

Industry Focus Group Session:

Registration and Grouping of Dental Products

24 and 25 November 2011
Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

Scope

- Recap on Product Registration – Dental Devices
- Grouping Rules for Dental Products
 - Alternative Dental Grouping Rules
 - Case Studies
- Special Considerations

Rationale for Regulating Health Products – Medical Devices

Protect public health by ensuring that the medical devices available in Singapore are:

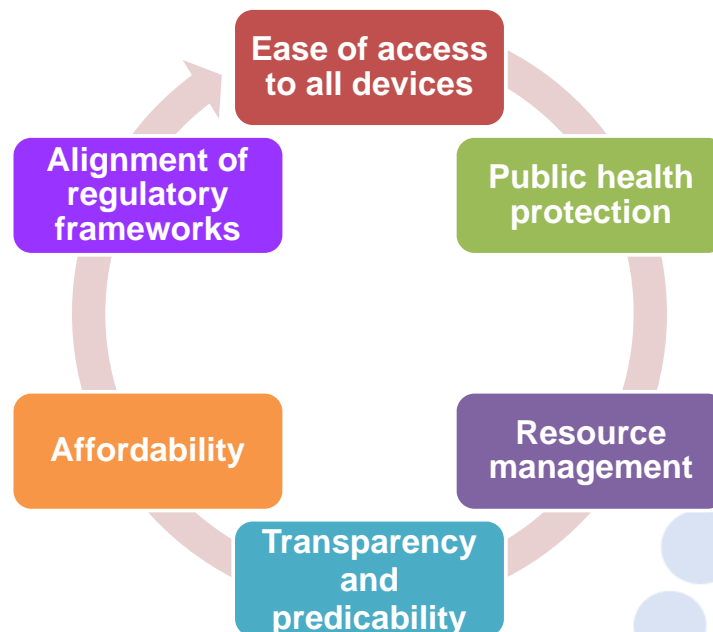
- SAFE
- EFFECTIVE (perform according to intended purpose)
- APPROPRIATELY USED

→ Absolute safety cannot be guaranteed



Mission:
**To be the LEADING INNOVATIVE AUTHORITY
protecting and advancing NATIONAL HEALTH and
SAFETY**

Developing the Regulatory Framework



Risk-based approach for a least burdensome regulatory framework that adds value

•Medical Device Branch



- To safeguard public health and safety by implementing regulatory controls through a programme of pre-market assessment of devices, manufacturing controls and post-market vigilance
- To ensure medical devices available in Singapore are of an acceptable standard in accordance to the Health Products Act and Health Products (Medical Devices) Regulations

•Key Statistics

| Total No. of Approved Medical Devices on the Singapore Medical Device Register (as of 30 Sept 2011) | 7,932 |
|---|-------|
| No. of listing received (Year 2010/11) | 3,659 |
| No. of listing approved (Year 2010/11) | 1,518 |

To be the LEADING INNOVATIVE AUTHORITY
protecting and advancing NATIONAL HEALTH and SAFETY
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Developing the Regulatory Framework - Without re-inventing the wheel



...AND I HAVE FOUND THIS ONE WORKS A LOT BETTER.

Singapore Medical Device Regulatory Framework (Pre-, On-, Post-market)

- Built on the strengths of [model regulatory agencies](#) - US FDA, Health Canada, European Union system and Australia TGA.
- These 5 are the founding members of the [Global Harmonisation Task Force \(GHTF\)](#).
- GHTF Guidance documents – used as reference.

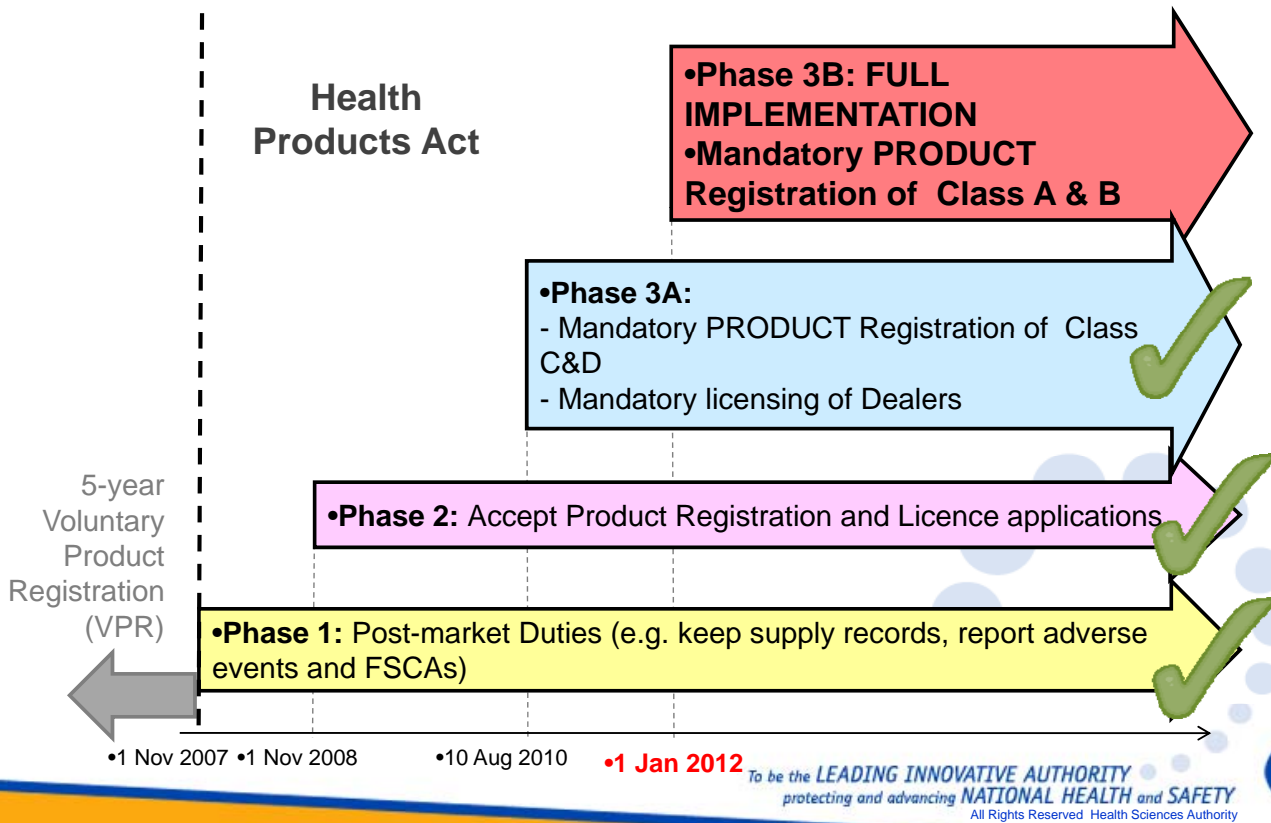


•Health Products Act – our Legal Authority

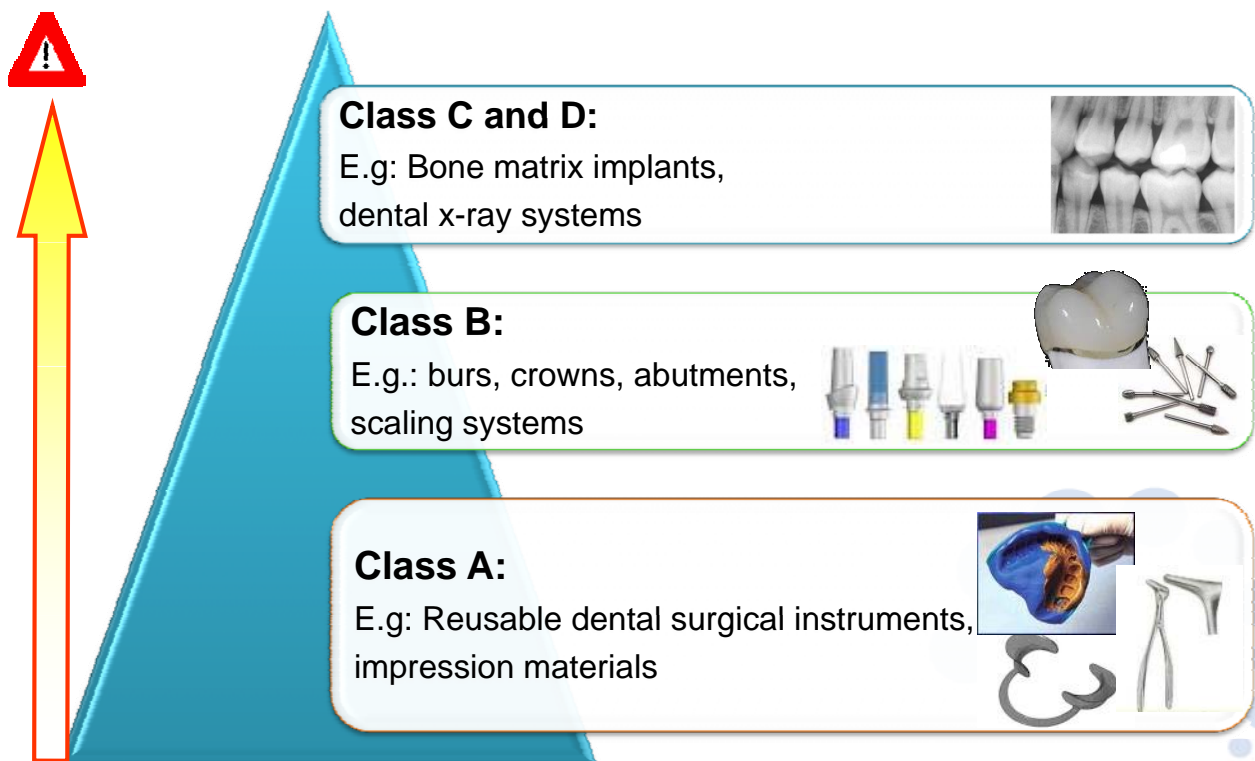
- Regulates the manufacture, import, supply, presentation and advertisement of health products and of active ingredients used in the manufacture of health products
 - Part II Administration of the Act
 - Part III Manufacture & Import of Health Products
- [Duties of Manufacturers, Importers, etc. covered in Part VIII]
 - Part IV Supply of Health Products
 - Part V Advertisement of Health Products
 - Part VI Licences
 - Part VII Registration of Health Products
 - Part X Enforcement & Part XII Offences and Prosecution

PRODUCT REGISTRATION

Implementation Timeline



Dental Devices: Risk Classification



Class A and B Devices

- (i) Registered Devices:
 - Listed on the Singapore Medical Device Register (SMDR)
 - Can be imported and supplied in Singapore

- (ii) Devices on the Transition List:
 - Submitted (by 30 November 2011) but under processing
 - Criteria apply
 - Can be imported and supplied in Singapore

- (iii) Devices supplied through Special Authorisation

- (iv) Devices that do not fulfill (i) or (ii) above:
Prohibited from import and supply in Singapore from 1 Jan 2012 onwards

Class C and D Devices

- (i) Registered Devices:
 - Listed on the Singapore Medical Device Register (SMDR)
 - Can be imported and supplied in Singapore

- (ii) Devices on the Transition List:
 - Submitted (by 30 April 2010) but under processing
 - Criteria apply
 - Can be imported and supplied in Singapore

- (iii) Devices supplied through Special Authorisation

- (iv) Devices that do not fulfill (i) or (ii) above:
Prohibited from import and supply in Singapore

Pro-Enterprise Steps

1. **5 year period (2002-2007)** – No fees for Voluntary Registration
2. **Exemption for most Class A devices** – 6,000 items exempted
 - (Class A constitutes 60% of Singapore's total •low risk MD market)
3. **Phased implementation (2002-2012)** – Industry has time to adjust to a regulated environment
4. **Incentive Fee (reduced by 20%)**
5. **Grouping of devices for registration** – 1 application fee for groups of medical devices
6. **Abridged evaluation of devices** – resulting in lower registration cost & faster market entry



Reaching Out to Our Stakeholders

•Conducted **60 free-of-charge** industry training and briefing sessions (2009 – 2011)

