wholesaler’s licence
Medical Device Controls

Health Products Act

Mandatory PRODUCT Registration of all risk classes of medical devices, including risk class A and B

1. Mandatory PRODUCT Registration of Class C & D medical devices
2. Mandatory LICENSING of Dealers

## Requirements of Dealer’s Licence

<table>
<thead>
<tr>
<th>Manufacturer’s Licence</th>
<th>Importer’s Licence</th>
<th>Wholesaler’s Licence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13485 (for finished medical device manufacturing)</td>
<td>GDPMDS * OR ISO 13485 certificate or letter from certification body should state that scope of storage and distribution is included (for local manufacturers)</td>
<td>GDPMDS * OR ISO 13485 certificate or letter from certification body should state that scope of storage and distribution is included (for local manufacturers)</td>
</tr>
</tbody>
</table>

*Exceptions: GDPMDS is not required for
- Import for Re-Export only
- Import for Non-Clinical Use only

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

HEALTH PRODUCTS REGULATION

Medical Devices

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

Regulatory Updates
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

Contact Info

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How to access SMDR (4)

E-SERVICES & FORMS

Singapore Medical Device Register

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

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How to access SMDR (6)

### Device Info

**Device Name**
(Applicator, knife, water jet unit)
Intended to cut, ablate and remove tissue from wounds and to resect and remove material in various surgical procedures including wound debridement.

**Model**
(Class C medical device) [General Hospital]
Device Registration No.: DEX000000, Listing Date: 21/07/2009

**Brand Owner**
1. <Brand Owner Details>
   - Authorised Rep.
2. <Registrant Details>
   - Distributed By:
     - No records found

**Registered model information**

**Approved risk class**

**Device listing Number**

**Approved intended purpose**

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**Registrant details**

**Brand Owner details**

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

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Device Category</th>
<th>GMDN</th>
<th>Registrant</th>
<th>Product Owner</th>
<th>Importer</th>
<th>Wholesaler</th>
<th>Advanced Search</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bausch &amp; Lomb Optima™ 38 (polyacon) Visibility Tinted Contact Lens</td>
<td>[Bausch &amp; Lomb]</td>
<td>(Contact lens, v...)</td>
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<tr>
<td>Bausch &amp; Lomb OPTINA™ Toric (heficon B) Contact Lenses</td>
<td>[Bausch &amp; Lomb]</td>
<td>(Contact lens, vision correction...)</td>
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</tr>
<tr>
<td>Bausch &amp; Lomb PUREVISION™ (balaflacon A) Visibility Tinted Soft Contact Lenses</td>
<td>[Bausch &amp; Lomb]</td>
<td>(Cont...)</td>
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<td>Bausch &amp; Lomb PureVision™ Toric (balaflacon A) Visibility Tinted Contact Lens</td>
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<tr>
<td>Bausch &amp; Lomb SeeQuence™ (polyacon) Visibility Tinted Contact Lens</td>
<td>[Bausch &amp; Lomb]</td>
<td>(Contact lens, v...)</td>
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<tr>
<td>Bausch &amp; Lomb SILSOFT™ (elastofilon A) Contact lens</td>
<td>[Bausch &amp; Lomb]</td>
<td>(Contact lens, vision correction...)</td>
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<tr>
<td>Bausch &amp; Lomb SoftLens® Daily Disposable (hilaflacon B) Visibility Tinted Contact Lenses</td>
<td>[Bausch &amp;...]</td>
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<td></td>
<td></td>
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<tr>
<td>Bausch &amp; Lomb SoftLens® Toric (Alphaficolon A) Visibility Tinted Contact Lens</td>
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Total 132 matching record(s)

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

Overseas supplier

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Importation

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Optical outlet A

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Wholesale

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Optical outlet B

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Retail supply

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Importer’s Licence required by Optical outlet A

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Wholesaler’s Licence required by Optical outlet A

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Importer’s/ Wholesaler’s licence not required for retail supply.

After 01 Jan 2012, only contact lens registered on SMDR or listed on Class A & B Transition List can be supplied at retail level.
Scenario 3

**Scenario 3**

**Overseas supplier** → **Optical outlet A**

Importation

**Optical outlet A** → **Overseas consignee**

Export

**Importer’s Licence** required by Optical outlet A

**Wholesaler’s Licence** required for export by Optical outlet A

**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.

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

Implications
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.