

# **Updates by WG1 –Pre-Market Submission & CSDT**

**Co-Chair: Alfred Kwek**

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**Secretary: Carol Yan**

# Status of Previous WG Items (Completed)

No.	Previous Work Item	Status
1	Mapping of CSDT to STED	Completed mid 2012 Information published on AHWP website <i>AHWP/WG1/R001:2012</i>
3	Review of amended GHTF definition of medical device	Completed end 2012
4	Introduction & Training on Medical Software	Completed mid 2012 Catered for training on software in Manila meeting (Jun 2012)
5	Medical software guidelines for pre-market registration	Summary of qualification practices in regulatory agencies, globally <b>Completed Dec 2013</b> White paper on Qualification of Software as a Medical Device <b>Completed Nov 2014</b>
6	Combination products (Medical Device) guidelines	Information gathering on combination product classification & review practices in ASEAN and IMDRF member economies <b>Completed Nov 2013</b> White paper on summary of combination products guidelines in AHWP and IMDRF jurisdictions First Draft <b>completed in Nov 2013</b>
7	Medical Device Grouping guidelines (new)	Data search on jurisdictions that currently have grouping guidelines & tabulate and present results <b>Completed Oct 2014</b>

# Work Item: Medical software (Software as a Medical Device)

# Software

## Objective

- Initiated due to recent global developments in medical device regulation, especially **Software as a Medical Device (SaMD)**

## Challenges

- Different approach & criteria for classification of software as medical devices – Common ground is summarised in White Paper published on AHWP website
- On global front, best practice approach for software regulation still evolving

## Future proposed work

- Be mindful of & update on global changes on SaMD regulation
- Guidance documents on software qualification & technical review

# Work Item: Medical software (Software as a Medical Device)

# Stage 1: Benchmark

## (Data Search)

# Proposed Timelines

Work Item	Deliverables	Action Plan and Timeline
<b>Medical Device Grouping Guidelines</b>	Data search on jurisdictions that currently have grouping guidelines & tabulate and present results	Q2 (Jun) 2014
	Identify best practices & perform gap analysis of guidelines. Road map proposal to bridge the gaps – Position paper	Q3 (Sept) 2014
	Propose a guideline document	Q2 (Jun) 2015

# Benchmark

**The following Jurisdictions were selected for medical devices grouping benchmark :**

USA, EU, Canada, Singapore, Saudi Arabia and Malaysia

**The countries were selected based on the followings:**

- Clear published guidance dedicated to medical device grouping
- Good geographical and market profile spread of guidelines sampled



## Chapter 2—Australian Register of Therapeutic Goods

### 9A Australian Register of Therapeutic Goods

- (1) The Secretary is to cause to be maintained a register, to be known as the Australian Register of Therapeutic Goods, for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.
- (2) Subject to subsection (3), the Register is to be kept in such form as the Secretary determines.
- (3) The Register is to contain these 4 parts:
  - (a) a part for goods to be known as registered goods; and
  - (b) a part for goods to be known as listed goods; and
  - (ba) a part for biologicals included in the Register under Part 3-2A; and
  - (c) a part for medical devices included in the Register under Chapter 4.
- (4) The regulations may prescribe:
  - (a) the therapeutic goods, or the classes of therapeutic goods, that are required to be included in each part of the Register; and
  - (b) the ways in which goods that are included in one part of the Register may be transferred, or may be required to be transferred, to another part of the Register; and
  - (c) the ways in which goods that have been assigned a registration or listing number may be assigned a different registration or listing number; and
  - (ca) the ways in which a biological that has been assigned a number under subsection 32DB(2), 32DF(2) or 32DN(5) may be assigned a different number (which may be any combination of numbers and either or both of letters and symbols); and