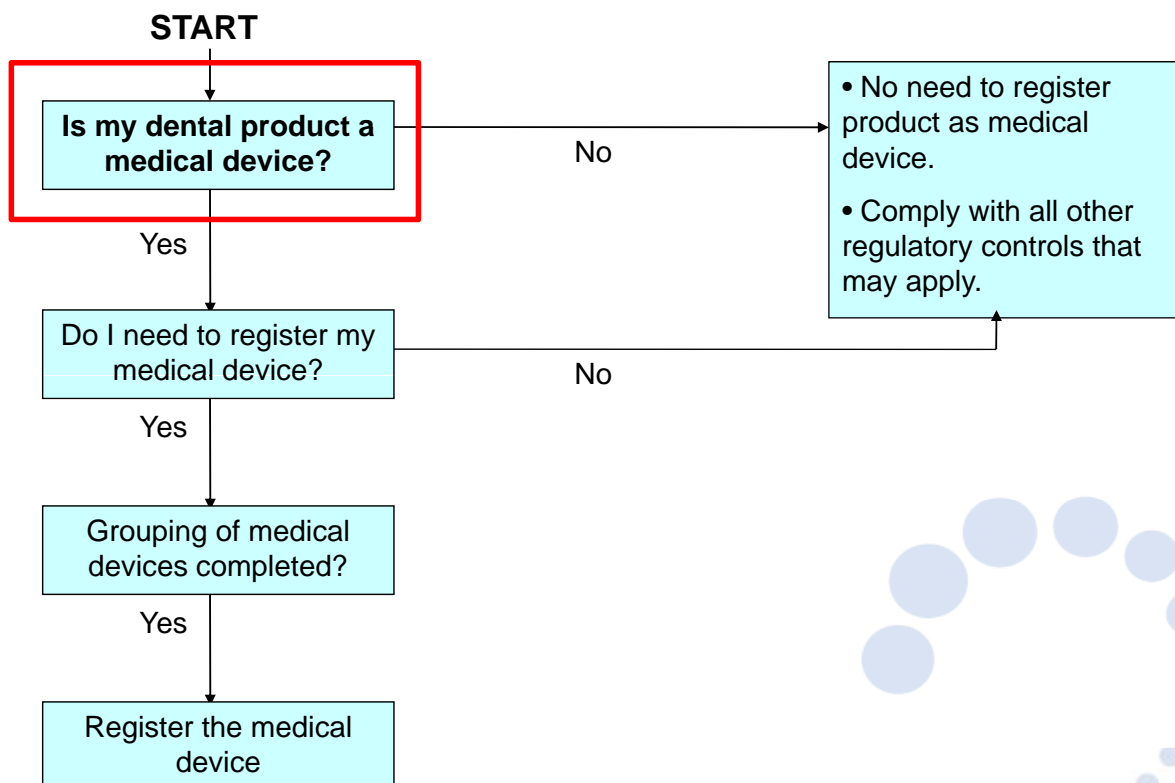
•**Availability of Public Information:**

- Website: www.hsa.gov.sg
 - ❑ Frequently Asked Questions (FAQ) Section
 - ❑ Regulatory Guidances
 - ❑ Quick Guide
 - ❑ MEDICS Application Guides
 - ❑ Published Industry Briefing slides



PRODUCT REGISTRATION

Product Registration



What is a medical device?

Qn: 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 manufacturer 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.
- **Definition is from the First Schedule of Health Products Act 2007 (Act)**

Dental Products that are not medical devices

Examples of dental products that are not medical devices

- i. Teeth whitening products (no medical claims)
- ii. Dental floss
- iii. Machining or polishing equipment for fabricating/customising dental products in dental labs
- iv. Research-use only products*
- v. Teaching aids

Research-use only

Intended and labeled by the Product Owner for bench/animal testing.
NOT for use on humans.

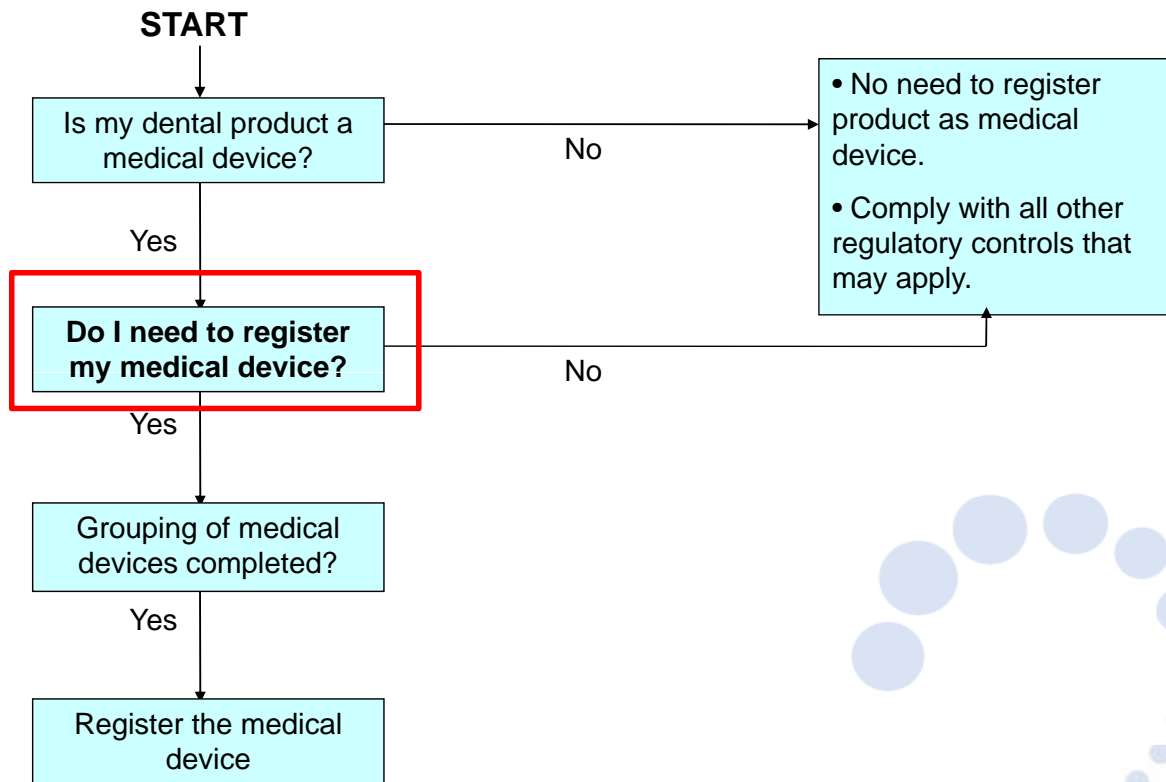
NOT regulated as a medical device.

For clinical trial or investigation

A device supplied for a clinical trial or clinical investigation on human beings.

Exempted from registration.
Apply for "import permit" using CTM (MD) form (HSA Clinical Trial Branch)

Product Registration



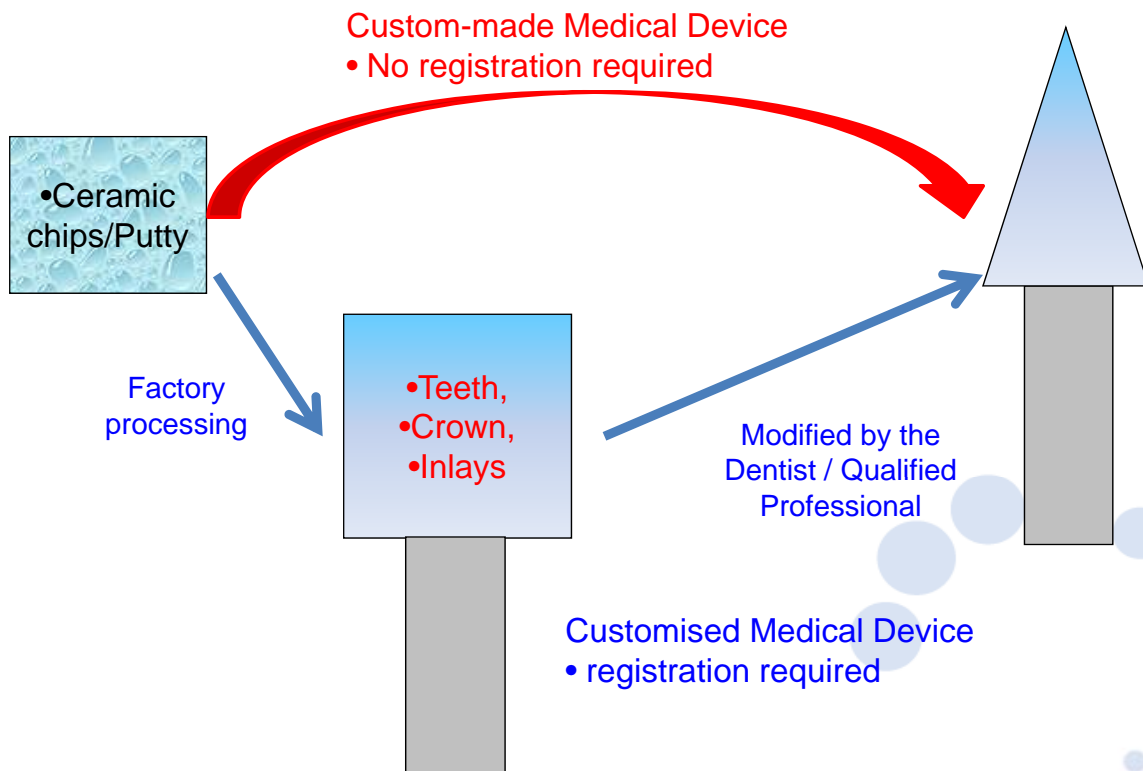
Must all medical devices be registered?

QN: Must all medical devices be registered?

No. The following medical devices shall not require registration:

- i. Custom-made medical devices
- ii. Class A device that is exempted from product registration (GN-22)

Custom-made Vs Customised Medical Device



Exempted Dental Medical Devices

Important note

Only medical devices that are listed in GN-22 (Guidance to the List of Medical Devices Exempted from Product Registration) shall be exempted from product registration, for the description found in GN-22.

Examples:

1. Dental chairs
2. Dental amalgamator
3. Dental curing light
4. Dental lights
4. Dental handheld mirror
5. Orthodontic pliers
6. Class A reusable dental surgical instruments

Examples of Exempted Dental Products

Class A Reusable **dental** surgical instruments

E.g:

- dental extraction forceps
- root elevators
- dental scalpels
- dental scissors
- retractors (e.g. cheek retractors)
- rubber dam instruments
- crown removers



Important note

Only reusable dental surgical instruments that satisfy **ALL of the following conditions shall be eligible for exemption:**

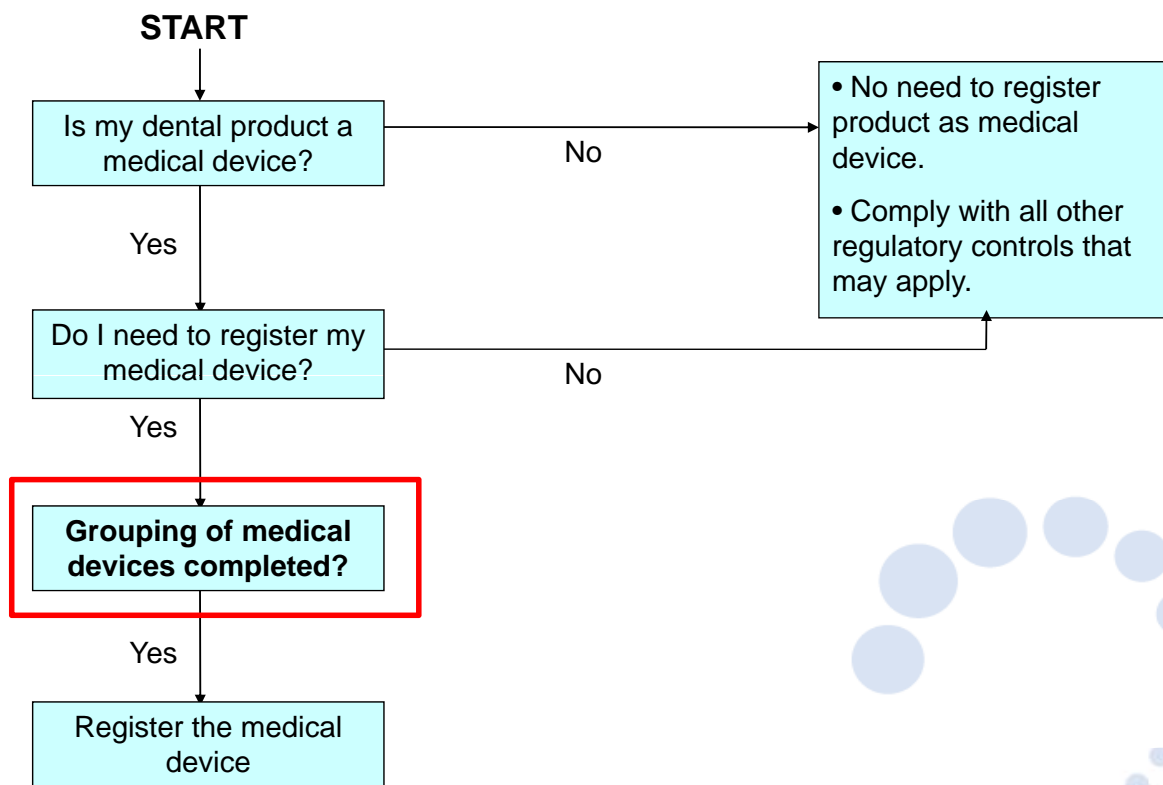
- Use solely in the oral cavity
- Class A
- Non-sterile
- Non-active

Examples of Dental Devices that Require Product Registration

- (i) **Sulphide detection device** (class B)
 - intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.
- (ii) **Root apex locator** (class B)
 - intended for locating the apex of the tooth and measuring the length of the root canal.
- (iii) **Dental autoclave** (class C)
 - Intended for sterilising dental instruments prior to surgery.



