Medical Device Regulation --
Implications On Dental Practice

Health Products Regulation Group
Overview

• Introduction
• Issues highlighted
• Enhancements to the medical device regulatory framework
• Current initiatives
• Upcoming events/ further enhancements
• Dental medical devices
Regulation of Health Products

OBJECTIVES

- **SAFEGUARD PUBLIC HEALTH**
  - Ensure appropriate safety, quality, technical and efficacy standards are met
  - Facilitate recalls, product withdrawals

- **FACILITATE**
  - Support development of a high quality healthcare system

- **ASSURE**
  - Instill trust, confidence and credibility of products at home and abroad
Global Medical Device Regulations

* status as of 2010

Source: WHO BASELINE COUNTRY SURVEY on Medical Devices 2010
Global Harmonization Task Force
(International Medical Device Regulators Forum)
IMDRF

An international forum for medical device regulators and (medical device trade associations)

Objective
To develop harmonised principles relating to the regulation of medical devices
Phased Approach: Medical Device Regulations Roll-Out

Phase I: Post-Marketing Duties (e.g. keep supply records, report adverse events and FSCAs)
- Nov 2007

Voluntary Product Registration (VPR)

Phase II: Commence Product Registration and License Applications
- Nov 2008
- May 2010
- Aug 2010

Phase III: Evaluation and Registration of Class C and D Medical Devices (On Transition List prior to 1 May 2010)
- Nov 2008

Phase IV: Mandatory Licensing of Medical Device Dealers (who can manufacture, import or wholesale medical devices)
- Aug 2010

Phase V: Final Date of Submission for Class A and B Medical Devices (On Transition List prior to 1 Dec 2011)
- May 2010
- Jan 2012

Phase VI: Evaluation and Registration of Class A and B Medical Devices

Health Products (Medical Devices) Regulations 2007

Health Products (Medical Devices) Regulations 2010

No fees for product registration

Full Implementation

Controls are aligned with the device lifecycle
Post-market controls complement pre-market product controls because:
1. Impossible to design a device with zero risk of failure
2. Impractical to prospectively study each incremental change made in the devices
# Medical Device Risk Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class D</td>
<td>High Risk</td>
<td>E.g. Absorbable sutures, implantable cardiac pacemaker, heart valves, heart stents, IUDs</td>
</tr>
<tr>
<td>Class C</td>
<td>Medium-high Risk</td>
<td>E.g. Lung ventilator, orthopaedic implant, IOLs, baby incubators, blood bags</td>
</tr>
<tr>
<td>Class B</td>
<td>Medium-low Risk</td>
<td>E.g. Hypodermic needles, single-use catheters, contact lenses, digital blood pressure monitors, hearing aids</td>
</tr>
<tr>
<td>Class A</td>
<td>Low Risk</td>
<td>E.g. Sterile plasters, manual spirometers, surgical face masks, ear syringes, guide wires</td>
</tr>
<tr>
<td>Class A (Exempt)</td>
<td>Minimal Risk</td>
<td>E.g. tongue depressor, bandage, walking aid, reusable surgical instruments, walking frames</td>
</tr>
</tbody>
</table>
Dental Devices: Risk-Based Approach

Class C and D:
E.g: Bone matrix implants, dental x-ray systems

Class B:
E.g.: burs, crowns, abutments, scaling systems

Class A:
E.g: Reusable dental surgical instruments, impression materials

HSA Guidance GN-13: Guidance on risk classification of general medical devices
Refinements

2007
- Commencement of Health Product Act for Medical Devices

2009
- Step-wise expansion of exempted Class A devices
- Transition List (T List)
- Extension of timeline for Class C and D T-list application

2011
- Extension of timeline for Class A and B T-list application
- Introduction of Dental Grouping Terms
- Modification of Special Authorisation Route to allow consolidation from different healthcare institutions
Access Routes to Market

**Product Registration**
- Devices are reviewed under stratified routes depending on its prior approval in medical device reference agencies*
- Product dossier consisting of quality, pre-clinical and clinical documents

* European Union, Health Canada, Japan Ministry of Health Labour and Welfare, United States Food & Drug Administration, Australia Therapeutics Goods Administration

**Exempted lower low-risk devices**
- Immediate entry for these devices
- Dealers of such devices need to be licensed with HSA but NOT the product

**Devices for Clinical Trials**
- Import of unregistered devices for clinical trials conducted in Singapore
- Clinical Trial Test Materials (CTM for Medical Devices) application form