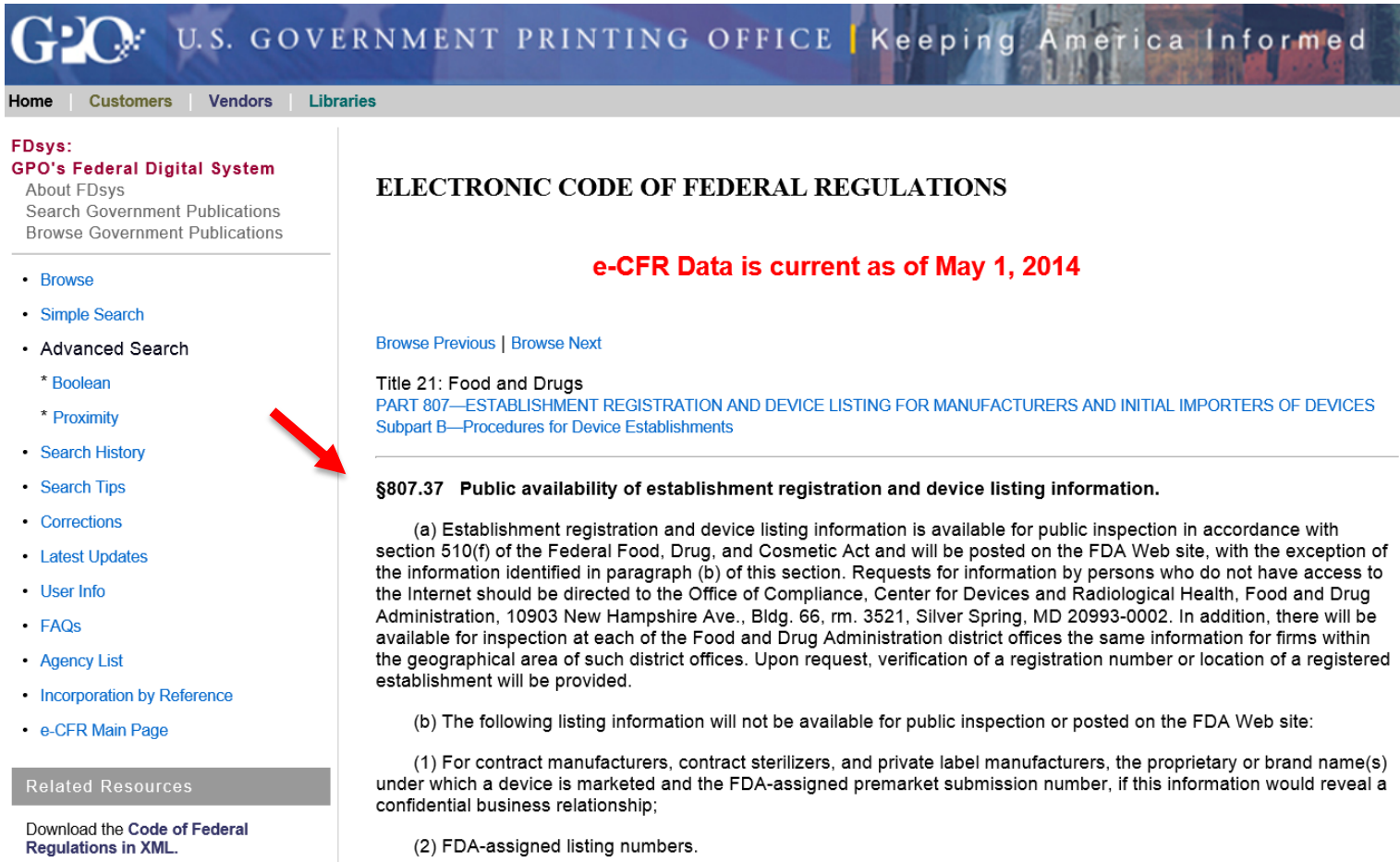
## Therapeutic Goods Act 1989

No. 21, 1990 as amended

**Compilation start date:** 12 March 2014

**Includes amendments up to:** Act No. 4, 2014

# Public Register - USA



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Related Resources

Download the **Code of Federal Regulations in XML.**

## ELECTRONIC CODE OF FEDERAL REGULATIONS

**e-CFR Data is current as of May 1, 2014**

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Title 21: Food and Drugs  
[PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES](#)  
[Subpart B—Procedures for Device Establishments](#)

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**§807.37 Public availability of establishment registration and device listing information.**

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA Web site, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.