Product Registration

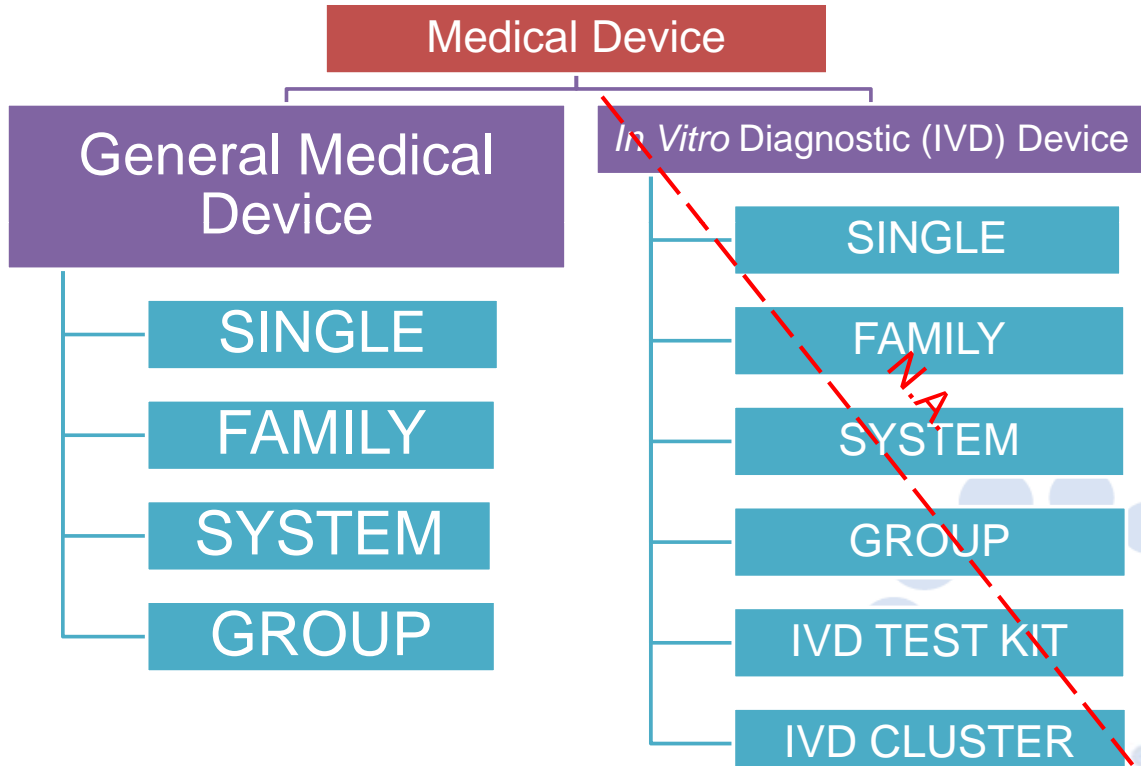


Grouping Process

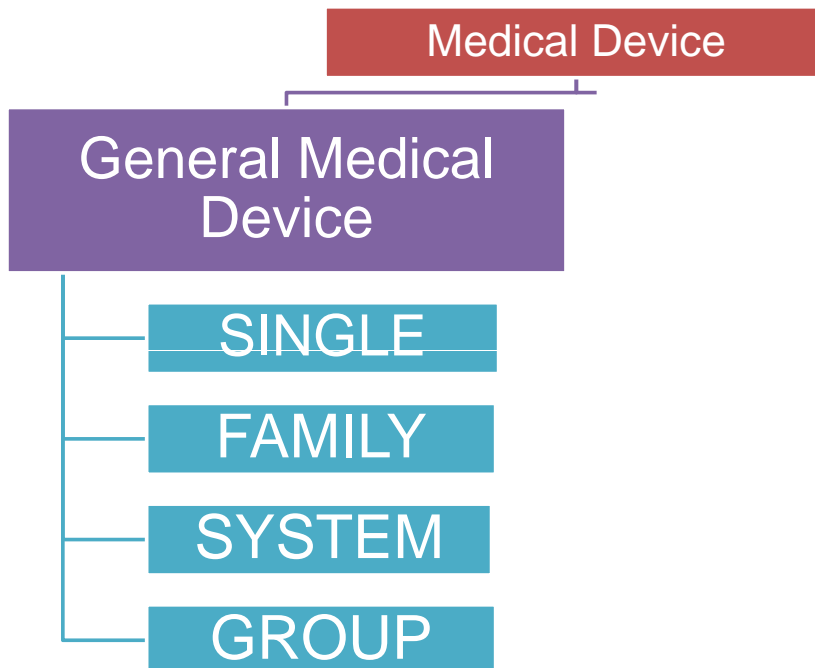
- Who should perform grouping of the medical devices?
 - The registrant (verify with Product Owner)
- When should grouping be performed?
 - Before submission of product registration application
- What are the advantages of grouping?
 - Cost savings for the industry
 - Reduce number of registration applications
 - Reduce product registration fees
 - Reduce number of listings on SMDR, i.e. reduce annual retention fees
- Where can I find the rules to group medical devices?
 - GN-12 Guidance on grouping of medical devices for product registration

EXISTING GROUPING RULES

Types of grouping: GN-12 Guidance Document



Types of grouping: GN-12 Guidance Document



Dental Impression Materials

- A material designed to reproduce the structure of a patient’s teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth. This is a single-use device.



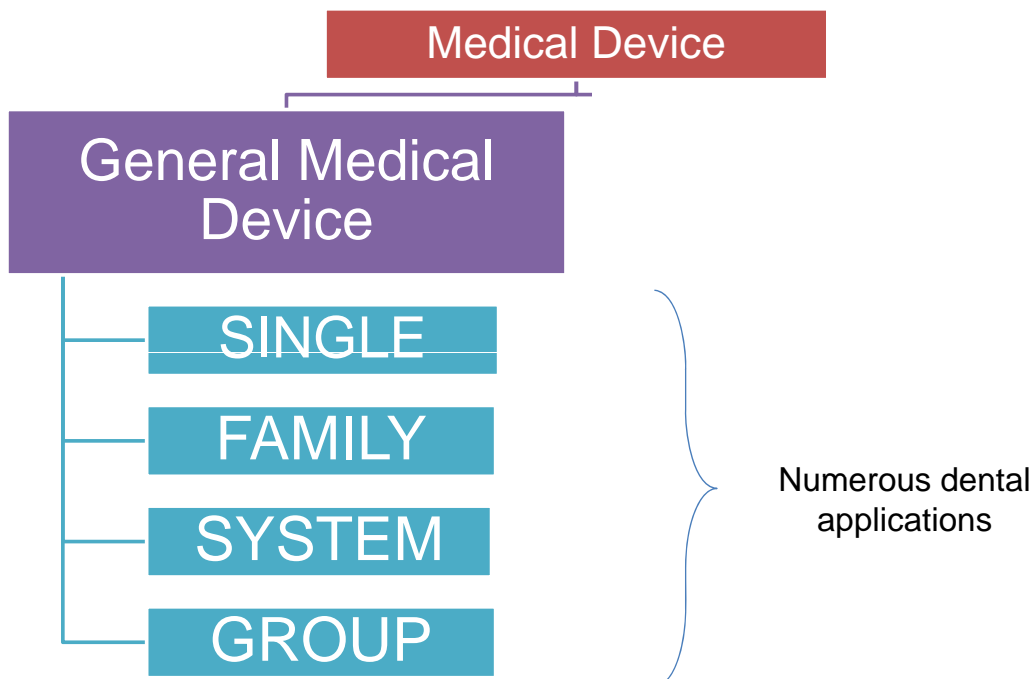
| Product name | Main constituent |
|---------------------------------|--------------------|
| XYZ Impresso™ dental impression | Alginate |
| XYZ FastSet™ dental impression | Polyvinyl Siloxane |
| XYZ SuperSet™ dental impression | Polyether |

EXISTING RULES:

- 3 separate applications required because:
Different impression material



Types of grouping: GN-12 Guidance Document

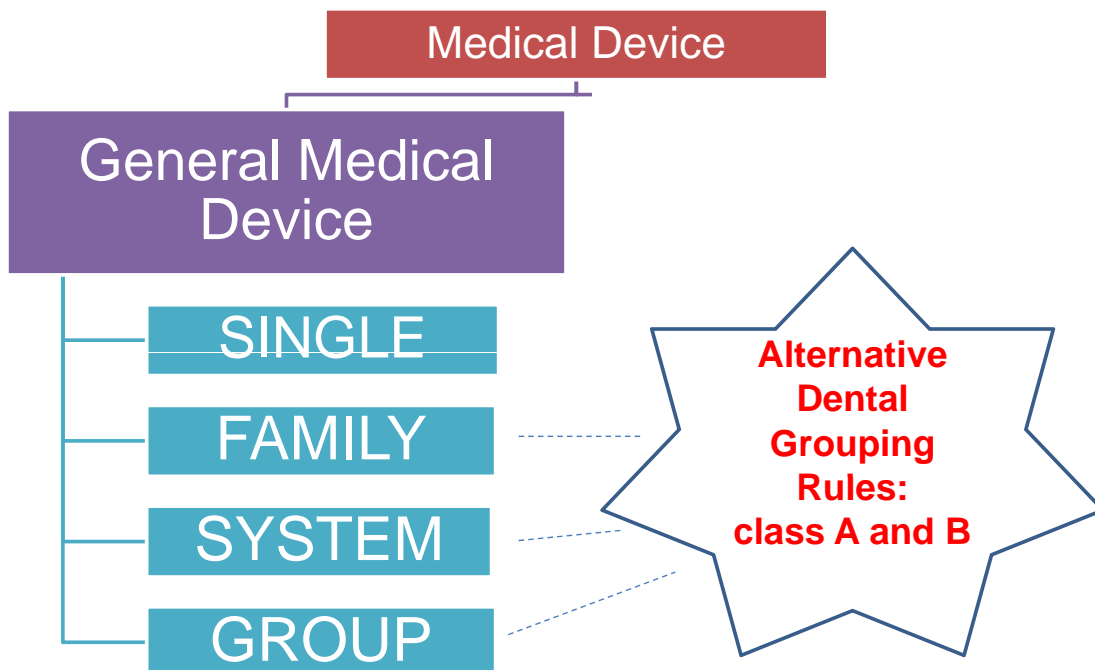




Continuous Pro-enterprise Efforts....