**Transition List (T-list)**
- Unimpeded access for medical devices that are submitted for registration
- Product applications have to be submitted before a stipulated date and fulfill the T-list criterion

**Special Authorisation**
- Access for unregistered medical devices
- Device information & request from the doctor or healthcare facility
# Access Routes to Market

## Product Registration

- Devices are reviewed under stratified routes depending on its prior approval in medical device reference agencies*
- Product dossier consisting of quality, pre-clinical and clinical documents

* European Union, Health Canada, Japan Ministry of Health Labour and Welfare, United States Food & Drug Administration, Australia Therapeutics Goods Administration

## Exempted lower low-risk devices

- Immediate entry for these devices
- Dealers of such devices need to be licensed with HSA but NOT the product

## Devices for Clinical Trials

- Import of unregistered devices for clinical trials conducted in Singapore
- Clinical Trial Test Materials (CTM for Medical Devices) application form

## Transition List (T-list)

- Unimpeded access for medical devices that are submitted for registration
- Product applications have to be submitted before a stipulated date and fulfill the T-list criterion

## Special Authorisation

- Access for unregistered medical devices
- Device information & request from the doctor or healthcare facility
Regulatory costs (Class B)

- **Pre-market activities**
  - Medical device product design
  - Investigational testing / clinical trial
  - Product approval for sale

- **Post-market activities**
  - Product manufacture
  - Product available for sale/supply
  - Product purchase/use

1 time registration fee: $900/1800 + 500

Annual retention fee: $35

Cost recovery

Public good funding

Registration one-time for whole product life cycle in market
Grouping Example: System

Dental implant fixation system

- Standard screws and auto-drive screws
- Ligature wires
- Dental plates
- Dental drills
- Plate-holding forceps
- Plate-cutters
- Cannulas

Qualifies to be grouped as **SYSTEM**

Same product owner and used in combination to complete a common intended purpose

Submit 1 product registration application.
Dental grouping term (DGT)
- Generic term to describe similar dental devices with similar intended purpose

Dental grouping rules
- Members have to be Class A or B devices
- Fall within the description of 1 DGT
- Are of the same risk class
- Are from the same product owner

If all dental grouping rules are met:
Qualifies to be grouped as Dental group
Submit 1 product registration application.
Grouping example: DGT

- **Dental burs**
  - Rotary cutting devices designed to fit into a dental handpiece and intended to cut hard structures in the mouth.

<table>
<thead>
<tr>
<th>Product name</th>
</tr>
</thead>
<tbody>
<tr>
<td>XYZ Impresso™ dental bur</td>
</tr>
<tr>
<td>XYZ Supra™ dental bur</td>
</tr>
<tr>
<td>XYZ Super™ dental bur</td>
</tr>
</tbody>
</table>

- To submit 1 application using DGT “dental burs”
## Grouping and Cost Savings

### Example 1: Class B Lacrimal Duct Catheter Kit
- Multiple models can be in 1 application --- Inflation Device, Bilateral Stopclock, Lacrimal Duct Balloon Catheter

### Example 2: Groupings of BD Eclipse™ Injection Needle with Luer Lok™ Syringe by Needle size, length (Class B)

<table>
<thead>
<tr>
<th>SN.</th>
<th>Safety Needles with Syringe (12 types) – examples:</th>
<th>Abridged Evaluation Costs (S$)</th>
<th>Grouping savings (S$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3ML, 21G, 1 inch</td>
<td>500+1,800 = 2,300</td>
<td><strong>Grouping rules allowed 1 application of different syringe and needle sizes:</strong></td>
</tr>
<tr>
<td>2</td>
<td>1ML, 25G, 5/8 inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3ML, 25G, 5/8 inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3ML, 23G, 1 inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>3ML, 22G, 1-1/2 inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>1ML, 27G, ½ inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1ML, 30G, ½ inch</td>
<td>500+1,800 = 2,300</td>
<td></td>
</tr>
</tbody>
</table>

Total costs: 15,100

**Savings:** S$13,800
Stratified Approach (A)

Class A

- Exempt all lowest risk Class A devices except for sterile devices (e.g. single-use speculum, blood collection tubes)

- Sterile devices with the CE mark will be cleared faster

- All exempted devices will need to be declared in the importers and manufacturer’s license every half yearly – *For traceability purposes for post-market surveillance*

Post-market duties and obligations stipulated in HP Act applicable

- TAT ↓ to 30 WD
- 1 May 2012
- S$25
Stratified Approach (B)