(b) The following listing information will not be available for public inspection or posted on the FDA Web site:

- (1) For contract manufacturers, contract sterilizers, and private label manufacturers, the proprietary or brand name(s) under which a device is marketed and the FDA-assigned premarket submission number, if this information would reveal a confidential business relationship;
- (2) FDA-assigned listing numbers.

Singapore	Australia	USA
Establishment Licensing	the person in relation to whom a kind of medical device is included in the Register	Establishment Registration
Device Registration	Therapeutic Goods Registration	Device Listing

<b>Device Name:</b>	3M Bair Hugger™ Temperature Management Units	<b>Product name</b>	Echo Bi-Metric Collarless Porous Stem - Prosthesis, internal, joint, hip, femoral component	<b>Proprietary Name:</b>	LTX240AA01; LTX240AA01-A
<b>Description:</b>	...is intended to prevent and treat hypothermia....	<b>Sponsor name</b>	Biomet Australia Pty Ltd	<b>Classification Name:</b>	SOLID STATE X-RAY IMAGER (FLAT PANEL/DIGITAL IMAGER)
<b>Medical Specialty Area:</b>	General Hospital	<b>ARTG entry for</b>	Medical Device Included Class III	<b>Product Code:</b>	<a href="#">MQB</a> <sup>6</sup>
<b>HS Code:</b>	90189030	<b>Public ARTG summary</b>	<a href="#">ARTG ID 223029 - public ARTG summary (pdf)</a>	<b>Device Class:</b>	2
<b>HSA Product code:</b>	Refer to CRPNS			<b>Regulation Number:</b>	<a href="#">892.1680</a> <sup>7</sup>
<b>Medical Device Class:</b>	Class C medical device	<b>Postal Address</b>	NSW, Australia	<b>Medical Specialty:</b>	Radiology
<b>Device Registration No:</b>	DE0002084	<b>ARTG Start Date</b>	1/05/2014	<b>Registered Establishment Name:</b>	<a href="#">SAMSUNG DISPLAY CO., LTD.</a> <sup>8</sup>
<b>Registration Date:</b>	04/11/2005	<b>Status</b>	Active	<b>Registered Establishment Number:</b>	3008976963
<b>Change Notification Approval Date:</b>	04/07/2013	<b>Approval Area</b>	Medical Devices	<b>Owner/Operator:</b>	<a href="#">SAMSUNG Display Co., LTD.</a> <sup>9</sup>
<b>Expiry Date:</b>	09/08/2014	<b>Conditions</b>	Each sponsor shall retain records of the distribution....	<b>Owner/Operator Number:</b>	10031642
<b>Product Owner</b>		<b>Manufacturer Name &amp; Address</b>		<b>Establishment Operations:</b>	Manufacturer
<b>Registrant Imported by</b>		<b>Product Type</b>	Single Device Product		
<b>Product Code for Accessories</b>	HSAMDZ00100	<b>GMDN</b>	35666 Prosthesis, internal, joint, hip, femoral component		
		<b>Intended Purpose</b>	... is part of the Hip System... hemi hip arthroplasty...		