Types of grouping: **GN-12 Guidance Document**



- ✓ Class A and B Dental Devices Only
- ✓ Same Product Owner
- ✗ Class C and D Dental Devices
- ✗ Standalone software

Dental Devices

Class A or B

Class C or
D

Alternative
Grouping rules for
Dental Devices

Grouping as per
GN-12 Guidance

Grouping as per
GN-12 Guidance

Dental Grouping Terms (DGT)



- Generic term to describe similar dental devices with similar intended purpose
- Eg:

Step 2:

Step 1:

| Dental Grouping Term (DGT) | DGT Description |
|----------------------------|---|
| Dental adhesives/ primers | A material primarily used as a bonding promoting substance between dental materials. This is a single-use device. It does not include cements. |
| Dental cement | Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations, to protect dental pulp, and to line cavities. It includes accessories e.g. mixing pad, dispenser and other components required to complete the cementing procedure. |
| Dental crowns/ bridges | A collection of solid blocks or liquid materials used to manufacture partial or full crowns and bridges. |

Dental Grouping Terms (DGT)



- Examples:

Step 2:

Step 1:

| Dental Grouping Term (DGT) | DGT Description |
|----------------------------|--|
| Orthodontic appliances | Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force. It includes orthodontic anchor plate, orthodontic anchoring screw, orthodontic archwire, orthodontic archwire/bracket fixation ring, orthodontic bands, orthodontic brackets, orthodontic bracket adhesive, orthodontic clasps, orthodontic chin cap, orthodontic extraoral headgear, orthodontic face bow, orthodontic ligature, orthodontic magnet, orthodontic spring, orthodontic tube, orthodontic wire. |
| Palatal impression kit | A collection of non-sterile devices designed to obtain a negative imprint of the upper palate (i.e., the roof of the mouth with the gums and teeth) which is subsequently used to make a mould for the manufacture of a custom-made oral appliance. The kit typically includes a dental impression tray(s) and impression materials. Impression material is placed on the tray and the tray is then positioned in the mouth of the patient until the material becomes firm creating the mould. This is a single-use device. |

Dental Grouping Terms (DGT)



74 Dental Terms Available:
(Find the relevant description)

| No. | Terms |
|-----|--|
| 1 | Adhesive kit for dental composite |
| 2 | Cryoaesthesia device, dental |
| 3 | Cryogenic spray, dental |
| 4 | Cusps, dental |
| 5 | Dental abrasives |
| 6 | Dental adhesives/ primers |
| 7 | Dental burs |
| 8 | Dental caries detector, electrical impedance |
| 9 | Dental caries detector, optical induced fluorescence |
| 10 | Dental caries removal solution |
| 11 | Dental casting materials |
| 12 | Dental cavity liner |
| 13 | Dental cement |
| 14 | Dental cement kit |
| 15 | Dental crowns/ bridges |
| 16 | Dental dry field device |
| 17 | Dental dry field kit |
| 18 | Dental etching composite |
| 19 | Dental implant debridement brush |
| 20 | Dental implant extractor |

| No. | Terms |
|-----|--|
| 21 | Dental implant, accessories |
| 22 | Dental implant, prosthetic teeth bar |
| 23 | Dental implant, suprastructure |
| 24 | Dental implant/prosthesis, surgical procedure kit |
| 25 | Dental impression materials |
| 26 | Dental precision attachments |
| 27 | Dental procedure console and accessories, hydraulic (for use with handpieces) |
| 28 | Dental procedure console and accessories, line-powered (for use with handpieces) |
| 29 | Dental procedure console and accessories, pneumatic (for use with handpieces) |
| 30 | Dental procedure handpiece, hydraulic |
| 31 | Dental procedure handpiece, line-powered |
| 32 | Dental procedure handpiece, pneumatic |
| 33 | Dental pulp testing electrode gel |
| 34 | Dental pulp-capping material |
| 35 | Dental reinforcing fibre |
| 36 | Dental restorative / cavity varnish |
| 37 | Dental restorative materials |
| 38 | Dental restorative/ repair kit |
| 39 | Dental retention pin |
| 40 | Dental retention pin kit |

Dental Grouping Terms (DGT)



| No. | Terms |
|-----|--|
| 41 | Dental scalers, ultrasonic |
| 42 | Dental scalers, rotary |
| 43 | Dental scalers, pneumatic |
| 44 | Dental solution, scaling |
| 45 | Dental scaling system, ultrasonic |
| 46 | Dental scaling system, rotary |
| 47 | Dental scaling system, pneumatic |
| 48 | Dental sealants, endodontic |
| 49 | Dental sealants, pit/fissure |
| 50 | Dental shaded pontic kit |
| 51 | Denture clasps |
| 52 | Denture reliners |
| 53 | Facebow |
| 54 | Fixture/appliance dental drill, single-use |
| 55 | Gingiva bleaching protector |
| 56 | Gingival retraction cord, non-medicated |
| 57 | Gingival retraction kit |

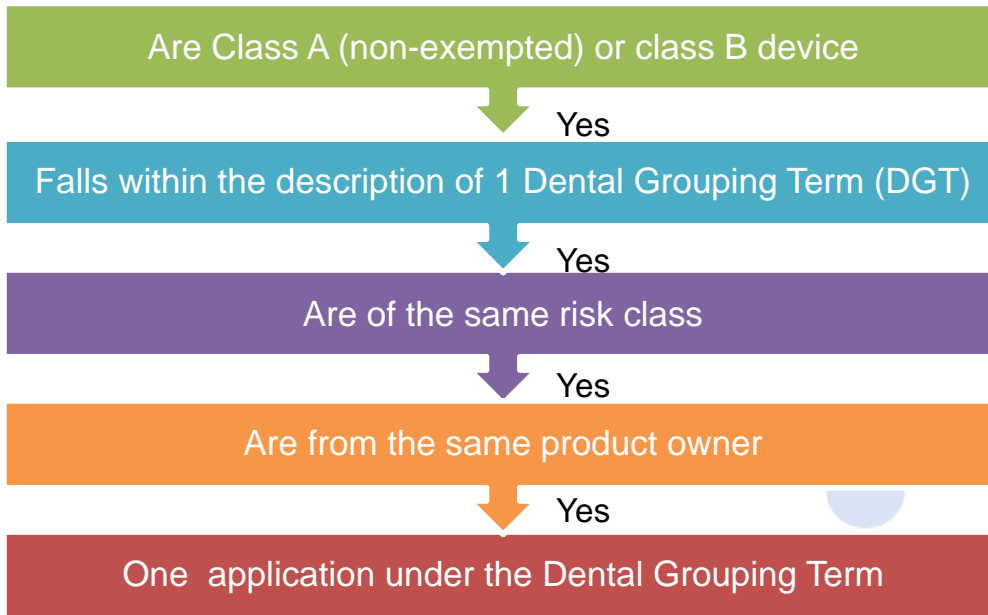
| No. | Terms |
|-----|---|
| 58 | Gingival retraction solution |
| 59 | Non-medicated dental surgical procedure kit, single-use |
| 60 | Oral wound dressing, non - animal/ microbial- derived |
| 61 | Orthodontic appliance archwire-cooling device |
| 62 | Orthodontic appliance force-measuring gauge |
| 63 | Orthodontic appliances |
| 64 | Orthodontic space maintainer (for prematurely lost deciduous teeth) |
| 65 | Palatal impression kit |
| 66 | Periodontal dressing, non -animal/ microbial- derived |
| 67 | Root canal filling-removal solution |
| 68 | Root canal irrigation/ rinsing solution |
| 69 | Root canal obturation kit |
| 70 | Root canal post kit |
| 71 | Root canal posts |
| 72 | Root surface conditioner |
| 73 | Tooth preservation kit |
| 74 | Warm-bonded endodontic obturation system |

Refer to Annex 2 for detailed list of DGT and their descriptions

Dental Grouping Rule

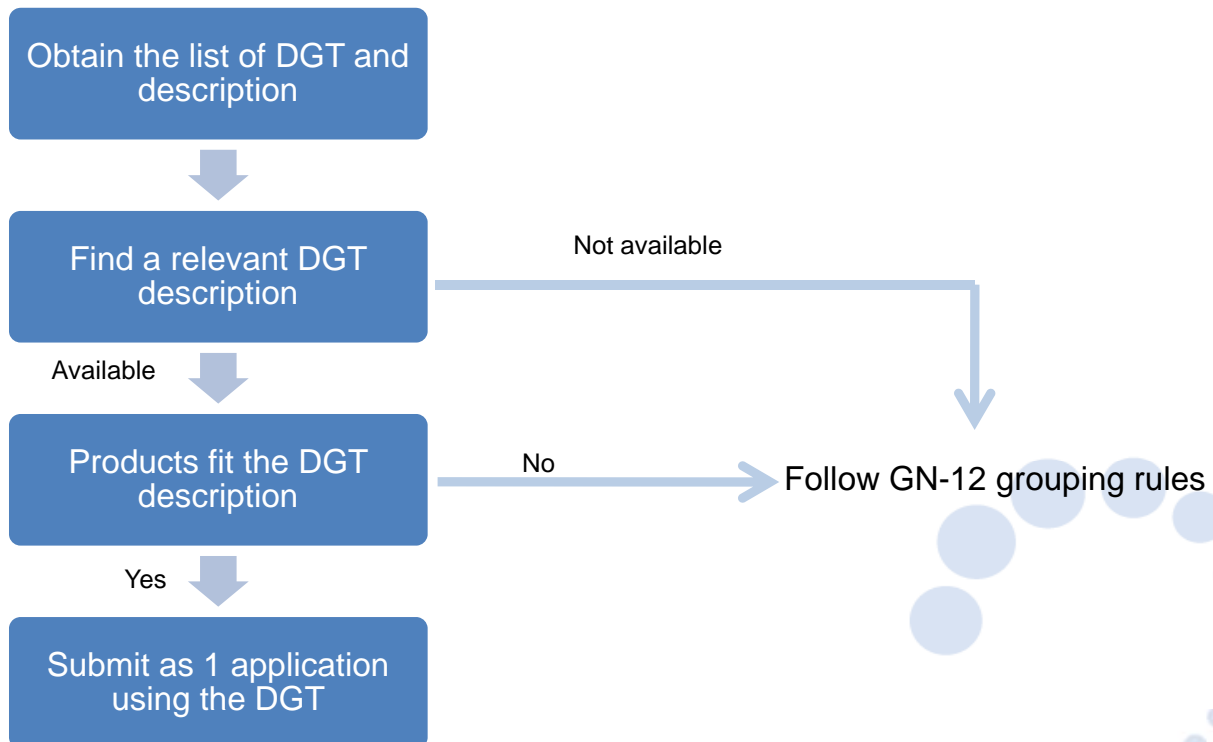


- Each Dental member:



- The application may contain accessories of lower risk class, if they are intended to be used together with the dental device.

Finding the Dental Grouping Term (DGT)



Case Study 1

Dental Impression Materials

- A material designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth. This is a single-use device.



| Product name | Main constituent |
|---------------------------------|--------------------|
| XYZ Impresso™ dental impression | Alginate |
| XYZ FastSet™ dental impression | Polyvinyl Siloxane |
| XYZ SuperSet™ dental impression | Polyether |

EXISTING RULE:

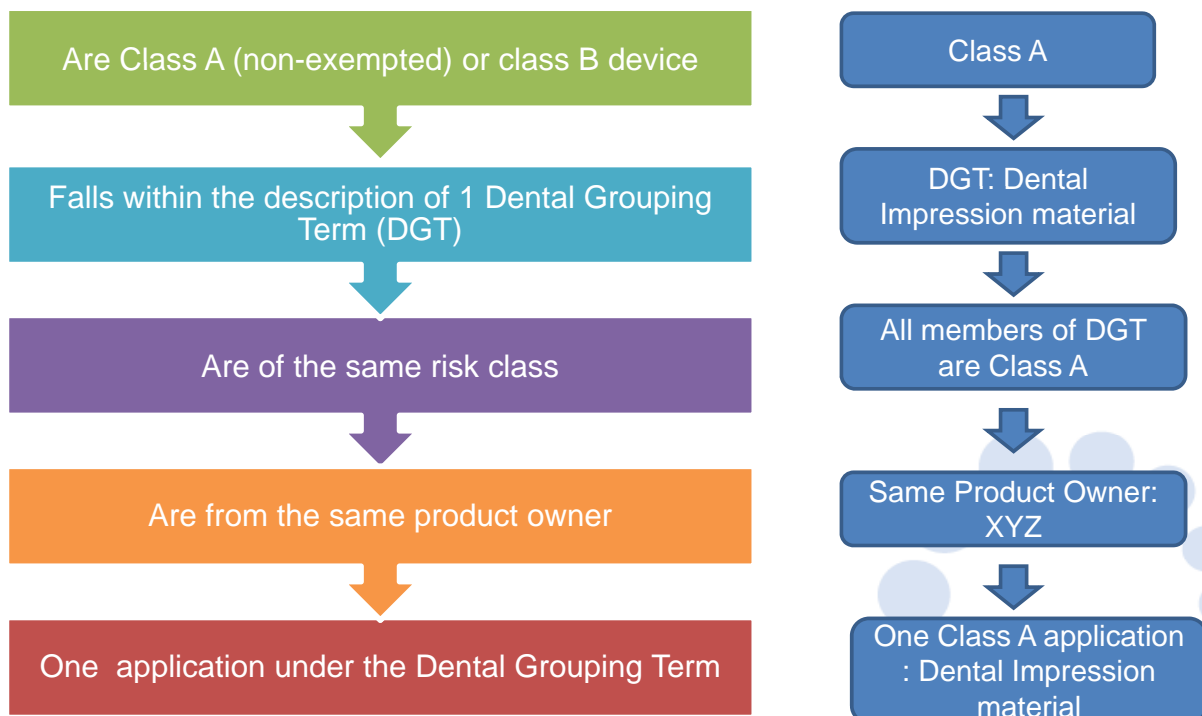
3 separate FAMILY applications

because:
Different impression material

ALTERNATIVE GROUPING:

USING DGT...

Case Study 1 – Dental Grouping Rules



Case Study 1

Dental Impression Materials

- A material designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth. This is a single-use device.



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| XYZ SuperSet™ dental impression | Polyether |

EXISTING RULE:
3 separate FAMILY applications
 because:
 Different impression material



Dental Grouping Rule:
1 application using DGT
"Dental Impression Material"

Case Study 2

Dental cements

- Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations.