Class B
- Judicious referencing of reputable agencies

(a) **Immediate registration route** for products approved by two of HSA’s reference agencies and marketed without safety concerns for at least three years;
(b) **Expedited registration route** for Class B devices that **either** have been approved in two of the reference agencies, **or** approved in one of those agencies and marketed in Singapore or this jurisdiction without safety concerns for at least three years

Independent reference agency: US FDA, Health Canada, Japan and EU / TGA*

<table>
<thead>
<tr>
<th>S$1400</th>
<th>TAT ↓ to 60 WD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sept 2012</td>
<td></td>
</tr>
</tbody>
</table>
Class B Evaluation Routes

• In June 2012, HSA published the draft guidance on the 4 registration routes:
  – Expedited Class B Registration (EBR 1)
  – Expedited Class B Registration (EBR 2)
  – Abridged
  – Full

• A total of 3 focus groups involving 44 industry members were conducted and over 80 comments were received
# Qualifying Criteria

## Routes for Product Registration

<table>
<thead>
<tr>
<th>Immediate class B Registration IBR</th>
<th>Expedited Class B Registration EBR-1</th>
<th>EBR-2</th>
<th>Abridged</th>
<th>FULL</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Registered in 2 or more independent reference agencies*</td>
<td>-Registered in 1 reference agency</td>
<td>-Registered in 2 or more independent reference agencies*</td>
<td>Registered in 1 reference agency</td>
<td>Not Registered in any of the reference agencies</td>
</tr>
<tr>
<td>- Marketed in the above 2 agencies jurisdictions for ≥ 3 years</td>
<td>-Marketed in the above agency jurisdiction or in Singapore for ≥ 3 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No safety issues globally</td>
<td>- No safety issues globally</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No prior rejection/withdrawal by independent reference agencies* and Singapore</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* EU and TGA Australia considered as one reference agency approval

For IBR, EBR and abridged routes, the medical device submitted should have similar intended as that approved by reference agencies.
Why 2 Reference Agencies?

US FDA 510K (80%):
Comparison of the device to >1 similar legally marketed devices and support their substantial equivalency claims.

Substantial equivalence need only to demonstrate that the new device is at least as safe and effective as the predicate (commonly through literature review).

PMA (20%): Evaluates the safety and effectiveness of Class III medical devices.

EU - Notified Bodies
Requirements of directives focus on device performance, not effectiveness.

Each Member State accredits its own Notified Bodies:
- Disparity of standards of CE-marked (approved) medical devices.

Notified Bodies are private business entities:
- Possible conflicts of interest with industry clients.

CE-marked medical devices can be marketed in all EU Member States.

Mutual Recognition Agreement with Australia TGA.
→ No safety issues globally: (IBR/EBR)

– No deaths,

– No serious deterioration in the state of health¹,

Associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years;

AND

– No open field safety corrective actions (including recalls) at the point of submission.

¹ Serious deterioration in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person’s body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.
## Submission Requirements

<table>
<thead>
<tr>
<th>Documentary Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>EBR -1 and 2 (NEW for feedback)</th>
<th>IBR (NEW for feedback)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Letter of authorization</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2  Annex 2 List of Configurations</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3  Proof of reference agency’s approval(s)</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4  Proof of marketing history in the reference agencies’ jurisdictions e.g. Invoice with date,</td>
<td></td>
<td></td>
<td>Only required for EBR-1</td>
<td></td>
</tr>
<tr>
<td>5  Declaration of no safety issues globally</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6  Executive Summary</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7  Essential Principles Checklist and Declaration of conformity</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8  Device description</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9  Design verification and validation documents including:</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Preclinical studies</td>
<td>Detailed reports¹</td>
<td>Summary²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Clinical evidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Proposed device Labelling</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Risk Analysis</td>
<td>✔</td>
<td>If applicable</td>
<td>If applicable</td>
<td></td>
</tr>
<tr>
<td>12 Manufacturing site’s name and address</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Manufacturing Process – Flow Chart</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Turn-Around-Time (TAT) and Fees