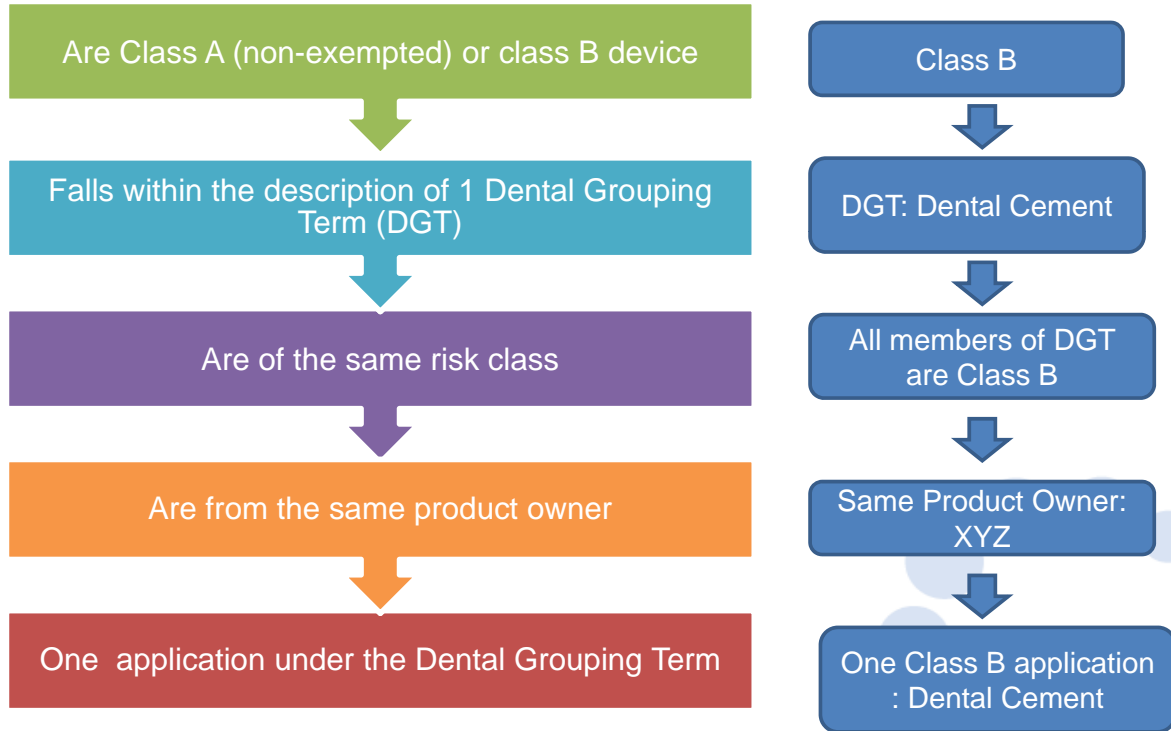


| Product name | Description |
|----------------------|--|
| XYZ Impresso™ cement | Main constituent: Zinc phosphate Available as 2g and 4g syringes |
| XYZ FastSet™ cement | Main constituent: Polycarboxylate Available as 2g syringe and 2g kit (dispenser, etchant, adhesive, primer) |
| XYZ SuperSet™ cement | Main constituent: Glass Ionomer Available as 2g and 4g syringes |

EXISTING RULE:
3 separate FAMILY applications
 because:
 Different cement material

ALTERNATIVE GROUPING:
USING DGT

Case Study 2 – Dental Grouping Rules



Case Study 2



Dental cements

- Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations.

| Product name | Description |
|----------------------|--|
| XYZ Impresso™ cement | Main constituent: Zinc phosphate Available as 2g and 4g syringes |
| XYZ FastSet™ cement | Main constituent: Polycarboxylate Available as 2g syringe and 2g kit (dispenser, etchant, adhesive, primer) |
| XYZ SuperSet™ cement | Main constituent: Glass Ionomer Available as 2g and 4g syringes |

EXISTING RULE:

3 separate FAMILY applications

because:
Different cement material



Dental Grouping Rule:

**1 application using DGT
"Dental Cement"**

Case Study 3

Prosthodontic Tooth Restoration Procedure Kit

Description: A Kit of devices that consist of various dental filling materials and dental products intended for use during a normal tooth restoration procedure. This kit includes the following:

- i. Resin tooth bonding agent
- ii. Cavity liner
- iii. Cavity varnish/primer
- iv. Coating material for resin fillings
- v. Tooth shade resin material

2 Device proprietary name on label:

- ABC Clinic Prosthodontic Tooth Restoration Procedure Kit
- XYZ Clinic Prosthodontic Tooth Restoration Procedure Kit

Case Study 3

Prosthodontic Tooth Restoration Procedure Kit

1. 4 syringes for tooth bonding purposes, consisting of the following:
 - 1x syringe with single light-cure resin component
 - 1 x syringe with pre-filled self-cure resin adhesive
 - 1x syringe with ethchant
 - 1 x syringe with coupling agent
2. Caries indicator (contain FD&C dyes in a glycol base that stain carious dentin)
3. 1 x syringe with cavity liner
4. 1 x syringe containing cavity primer + 1 x syringe containing cavity varnish
5. 1 x syringe containing Luminescence light-cured coloring resin (coating material for resin fillings)
6. 1 x syringe containing PermanentFlo Flowable composite (tooth shading resin material)
7. 1 x Tongue guard
8. 1 x Mouth prop

Prosthodontic Tooth Restoration Procedure Kit

2 Device proprietary name on label:

- ABC Clinic Prosthodontic Tooth Restoration Procedure Kit
- XYZ Clinic Prosthodontic Tooth Restoration Procedure Kit

EXISTING RULE:

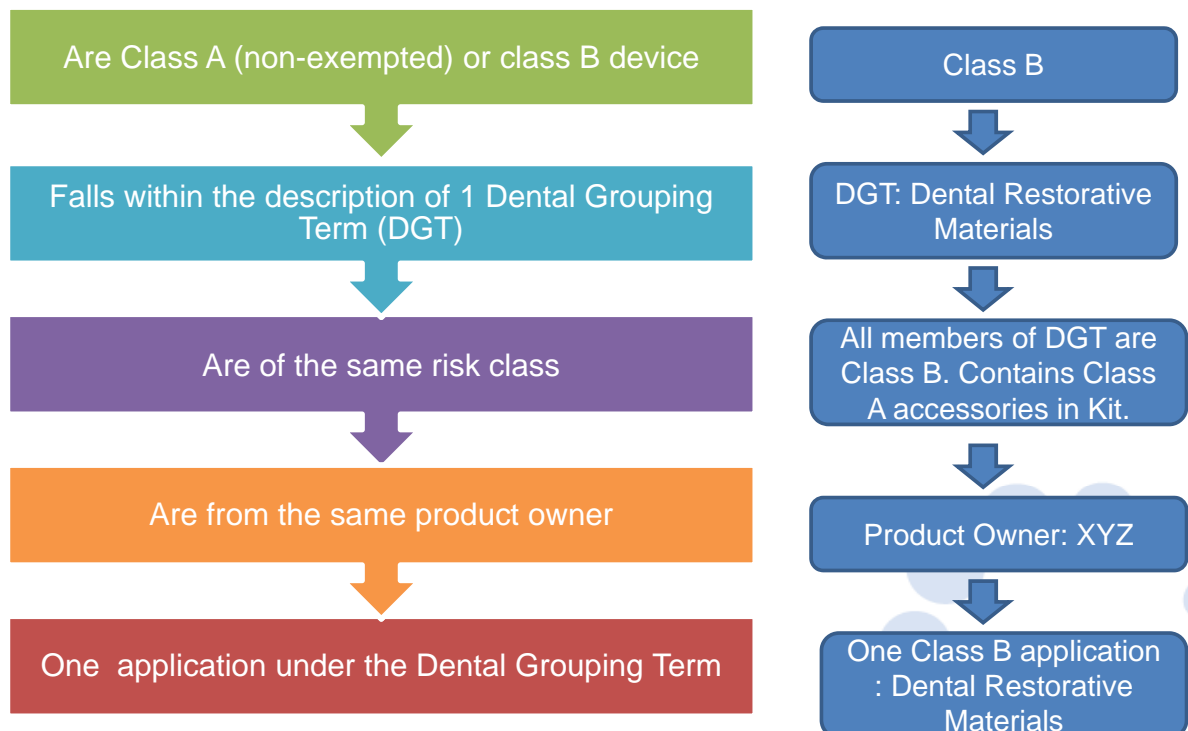
2 separate GROUP applications

because:
Different GROUP proprietary name

ALTERNATIVE GROUPING:

USING DGT...

Case Study 3 - Dental Grouping Rules



Prosthodontic Tooth Restoration Procedure Kit

2 Device proprietary name on label:

- ABC Clinic Prosthodontic Tooth Restoration Procedure Kit
- XYZ Clinic Prosthodontic Tooth Restoration Procedure Kit

EXISTING RULE:

2 separate GROUP applications

because:
Different GROUP proprietary name



Dental Grouping Rule:

1 application using DGT
"Dental Restorative Materials"

Quiz 1: Qualifies for New Dental Grouping rules?



Endosseous Implant

Descriptor: An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

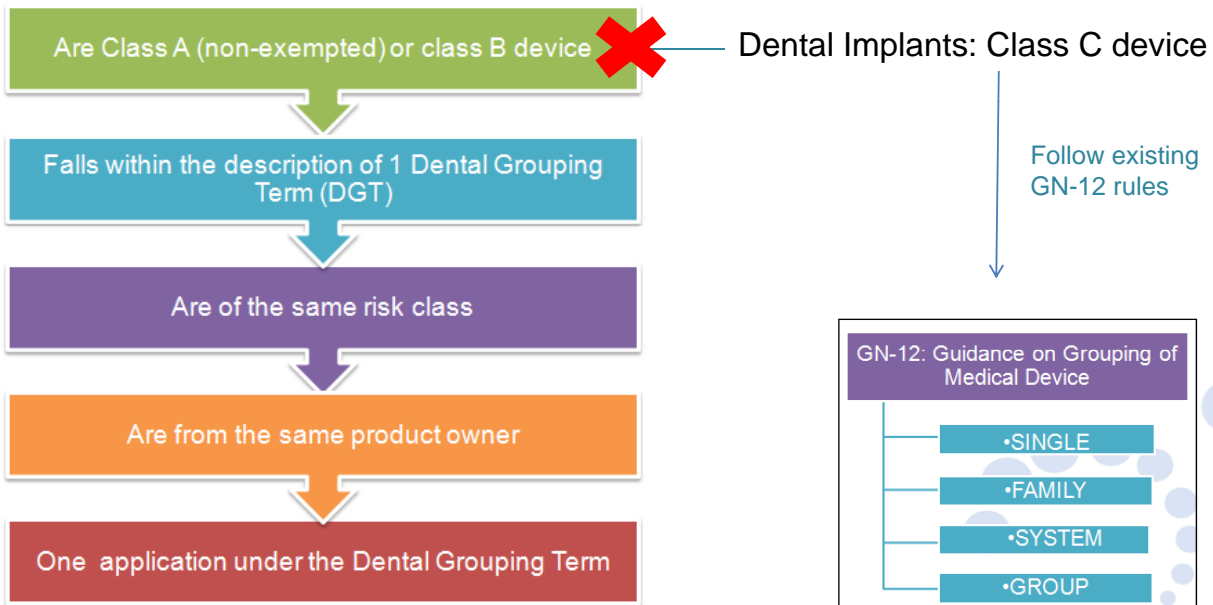
Endosseous Implant System

XYZ ELEMENT Endosseous Implant – indicated for for subgingival implantation only

Other product information:

- Implants are of different sizes, shapes (cylindrical vs conical-cylindrical), diameters and lengths

Quiz 1: Qualifies for New Dental Grouping Rules?



LISTING ONTO THE SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Listing Following New Dental Grouping Rules

Case Study 1: Dental Impression Materials

- A material designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth. This is a single-use device.

| Product name | Main constituent |
|---------------------------------|--------------------|
| XYZ Impresso™ dental impression | Alginate |
| XYZ FastSet™ dental impression | Polyvinyl Siloxane |
| XYZ SuperSet™ dental impression | Polyether |

Dental Grouping Rule:

**1 application using DGT
"Dental Impression Material"**

Listing Following New Dental Grouping Rules

Case Study 1: Dental Impression Materials Listing on SMDR

| Device Info | |
|-------------------------|---|
| Device Name: | XYZ Dental Impression Materials |
| Description: | It is designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, |
| Medical Specialty Area: | Dental |
| HS Code: | |
| HSA Product code: | |
| Medical Device Class: | Class A medical device |
| Device Registration No: | NFY-DEV-000123-11 |
| Registration Date: | 01 Dec 2011 |

| Models | | |
|-------------------------------|-----------------------------|------------|
| Product Code for Accessories: | | |
| No. | Model Name | Identifier |
| 1 | Impresso™ dental impression | 6123 |
| 2 | FastSet™ dental impression | 6223 |
| 3 | SuperSet™ dental impression | 6323 |

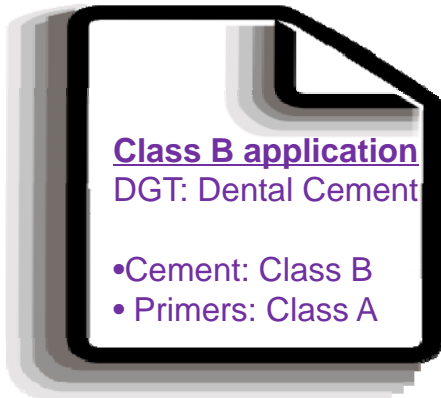
Listing Following New Dental Grouping Rules

ONE grouped application
could result in
multiple listings on the SMDR.



Questions....





- Q: What are the dossier requirements for the Class A device within the class B application?
- A: The Class A device will follow the Class A dossier requirement.

Dental cement



| No. | DGT | DGT Description |
|-----|-------------------|---|
| 1 | Dental cement | Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It includes accessories e.g. mixing pad, dispenser and other components required to complete the cementing procedure. |
| 2 | Dental cement kit | A collection of components designed to complete a cementing procedure. |

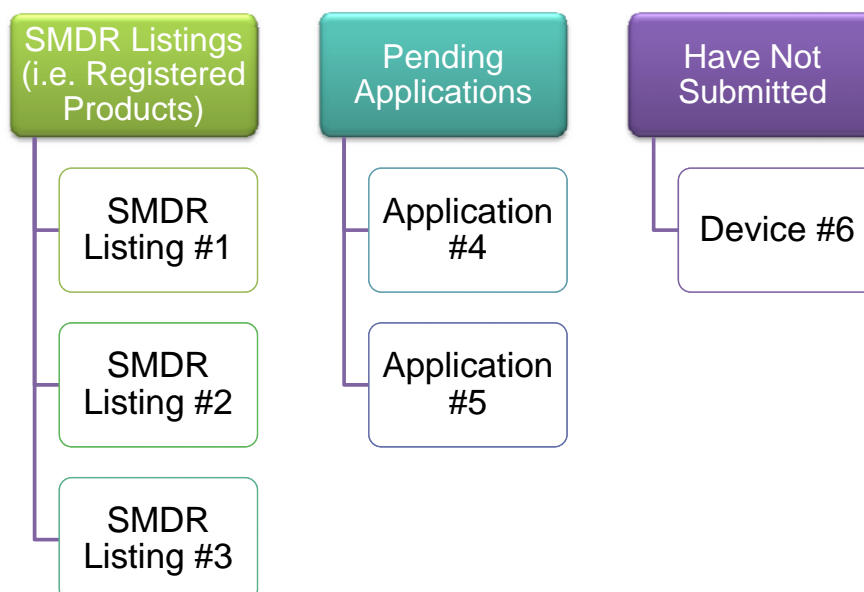
- Q:For devices that fall under multiple dental grouping terms, which grouping term should be used?
- A: The device is only required to be submitted using one of the DGT, 1 or 2. It is the company's choice.

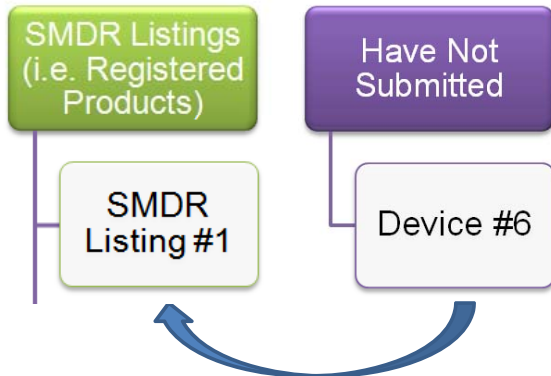
Dental Rules vs Existing Rules

- Q: Can I choose to follow the existing grouping rules for general medical devices?
- A: Yes. For class A and B devices, Registrants may choose to use either the existing grouping rules or alternative dental grouping rules.

Current SMDR Listings and Registration Applications

Company A has the following applications that can be grouped under 1 Dental Grouping Term:





Company has a new device (#6) that is of the same DGT as a registered product (#1).

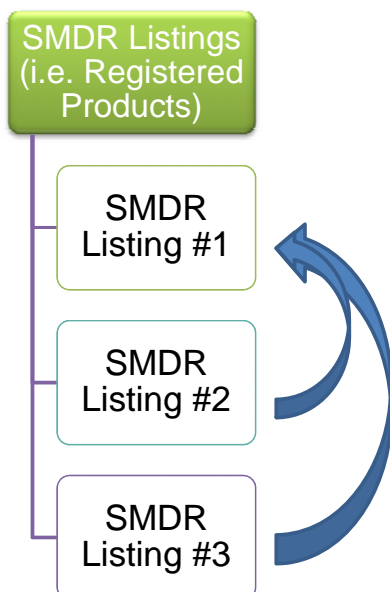
Q: Can Company A submit a new device to an SMDR listing (1 Dental Grouping Term)?

A: Yes.

Procedure:

1. Verify that the devices can be combined under 1 Dental Grouping Term.
2. Submit Change Notification application (Technical Change: addition of models) and state the Dental Grouping Term. CN Fee payable.
3. After HSA's review, the listing will be changed to reflect the DGT.

Company A has 3 registered products that can be grouped under 1 Dental Grouping Term:



Q: Can Company A combine the 3 SMDR listings into 1 (1 Dental Grouping Term)?

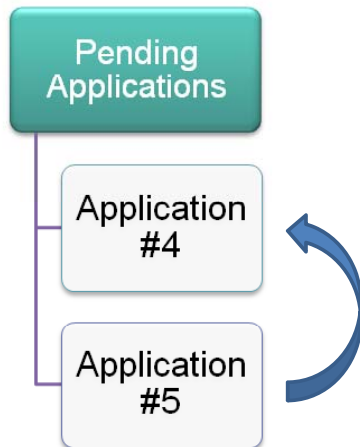
A: Yes.

• From 1 Jun 2012 onwards

Procedure:

1. Verify that the listings can be combined under 1 Dental Grouping Term.
2. Submit Change Notification (CN) for the listing to be retained (e.g. #1). CN application should include all documents in listing #2 and #3 and declaration that only registered models are added. CN Fee payable.
3. After the CN is approved and the SMDR listing amended, company A can cancel the other listings (i.e. #2 and #3).

Company A has the following applications that can be grouped under 1 Dental Grouping Term:



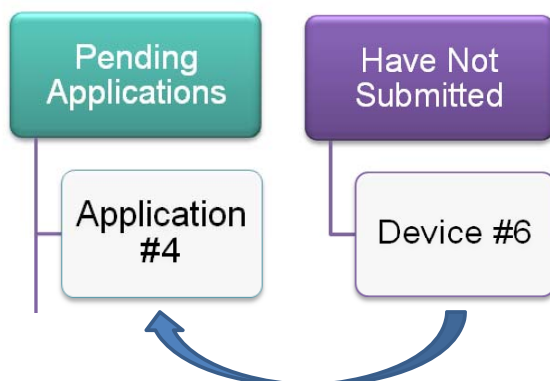
Q: Can Company A combine the 2 applications into 1 (1 Dental Grouping Term)?

A: Yes.

Procedure:

1. Verify that the applications can be combined under 1 Dental Grouping Term.
2. Email HSA the affected job reference numbers and confirm which application is to be retained (e.g. app #4).
3. HSA will send input request for company A to add the documents in app #5 to #4.
3. Company A withdraws app #5.

Company A has a new device that falls under the same Dental Grouping Term as a pending application:



Q: Can Company A submit a new device to a pending application (1 Dental Grouping Term)?

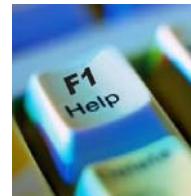
A: Yes, only if the application in screening stage.

Procedure:

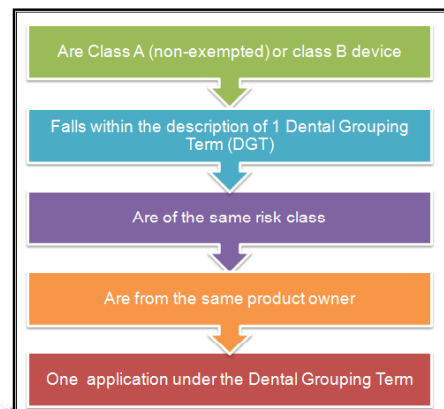
1. Verify that the applications can be combined under 1 Dental Grouping Term.
2. Check status in MEDICS workbench. Email HSA the affected job reference number.
3. HSA will send input request for company A to add the documents relating to device #6.

- Q: Any special considerations for post-market supply?
- A: To ensure traceability, the device proprietary names and identifiers should be properly listed in the annex 2 list of configurations.
- Please maintain proper distribution records.

| Name as per device label | Identifier | Description |
|--------------------------|--------------|---|
| XYZ Impresso™ cement | XYZ-IM111-2G | Zinc phosphate ,2g syringe |
| XYZ Impresso™ cement | XYZ-IM111-4G | Zinc phosphate, 4g syringe |
| XYZ FastSet™ cement | XYZ-FA033-2G | Polycarboxylate, 4g syringe |
| XYZ FastSet™ cement kit | XYZ-FAK33-2G | Polycarboxylate, 4g syringe with XYZ Addy adhesive, XYZ PP primer |
| XYZ Addy Adhesive | XYZ-AA44 | XYZ Addy adhesive, 2 ml |
| XYZ PP Primer | XYZ-PP10 | XYZ PP primer, 5 ml |



- Q: I have walked through the process but need to verify if my dental grouping is correct.
- A: Please email the answer to hsa_md_info@hsa.gov.sg (subject heading: DGT) with the following info:
 - Annex 2 List of Configurations
 - Product Labels and IFUs
 - Answers to the decision flow
 - Conclusion from the decision flow



Dental Products that Require Clarification on Product Classification

- Examples: Fluoride gels to prevent dental caries, hydrogen peroxide bleaching agents
- General Rule-of-thumb:
 - Q: Is it intended for a medical procedure or treatment as specified in the Health Products Act (for a medical device) and Medicines Act (for a medicinal product)?
 - Q: Does it contain a scheduled Poison?
 - Q: How are similar products regulated?



Dental Products that Require Clarification

- Search for similar products:
 - Registered medicinal products and Notified Cosmetic Products:
<http://www.hsa.gov.sg/publish/hsaportal/en/services/prism/infosearch.html>
- Please verify with HSA using the Health Product Enquiry Form. Respective Branches will advise you:
- http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/western_medicines/eservice_forms.html

Dental Products that Require Clarification

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

Rule 14. All devices manufactured from or incorporating

- animal cells, tissues and/or derivatives thereof, rendered non-viable, or
- cells, tissues and/or derivatives of microbial or recombinant origin are **Class D**.