<table>
<thead>
<tr>
<th>Routes</th>
<th>Immediate Class B registration – IBR</th>
<th>Expedited Class B registration – EBR1</th>
<th>Expedited Class B registration – EBR2</th>
<th>Abridged Evaluation</th>
<th>Full Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TAT</strong></td>
<td>Immediate listing upon successful submission</td>
<td>60 Working Days</td>
<td></td>
<td>100 Working Days</td>
<td>160 Working Days</td>
</tr>
<tr>
<td><strong>Fee</strong></td>
<td>$1400</td>
<td></td>
<td></td>
<td>$2300</td>
<td>$4000</td>
</tr>
</tbody>
</table>
Stratified Approach (C-D)

Class C and D
- Potential extension of this approach using reference agencies and history of safety to the higher risk Class C and D devices in an appropriate way at a later date

Independent reference agency: US FDA, Health Canada, Japan and EU / TGA*
Access Routes to Market

**Product Registration**

- Devices are reviewed under stratified routes depending on its prior approval in medical device reference agencies*
- Product dossier consisting of quality, pre-clinical and clinical documents

* European Union, Health Canada, Japan Ministry of Health Labour and Welfare, United States Food & Drug Administration, Australia Therapeutics Goods Administration

**Exempted lower low-risk devices**

- Immediate entry for these devices
- Dealers of such devices need to be licensed with HSA but NOT the product

**Devices for Clinical Trials**

- Import of unregistered devices for clinical trials conducted in Singapore
- Clinical Trial Test Materials (CTM for Medical Devices) application form

**Transition List (T-list)**

- Unimpeded access for medical devices that are submitted for registration
- Product applications have to be submitted before a stipulated date and fulfill the T-list criterion

**Special Authorisation**

- Access for unregistered medical devices
- Device information & request from the doctor or healthcare facility
Special Authorisation (SA) Routes

- Special access routes may be granted for unregistered devices
  - Novel devices for local health facilities and qualified practitioners
  - Support Singapore’s position as a regional trading and exhibition hub (import and re-export activities)
  - Facilitate biomedical research in Singapore
- Single application allowed for multiple devices (across risk class) and for multiple imports within the validity period
- At the expiry of the authorisation, importer shall submit returns for the number of devices imported and supplied
- Approval time of ~12 hours for urgent request to 14 working days (SAR hotline – 83889103)
Illustration - GN-27 consolidation

PHMC-licensed Hospital A
Device Name
ABC Stent
DEF Hip Implant System
GHI Stent

PHMC-licensed Hospital B
Device Name
ABC Stent
DEF Hip Implant System
GHI Stent

PHMC-licensed Hospital C
Device Name
ABC Stent
DEF Hip Implant System
GHI Stent

Importer and/or Wholesaler: Company Pte Ltd

1 GN-27 application, 1 fee (S$350)

3 applications consolidated into 1: Saved $700
# Extension of validity period of Authorization Route Licences

<table>
<thead>
<tr>
<th>Route Description</th>
<th>GN-26 (Named-Patient)</th>
<th>GN-27 (PHMC-licensed Facility)</th>
<th>GN-28 (Import for Export)</th>
<th>GN-29 (Non-Clinical Purpose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple import consignments</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Multiple medical devices in 1 application</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Validity period from 1 March 2012</td>
<td>6 months</td>
<td>6 months</td>
<td>12 months</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**Validity period for ALL routes:** 12 months
Revised SAR fee structure

<table>
<thead>
<tr>
<th>SAR Types</th>
<th>Current Fees ($)</th>
<th>New Fee Structure ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GN-26 (named-patient)</td>
<td>500</td>
<td>150</td>
</tr>
<tr>
<td>Requests by healthcare practitioners to import unregistered medical devices for use in specific named patients due to lack of registered alternatives.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GN-27 (PHMCA licensed facility)</td>
<td>500</td>
<td>350</td>
</tr>
<tr>
<td>Requests by licensed importers to import unregistered medical devices for use in specific PHMC-licensed healthcare institutions due to lack of registered alternatives.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GN-28 (import for re-export)</td>
<td>500</td>
<td>250</td>
</tr>
<tr>
<td>Requests by licensed importers to import unregistered medical devices for re-export purposes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GN-29 (non-clinical use)</td>
<td>500</td>
<td>250</td>
</tr>
<tr>
<td>Requests by licensed importers to import unregistered medical devices for non-clinical purposes e.g. exhibition, training purposes, in-vitro diagnostic medical devices for research-use only purposes, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Other Relevant Custom Clearance Routes

- Custom-made medical device:
  - Import solely for the supply on a Named-Patient basis
  - *Does not apply to* custom made devices made in Singapore by or for any PHMC Licensed facility in Singapore for use on patients under their care

- Refurbished medical device:
  - Export to an overseas product owner, manufacturer or their appointed representative for the purposes of refurbishment and subsequent importation into Singapore
  - Device returned to the original PHMC Licensed facility

- Application forms are downloadable from:
  - Authorisation is solely to facilitate Customs clearance purposes during importation
  - Application is provided *gratis*
Access Routes to Market

**Product Registration**
- Devices are reviewed under stratified routes depending on its prior approval in medical device reference agencies*.
- Product dossier consisting of quality, pre-clinical and clinical documents.