Note: Devices incorporating human cells/tissue: CTT framework

E.g: Bovine hemostatic sponges, dental regenerative membrane containing porcine collagen

- High biological risks
- In-depth review is required

Special Authorisation

Import of dental devices by a PHMC-licenced entity (e.g. dentistry centre in a hospital):

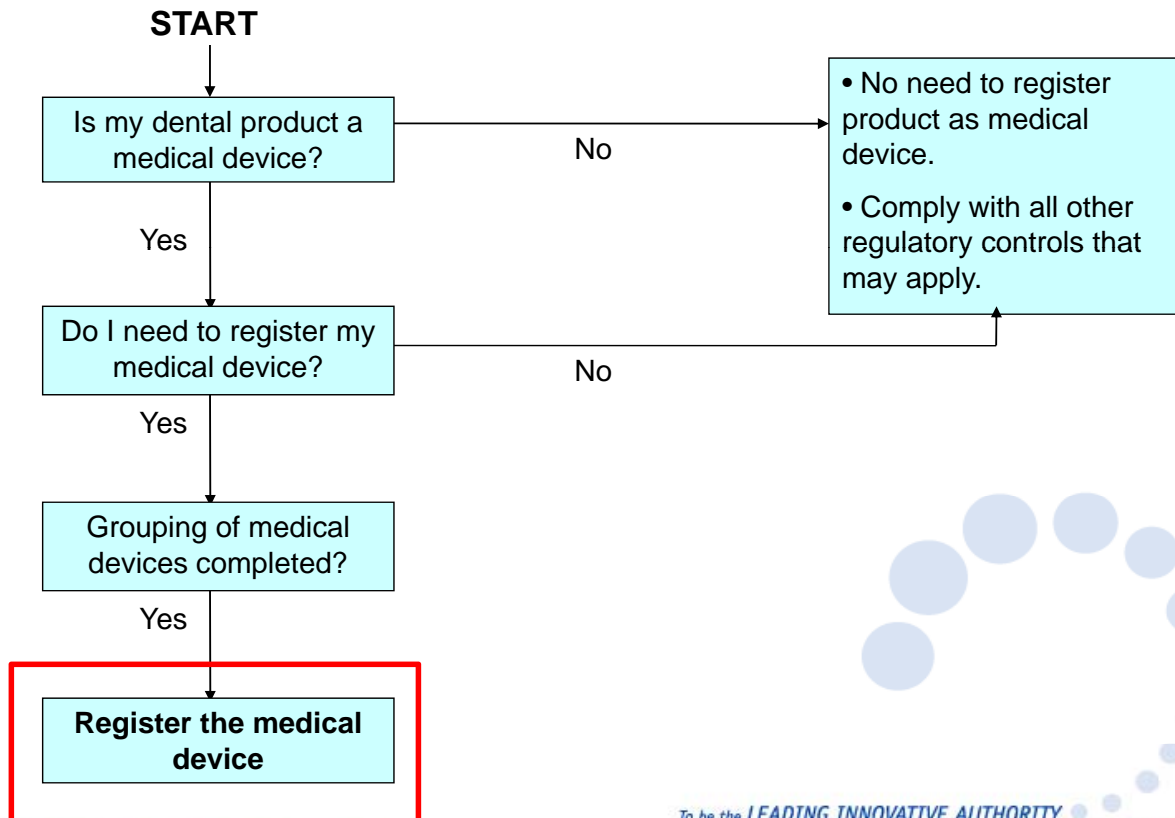
- 1 Special Authorisation application:

GN-27: Authorisation Route for Supply on Request of PHMC-Licensed Facility

covers:

- multiple devices
 - multiple imports within the 6 month validity period
 - different risk class
- Pre-requisite: valid Importer's Licence
 - At the end of authorisation, importer shall declare the number of devices imported and supplied.

Product Registration



Product Registration

Summary of steps for Product Registration application

1. Apply for a CRIS company account for Medical Device Information and Communication System (MEDICS),
[Link:http://eservice.hsa.gov.sg/osc/cris/welcome.do](http://eservice.hsa.gov.sg/osc/cris/welcome.do)
2. Apply for the Registrant's Account through MEDICS@HSA
3. Submit Product Registration Application through MEDICS
Specifically, for product registration, please refer to the following documents:
 - GN-15 Guidance on Medical Device Product Registration
 - GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
 - GN-13 Guidance on the Risk Classification of General Medical Devices

Important note

For dental products that contain pharmaceutical components (e.g. filling materials with the antibiotic tetracyclin), please verify with HSA whether registration as combination product is required.

Thank you

- Hsa_md_info@hsa.gov.sg
- Dental Grouping Rules will be published on HSA's website
 - T-list

Annex 2: Dental Grouping Terms (DGT)

| No | Dental Grouping Terms (DGT) | Description |
|----|-----------------------------------|---|
| 1. | Adhesive kit for dental composite | A collection of devices intended to be used to bond attachments such as hooks or buttons to the teeth and/or to an orthodontic aligner during dental or orthodontic teeth adjustment. The contents of this kit may include etchant, bonding resin, bonding paste, spatula, brushes, and a paper pad. This is a reusable device. |
| 2. | Cryoanaesthesia device, dental | A dental brace-like device that is chilled to freezing/subfreezing temperatures and then applied to the labial sulci (gums) in a patient's mouth for a period to provide a cold anaesthesia for the underlying nerves. It is typically made of a thermoplastic elastomer (TPE) and cryogenic materials. This noninvasive device may be used as a substitute for hypodermic drug delivery during dental procedures. This is a single-use device. |
| 3. | Cryogenic spray, dental | A refrigerant typically contained in an aerosol dispenser and used to cool down a tooth by spraying on it, mainly to find out if the pulp is vital. It can also be used as a local anaesthetic when extracting deciduous teeth in children. This device is disposable once its contents of gas is expended. |
| 4. | Cusps, dental | A device designed to provide an artificial projection on the chewing surface of the tooth to achieve a proper bite. |
| 5. | Dental abrasives | A dental material made from various base substances having some abrasive qualities [e.g., treated sodium bicarbonate (NaHCO ₃) or aluminium oxide (Al ₂ O ₃)] and applied with an appropriate device (e.g., a dental abrasive air jet system) to the surface of teeth or dental devices. It has a wide variety of both prophylactic and treatment applications such as the removal of plaque and stains, cleaning fissures (above and below the gingiva), the preparation of a tooth surface prior to bonding, the cleaning of orthodontic appliances (bands and brackets), the removal of adhesive residue, and the cleaning of implants prior to loading. This is a single-use device. It includes accessories e.g. mixing pad, dispenser and other components required for dental abrasion. |
| 6. | Dental adhesives/ primers | A material primarily used as a bonding promoting substance between dental materials. This is a single-use device. It does not include cements. |
| 7. | Dental burs | A dental bur is a rotary cutting device designed to fit into a dental handpiece and intended to cut hard structures in the mouth, e.g. teeth or bone. It can also be used to cut hard metals, plastics, porcelains and similar materials. |

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| 8. | Dental caries detector, electrical impedance | A device designed to measure resistance to the flow of electric current across teeth for the diagnosis of early stage dental caries and/or to monitor the progress of caries (cariou areas being less resistant due to higher concentrations of fluid). It typically consists of a probe with an electrode placed in contact with the tooth to be tested and a second counter electrode, separate from the probe, which is placed in contact with another part of the patient's body to complete an electrical circuit connecting the two electrodes; and an electronic control unit that quantifies the resistance. This procedure is also known as electronic caries monitoring/measurement (ECM). |
| 9. | Dental caries detector, optical induced fluorescence | A device designed to determine the changes in the fluorescence of teeth enamel and dentine due to mineral loss, mainly for the diagnosis of early stage dental caries and/or to monitor the progress of caries. It consists of a light source (typically a laser) that elicits fluorescence in teeth, and a unit that quantifies the altered fluorescence of the carious tooth tissue. |
| 10. | Dental caries removal solution | A liquid substance used in dentistry to detect and remove caries from an infected tooth. After application, this device cannot be reused. |
| 11. | Dental casting materials | Compounds associated with the formation of a dental cast [i.e. a positive copy of a part of the oral anatomy made in an impression (mould)]. |
| 12. | Dental cavity liner | A substance intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth from chemical irritation. The device is typically a thin layer of zinc oxide (ZnO) and eugenol (C ₁₀ H ₁₂ O ₂), or calcium hydroxide (Ca(OH) ₂). After application, this device cannot be reused. |
| 13. | Dental cement | Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It includes accessories e.g. mixing pad, dispenser and other components required to complete the cementing procedure. |
| 14. | Dental cement kit | A collection of components designed to complete a cementing procedure. |
| 15. | Dental crowns/ bridges | A collection of solid blocks or liquid materials used to manufacture partial or full crowns and bridges. |
| 16. | Dental dry field device | A pre-assembled device used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It forms a frame around the oral cavity and provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of cheek retractors, a tongue guard, suction adaptors, and tubing with Y-piece connection to a suction system; it is reusable after appropriate cleaning/sterilization. |

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| 17. | Dental dry field kit | A collection of devices and supplies used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of bite blocks, pad extenders, suction tips of varying sizes, and tubing that connects to a suction system. It is reusable after appropriate cleaning/sterilizing, and consumable products may be replenished. |
| 18. | Dental etching composite | Acid as solution in water or as gel which is used to create a retentive surface for a composite, an adhesive or a pit and fissure sealant. |
| 19. | Dental implant debridement brush | A sterile rotary dental instrument designed for the debridement of a patient's dental implants affected by peri-implantitis; a destructive inflammatory process of the soft and hard tissues surrounding dental implants. It is a brush-like device, typically consisting of titanium bristles at the distal end of a high-grade steel shaft, that is held in a dental handpiece which provides its rotation for the mechanical removal of biofilm from the surface of the implants. This is a single-use device. |
| 20. | Dental implant extractor | A manually-operated, dental device used to retrieve a dental implant, typically because of damage (e.g., a broken collar) or malfunction, from the oral cavity. It is typically made of toughened, high-grade steel and has a cylindrical design with a coarse, left-handed fluting with a steep pitch that spirals up the tapered working end and a hexagonal head at the proximal end that fits a torque wrench socket. Such a device is inserted into the implant to be removed and turned anticlockwise (counterclockwise). The anticlockwise torque exerted makes this device grip into the implant, which is then unscrewed. It is a single-use device. |
| 21. | Dental implant, accessories | A collection of accessories designed to be used for the surgical placement of a dental implant into alveolar and/ or basal bone of the mandible or maxilla to provide support and a means of retention for a dental prosthesis (e.g., bridge, single-tooth, overdenture). |
| 22. | Dental implant, prosthetic teeth bar | A small rod, usually cast or brazed, that bears prosthetic teeth and allows them to be attached to the dental implant abutments. |
| 23. | Dental implant, suprastructure | A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to mimic preparations of natural teeth. It is used during dental implant restorative procedures and will provide the permanent intermediate fixture level between the dental implant and the final restoration (e.g., bridge, single tooth, overdenture). The device can be used for, e.g., cement or screw retained restorations and will include, e.g., abutments and cylinders. It comes in a variety of shapes and designs and can be made of different materials (e.g., titanium, plastic, gold alloy). Also includes temporary suprastructures. |

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| 24. | Dental implant/prosthesis, surgical procedure kit | A collection of various dental instruments designed for the surgical placement of dental implants or prostheses. It does not contain pharmaceuticals. It typically contains various dental drills (drill bits), drill extensions, depth gauges, wrenches and torque wrench, screwdrivers, forceps, trays and osteotomes. |
| 25. | Dental impression materials | A material designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth. This is a single-use device and includes accessories that are used specifically with the material. |
| 26. | Dental precision attachments | Dental devices designed for attaching a fixed or removable prosthesis to the crown of an abutment tooth, dental restoration (including implants), or dental appliance. |
| 27. | Dental procedure console and accessories, hydraulic (for use with handpieces) | An assembly of devices designed to bore and excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). The system is powered by pressurized water via a connecting hose to the handpiece/motor water-driven turbine. This is a reusable device |
| 28. | Dental procedure console and accessories, line-powered (for use with handpieces) | An assembly of devices designed to bore and excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). This system is electrically-powered from the mains (e.g., 230 or 115 volt) and supplies the handpiece/motor with low-voltage electricity (e.g., 24 volt) through a control unit. This is a reusable device. |
| 29. | Dental procedure console and accessories, pneumatic (for use with handpieces) | An assembly of devices designed to bore/excavate bones and tough tissues (e.g., cartilage, ligaments) during a surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, screwdriver bits, and guide wires). The system is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece/motor. This is a reusable device. |
| 30. | Dental procedure handpiece, hydraulic | A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. The device incorporates a small water-powered turbine motor that is driven by a source of pressurized water; it will typically have a built-in water spray for cooling the rotating instrument. It is typically connected to a dental delivery system or a free-standing independent system. This is a reusable device |

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| 31. | Dental procedure handpiece, line-powered | A mains electricity (AC-powered), hand-held, dental device that includes a chuck or collet for attaching a dental drill, bur, reamer, and other similar rotating instruments used in dentistry to bore/excavate bones, teeth, and tough tissues. It is powered by a low-voltage electric micro-motor (e.g., 24 volt) that is an integral part of the device. It is typically connected through the dental delivery system or a free-standing independent control unit. This is a reusable device. |
| 32. | Dental procedure handpiece, pneumatic | A hand-held device used in surgery for drilling, cutting, and inserting procedures involving bones and tough tissues (e.g., cartilage, ligaments). It will typically include a built-in motor and a chuck for attaching drills, bone taps or wires. The device may be cannulated to allow for use of a guidewire and may be of the micro or macro design. It is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece. This is a reusable device. |
| 33. | Dental pulp testing electrode gel | An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current. After application, this device cannot be reused. |
| 34. | Dental pulp-capping material | A dental compound designed to cover an exposed or nearly-exposed dental pulp (e.g., due to deep cavities) to provide protection against external influences and to promote healing. This compound does not have dental cement or dental cavity liner intended uses. This is a single-use device. |
| 35. | Dental reinforcing fibre | A device used in general restorative dentistry and orthodontic treatment typically as reinforcement of dental polymer-based materials, used for the construction of dental prostheses, i.e., splints, posts, crowns, and bridges. This device is typically made of polyethylene fibres supplied in strands, braid, or ribbon in a variety of sizes. It may also be used for the stabilization of avulsed teeth maintaining diastema closures or split-tooth syndrome. The ultrahigh molecular weight polyethylene fibres increase the strength of composite materials, and provide improved safety by assisting in the retention of pieces in the event that a dental prosthesis is broken. This is a single-use device |
| 36. | Dental restorative / cavity varnish | A liquid substance used to cover dental filling material in the initial setting period after application typically to prevent moisture infiltration (especially when a dental silicate or glass ionomer cement is used as a filling material). The device typically consists of dissolved artificial resins. It is used for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations. After application, this device cannot be reused. |