* European Union, Health Canada, Japan Ministry of Health Labour and Welfare, United States Food & Drug Administration, Australia Therapeutics Goods Administration

**Exempted lower low-risk devices**
- Immediate entry for these devices.
- Dealers of such devices need to be licensed with HSA but NOT the product.

**Devices for Clinical Trials**
- Import of unregistered devices for clinical trials conducted in Singapore.
- Clinical Trial Test Materials (CTM for Medical Devices) application form.

**Transition List (T-list)**
- Unimpeded access for medical devices that are submitted for registration.
- Product applications have to be submitted before a stipulated date and fulfill the T-list criterion.

**Special Authorisation**
- Access for unregistered medical devices.
- Device information & request from the doctor or healthcare facility.
Import of MDs for Clinical Trials - CTM

• Import of unregistered medical devices into Singapore for use only in clinical trials – Facilitated via CTM

• The CTM (medical devices) application form can be found at:
  ▪ One CTM form is to be submitted for each clinical trial.
WHAT ARE WE PRESENTLY DOING?
Other Current Initiatives

Unfamiliarity with Dossier Requirements

- HSA-SMaRT E-Guide on Dossier Submission
- Pre-submission consultation

Backlog and TAT

- Engaging external resources (clinicians, joint appointments, locum pharmacists etc)
- Ramping up of internal resources

1. No pre-clinical studies, e.g. no biocompatibility study for implants
2. No clinical evaluation report, only provide clinical journal articles
3. No sterilization validation report, e.g. for implants
4. No electrical safety test for “active” devices
5. ISO 13485 certificate provided but for the wrong site
Industry consultations

- Change Notification for Class B medical devices
- GDPMDS for Class A medical devices
- Expedited route for Class C & D
Fee Review

• Continue to review fee framework to better stratify whole fee structure for devices

• Commence with low cost, low volume devices brought in through SAR
  – Lower tiered fee structure
  – Submission and consultation required
  – Implemented on 1 Aug 2012
Greater Emphasis: Post-marketing

Screening Evaluation Approval

Pre Post

Industry

• Stepping up its vigilance activities to encourage more voluntary reporting of adverse events
• More regular compliance, sampling and audit checks to ensure conformity and inspection of licensees
• Environmental scanning for overseas alerts and local signals
• Enforcement: Leverage on more stringent penalties under the Health Products Act as a deterrent for repeated errant dealers

Healthcare Professionals

Patients

Healthcare
Professionals

Patients
Adverse Event Reporting

• Healthcare professionals play an important role to help safeguard public health by reporting adverse events (AEs) suspected to be related to medical devices

• AEs can be submitted to HSA’s Compliance Branch via the web-link: www.hsa.gov.sg/ae_online
DENTAL MEDICAL DEVICES
### Common Dental Medical Devices

<table>
<thead>
<tr>
<th>Diagnostic Devices</th>
<th>Surgical Devices</th>
<th>Therapeutic Devices</th>
<th>Prosthetic Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dental X-ray system</td>
<td>• Bone cutting instruments and accessories</td>
<td>• Orthodontic appliances and accessories</td>
<td>• Dental cement</td>
</tr>
<tr>
<td>• Pulp tester</td>
<td>• Dental drills</td>
<td>• Orthodontic brackets (plastic/metal)</td>
<td>• Dental burs</td>
</tr>
<tr>
<td>• Gingival fluid measurer</td>
<td>• Dental hand-piece sand accessories</td>
<td>• Preformed tooth positioner</td>
<td>• Preformed crowns</td>
</tr>
<tr>
<td>• Caries detection device</td>
<td>• Dental electrosurgical units and accessories</td>
<td></td>
<td>• Endosseous dental implant</td>
</tr>
<tr>
<td></td>
<td>• Intraosseous fixation screws/wires</td>
<td></td>
<td>• Endosseous dental implant abutment</td>
</tr>
<tr>
<td></td>
<td>• Jet injector</td>
<td></td>
<td>• Crown and bridge resin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Root canal post</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Endodontic points</td>
</tr>
</tbody>
</table>
## Possible Risk Classes of Dental Devices