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| 37. | Dental restorative materials | Liquid compounds specially designed to fill dental cavities, restore damaged dental tissues, or for inlays, onlays and veneering. It includes accessories that are used specifically with the materials. It includes accessories e.g. mixing pad, dispenser and other components required to complete the restorative procedure. It does not include obturation of root canal. |
| 38. | Dental restorative/ repair kit | A collection of components designed to fill dental cavities or restore dental tissues. It does not include obturation of root canal. |
| 39. | Dental retention pin | A device intended to be placed permanently in the tooth to provide retention and/or stabilization for a dental restoration, e.g., a filling or a crown. It is typically made of stainless steel or titanium and comes in a variety of sizes, e.g., 1.0 mm to 3.2 mm. The device is inserted into a pre-drilled hole in the tooth and is secured by threading, friction and/or cementing. |
| 40. | Dental retention pin kit | A collection of various dental instruments, devices and materials intended for the insertion of permanent pins in healthy dentin to provide retention and/or stabilization of dental restorations such as fillings and crowns. It is typically presented as a kit and contains, e.g., retention pins of incrementing sizes, a selection of dental drills, and the necessary instruments to facilitate the procedure. This is a reusable device. |
| 41. | Dental scalers, ultrasonic | Consists of handpieces and scaler tip/insert (which function as part of an ultrasonic scaler system) that together transmit ultrasonic energy (e.g., 25kHz/30kHz) from a generator to the oral cavity for the removal of accretions from tooth surfaces during dental cleaning or periodontal therapy. Water or a rinsing solution (e.g., chlorhexidine) is also fed through the handpiece and attached tip to assist in the process. This device is typically designed with permanently attached cables in the form of a pen or pencil. This is a reusable device. |
| 42. | Dental scalers, rotary | An abrasive device intended to be attached to a powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. This is a reusable device. |
| 43. | Dental scalers, pneumatic | Consists of handpieces and scaler tip/insert, designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal therapy. Water is also fed through the handpiece and attached tip to assist in the process. It is typically designed with a standard 2-, 3-, or 4-hole connector utilizing the same connection to existing air driven handpiece tubing and the water spray for lavage. This is a reusable device. |

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| 44. | Dental solution, scaling | A liquid substance used in dentistry to soften and partially solubilize a dental calculus (a hard deposit that forms on the teeth) before scaling mechanically so that less force is required, especially when teeth are loose. It will typically contain acid as a solvent (e.g., hydrochloric) and include other elements (e.g., iodine and excipients). This is a single-use device. |
| 45. | Dental scaling system, ultrasonic | An assembly of devices that uses ultrasonic energy at its point of patient contact to remove accretions from tooth surfaces during dental cleaning or periodontal therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement. This is a reusable device. |
| 46. | Dental scaling system, rotary | An assembly of powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement. This is a reusable device. |
| 47. | Dental scaling system, pneumatic | An assembly of devices designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal therapy. It typically consists of a scaler handpiece and self-locking, removable tip. The handpiece may connect to any standard 2, 3 or 4-hole connector utilizing the same connection as an existing air driven handpiece tubing and the water spray for lavage. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement. |
| 48. | Dental sealants, endodontic | A prefabricated, solid dental substance used in endodontics to fill or permanently obturate the root canal of a tooth. The substance may set without assistance of moisture, and is typically intended for orthograde use (i.e., a root filling placed from the coronal aspect). The device has various metallic or polymeric compositions that include, but are not limited to, silver (Ag), methylmethacrylate, zinc oxide eugenol, glass alkenoate, and calcium hydroxide (Ca(OH) ₂). After application, this device cannot be reused. |

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| 49. | Dental sealants, pit/fissure | A resin-based dental material suitable for sealing pits and fissures on teeth. It may be chemically cured or external energy cured. After application, this device cannot be reused. It may include accessories e.g. mixing well, brush etc or other components required to complete the sealing procedure. |
| 50. | Dental shaded pontic kit | A collection of devices intended to be used to produce artificial tooth veneers (shaded pontics) typically inside clear plastic custom-made teeth aligners (retainer-style orthodontic appliances). This is used to create the appearance of teeth inside the aligner to cover spaces where teeth may be missing for aesthetic purposes during treatment to realign teeth. The contents of the device may include polymer-based materials, dispenser gun, mixing tips, applicator brushes and practice aligner. |
| 51. | Denture clasps | Dental devices designed to retain and stabilize removable partial dentures to stationary teeth. |
| 52. | Denture reliners | A device consisting of polymer based material, e.g. plastic resin, that is applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. Denture relining is defined as a process of providing a new fitting surface to a denture. |
| 53. | Facebow | A caliper-like dental instrument used to record the relative position of the maxillary arch to the temporo-mandibular joint (TMJ), or the opening axis of the jaw. It is used to orient dental casts in the same relationship to the opening axis of the articulator. |
| 54. | Fixture/appliance dental drill, single-use | A sterile shaft of metal (a drill bit) intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance. It is typically made of a high-grade stainless steel alloy. The device is typically available in a set of graduated sizes and various forms and functions (e.g., guide, pilot, twist, cortical, conical). It is attached to a motorized handpiece or other power source that provides rotation. This is a single-use device that is intended, in terms of sterility, for a single-patient use. |
| 55. | Gingiva bleaching protector | A non-sterile paste or gel-like substance designed to protect a patient's gums from the hydrogen peroxide found in teeth whitening agents used during chairside light-curing bleaching of the teeth. It is typically supplied in a disposable syringe and is applied with an applicator along the gingiva leaving the teeth exposed for treatment. After application, this device cannot be reused. |
| 56. | Gingival retraction cord, non-medicated | A non-medicated, cotton string used to temporarily hold off the gingiva during abutment preparation. This is a single-use device |
| 57. | Gingival retraction kit | A collection of sterile dental instruments and other items used to hold off the gingiva during abutment preparation. This is a single-use device. |

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| 58. | Gingival retraction solution | A liquid substance used in dentistry to induce gingival retraction by in situ impregnation of a non-medicated gingival retraction cord. It induces contraction of the upper strata of the free gingiva. This device may also induce a local stasis of gingival exudates and gingival haemorrhages. After application, this device cannot be reused. |
| 59. | Non-medicated dental surgical procedure kit, single-use | A collection of various sterile dental instruments, dressings and the necessary materials used to perform a dental surgical procedure. It does not contain any pharmaceuticals. This is a single-use device. |
| 60. | Oral wound dressing, non - animal/ microbial- derived | A non-sterile compound intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It is used for various types of dental wounds and sores such as oral ulcers (non-infected or viral) and lesions caused by dental prostheses/orthodontic braces; it may also be used to treat mucosal irritations/inflammation, dryness and gingivitis. It is supplied in various forms (e.g., gel, paste, fluid, spray solution of water/oil). It is normally available [non-prescription] over-the-counter (OTC) for use in healthcare facilities or home. After application, this device cannot be reused. This does not include pharmaceuticals. |
| 61. | Orthodontic appliance archwire-cooling device | An instrument used in orthodontic dentistry to intra-orally chill or cool thermally-activated archwires when placing bends in an orthodontic appliance. The device, after it has been precooled (typically with a cryogenic spray), is applied to a desired point of contact on the wire to extract heat and allow easy bending. As the archwire warms to body temperature it attempts to return to its former shape, and thus contributes to the application of forces within the mouth. The device is typically formed as a heavy-duty stainless steel rod with an insulated plastic handle and a slot at the distal end to accept wire. |
| 62. | Orthodontic appliance force-measuring gauge | An instrument used in orthodontic dentistry to accurately measure forces (in grams or ounces) applied by the elastics or springs used when setting up orthodontic appliances within the patient's mouth. The device is typically of cylindrical or tubular design (but can be dial-shaped with circular read out) and is made of metal (some partly plastic); it contains a spring-loaded mechanism which indicates the force exerted to pull the appliance elastic or spring to the desired length. |
| 63. | Orthodontic appliances | Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force. It includes orthodontic anchor plate, orthodontic anchoring screw, orthodontic archwire, orthodontic archwire/bracket fixation ring, orthodontic bands, orthodontic brackets, orthodontic bracket adhesive, orthodontic clasps, orthodontic chin cap, orthodontic extraoral headgear, orthodontic face bow, orthodontic ligature, orthodontic magnet, orthodontic spring, orthodontic tube, orthodontic wire. |

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| 64. | Orthodontic space maintainer (for prematurely lost deciduous teeth) | A dental prosthetic replacement for prematurely lost deciduous teeth intended to prevent closure of the space before eruption of the permanent successors. Often an urgent necessity in the buccal segment to prevent impaction of the permanent teeth and other complications. |
| 65. | Palatal impression kit | A collection of non-sterile devices designed to obtain a negative imprint of the upper palate (i.e., the roof of the mouth with the gums and teeth) which is subsequently used to make a mould for the manufacture of a custom-made oral appliance. The kit typically includes a dental impression tray(s) and impression materials. Impression material is placed on the tray and the tray is then positioned in the mouth of the patient until the material becomes firm creating the mould. This is a single-use device. |
| 66. | Periodontal dressing, non -animal/ microbial- derived | A dental material in paste form which is placed over the periodontal tissues as a dressing, normally after surgery. It is not derived from animal or microbial sources. This does not include pharmaceuticals. |
| 67. | Root canal filling-removal solution | A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetra chloroethylene, formamide, eucalyptol, excipients). This is a single-use device. |
| 68. | Root canal irrigation/ rinsing solution | A substance used in dentistry to facilitate cleansing/irrigation of the root canal (the canal space) during and/or after endodontic instrumentation for the removal of the smear layer, pulpal tissue, necrotic materials, and bacteria from the instrumented root canal, before placement of the endodontic filling. It is typically available as an aqueous solution delivered into the canal with an irrigation needle or similar device, providing mechanical and possibly chemical cleansing of the canal. After application, this device cannot be reused. |
| 69. | Root canal obturation kit | A collection of sterile dental devices, synthetic materials, and solutions designed to permanently prime, seal, and fill a tooth undergoing a root canal procedure. This device typically includes materials such as a primer (for bonding to the walls of the canal), a sealer (for bonding to the primer), and endodontic points and pellets (for the filling). This bonding process creates a monoblock filling resulting in increased resistance to bacteria penetration and fracture for root canal-treated teeth. This is a single-use device. |
| 70. | Root canal post kit | A collection of devices used for the insertion of root canal posts. These are typically prefabricated and made in a variety of shapes, dimensions and materials, e.g., they can be non-threaded, pre-threaded, or self-tapping, straight or tapered, and made of alloy, ceramic and fibre reinforced polymers. This device typically includes the root canal posts, drills and thread cutter. This is a reusable device. |

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| 71. | Root canal posts | A dental device (rod) intended to be inserted and cemented into a prepared root canal of a tooth to stabilize and support a restoration. Pre-fabricated root canal posts come in various shapes and dimensions, as well as materials, e.g. metal, fibre reinforced polymer and ceramic. |
| 72. | Root surface conditioner | A dental material, typically of neutral pH, used for topical application on exposed/scaled root surfaces for the removal of the smear layer (adherent debris produced when cutting the enamel or dentin in cavity or endodontic preparation, Circa 1 micron thick) during dental/periodontal surgery. The material is removed (washed off) after the recommended period to expose the collagenous matrix of dentine surfaces. It is typically presented in the form of a gel and consists of, e.g., edetate disodium (EDTA) and carboxymethylcellulose (CMC) with a neutral pH. After application, this device cannot be reused. |
| 73. | Tooth preservation kit | A convenient collection of sterile devices/supplies designed to preserve and transport a tooth that has been knocked out (i.e., avulsed) so it can be reimplanted. It typically includes instruments, preserving solutions, a container (e.g., a vial or cup with a plastic net inside to hold the tooth suspended in the preservation solution), and swabs/bandages. It is used to avoid tooth cell crushing and/or dehydration by immersing the tooth in a pH balanced solution compatible with periodontal cells, and is typically used in field emergency situations after traumatic knock out of teeth. This is a single-use device. |
| 74. | Warm-bonded endodontic obturation system | An assembly of devices designed to deliver preheated resin-based sealing, filling, and core materials into a root canal for direct warm bonding during an endodontic obturation procedure. It typically consists of a mains electricity (AC-powered) oven specifically used to heat the preloaded obturators, a series of root canal sizers (verifiers) used for the selection of the appropriate obturator, and preloaded obturators; other materials may be included (e.g., self-etch sealer). |