<table>
<thead>
<tr>
<th>Class A</th>
<th>Class B</th>
<th>Class C</th>
<th>Class D</th>
</tr>
</thead>
</table>
| • Reusable surgical instruments  
• Face shields  
• Dental examination chairs  
• Dental impression materials | • Dental drills/ hand-pieces  
• Ultrasonic scalar  
• Sulphide detection device  
• Root apex locator  
• Orthodontic appliances and accessories  
• Orthodontic brackets (plastic/metal)  
• Prefabricated crowns  
• Dental cement (e.g. glass ionomer restorative filling materials) | • intraoral/extraoral x-ray imaging systems  
• Transgingival dental implants (dental abutments)  
• Endosseous dental implants  
• Fixtures for dental implants | • Bio-active implantable bone reconstruction materials (e.g. Those containing collagen)  
• Absorbable wound dressings (e.g. those containing collagen) |
Common Class A Dental Devices

- Sterile, single-use surgical instruments

Exempted from registration:
- Bite registration materials
- Reusable dental surgical instruments
- Non-sterile endodontic needles and syringes (used for irrigation of root canal)
- Wax material used for modeling of wax-dentures
- Gingival retraction cords
- Dental sectional matrix bands
- Face masks with shield

Please refer to the risk classification guidance document GN-22 for more information on class A medical devices exempted from product registration.
Dental products that are not medical devices

• Teeth whitening products (no medical claims)
• Dental floss
• Machining or polishing equipment for fabricating/ customising dental products in dental labs
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.
# Public Enquiry - Singapore Medical Device Register (SMDR)

## Medical Device

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M Defib-Pads</td>
<td>(Defibrillator paddle pad)</td>
</tr>
<tr>
<td>3M ESPE Adper™ Easy One Self-Etch Adhesive</td>
<td>(Adhesive, dentine)</td>
</tr>
<tr>
<td>3M ESPE Adper™ Prompt™ / Adper™ Prompt™ L-Pop™ Self-Etch Adhesive</td>
<td>(Dental bond)</td>
</tr>
<tr>
<td>3M ESPE Adper™ Scotchbond™ Multipurpose Adhesive</td>
<td>(Adhesive, album)</td>
</tr>
<tr>
<td>3M ESPE Adper™ Single Bond 2 Adhesive</td>
<td>(Dental bonding agent, poly)</td>
</tr>
<tr>
<td>3M ESPE Cavit™ G Temporary Filling Material</td>
<td>(Dental material, filling/restorative)</td>
</tr>
<tr>
<td>3M ESPE Cavit™ Temporary Filling Material</td>
<td>(Dental material, filling/restorative)</td>
</tr>
<tr>
<td>3M ESPE Cavit™ W Temporary Filling Material</td>
<td>(Dental material, filling/restorative)</td>
</tr>
<tr>
<td>3M ESPE Clinpro™ Sealant</td>
<td>(Dental fissure sealant, Clinpro Sealant)</td>
</tr>
<tr>
<td>3M ESPE Concise™ Light Cure White Sealant System</td>
<td>(Dental fissure)</td>
</tr>
</tbody>
</table>

Total 10203 matching record(s)

Page 1 of 1021

Expired Medical Device.
Cancelled Medical Device.
Suspended Medical Device.
Revoked Medical Device.

Best viewed using Internet Explorer 7.0 and above.
Medical Device Regulation Update

30 December 2011

Dear Healthcare Professional

IMPORTANT INFORMATION ON THE REGULATION OF MEDICAL DEVICES IN SINGAPORE

Recognising the increasingly important role of medical devices in the delivery of good quality healthcare, the Health Sciences Authority (HSA) introduced the Health Products Act and its subsidiary legislation, i.e., the Health Products (Medical Devices) Regulations in 2007 to ensure that safe, effective and good quality medical devices are registered for use in Singapore. The legislation provides for controls on the manufacture, import, supply, presentation and advertisement of medical devices.

This letter serves to update healthcare professionals on the regulatory framework for medical devices in Singapore and to create awareness of the various ways in which supply of medical devices can continue without impeding the practice of healthcare professionals.

- Email hsa_md_info@hsa.gov.sg or hsa_ct@hsa.gov.sg
- Dedicated phone telephone for clinician : 6304 5861