# Catalogue or Register?

### Straight Handpiece

**ES-30A** U-Type Nose  
40,000rpm  
Ball Bearing



**ESG-30AR** U-Type Nose  
4:1 Speed Reduction  
Ball Bearing



### Air motor

**ME-20M** 20,000rpm (0.2MPa)  
ISO 4-Hole (Midwest Type)



**ME-20B** ISO 2-Hole (Borden Type)

**ME-80M** 5,000rpm (0.2MPa)  
ISO 4-Hole (Midwest Type)



**ME-80B** ISO 2-Hole (Borden Type)

### Contra Angle Handpiece 1:1

**EC-20L** 20,000rpm  
for **CA Bur**



**EC-20FG** 20,000rpm  
for **FG Bur**



**EC-20ML** 20,000rpm  
Miniature Head  
for **CA Bur**



**EC-30BL** 30,000rpm  
Ball Bearing  
for **CA Bur**



**EC-30BLP** 30,000rpm  
Ball Bearing  
Push Button Type  
for **CA Bur**



### Contra Angle Handpiece 4:1 Speed Reduction

**EG-20L** for **CA Bur**



**EG-30BL** Ball Bearing  
for **CA Bur**



**EG-30TL** for **ENDODONTIC**  
Twist (Quarter-Turn)



### Sheath

**SHS-EC** 1:1  
Compatible with Midwest Type



**SHS-EG** 4:1 Speed Reduction  
Compatible with Midwest Type



**SHS-ECN** 1:1  
Compatible with NSK and Star Titan Type

**SHS-EGN** 4:1  
Compatible with NSK and Star Titan Type

### Spare Head

EH--Compatible with Midwest Type  
EHN--Compatible with NSK and Star Titan Type

**EH-20L** 20,000rpm  
for **CA Bur**

**EH-20ML** 20,000rpm  
Miniature Head  
for **CA Bur**

**EH-20FG** 20,000rpm  
for **FG Bur**

**EH-30BL** 30,000rpm  
Ball Bearing  
for **CA Bur**

**EH-35BL** 30,000rpm  
Ball Bearing  
Slide Latch Type  
for **CA Bur**

**EH-30BLP** 30,000rpm  
Ball Bearing  
Push Button Type  
for **CA Bur**

**EH-30TL** for **ENDODONTIC**  
Twist (Quarter-Turn)



**9490 - BASIC EXAMINATION SET OF 4 - ECONOMY**

- Mirror Handle #5 C/S
- Cotton-College Plier, Serrated Tips 6"
- Explorer #5 DE
- Excavator #17
- Cardboard Box



**8813 - PERIO EXAM SET OF 6 - DELUXE**

- Lightweight Hollow Handles
- German 420 Stainless Steel
- Explorers, EXDs, 6EZ ODU11/12, 6EZ, Color probe, CP15UNC(1-15mm) 6FZ, CPO2N (3-6-9-12mm) 6EZ Forceps
- London College 3 Holes, Mirror Handle #6, C/S Mirror #5, C/S-Front Surface
- Optional Sterilization Cassette MIDI (18cm x 14cm DIN Standard)



**8801 - DIAGNOSTIC EXAMINATION SET OF 3 - DELUXE**

- Tweezers Ergonomic College
- Mirror Handle With Silicon Sleeve
- Rhodium Mouth Mirror #4
- Explorer With Silicon Sleeve
- Optional Sterilization Cassette MINI (18cm x 7cm DIN Standard)

# Grouping Terminology Identified by AHWP

## **SINGLE**

a medical device from a manufacturer identified by a medical device proprietary name with a specific intended purpose.

## **FAMILY**

made by the same manufacturer, that differ in only certain variations (shape, colour, flavour or size) that have the same design and manufacturing process and the same intended use.

## **IVD TEST KIT**

reagents or articles, or any combination of these, that are used together to conduct a specific in-vitro diagnostic test.

## **SYSTEM**

Comprises of a number of constituent-components to be used in combination to complete a common-intended use, are compatible when used in that system and sold under a single system name.

## **IVD CLUSTER**

Comprises of a number of IVD reagents or articles from the same manufacturer that are of more than one IVD medical device type but have multiple commonalities to allow a single review (e.g. same risk class, same test methodology, with a common diagnostic profile).

(Note: There is variation in criteria for this grouping across jurisdictions: Saudi Arabia, Singapore, USA. Further analysis to be done for a definition based on best practices.)

## **GROUP**

(includes PROCEDURE PACKS and CONVENIENCE KITS): a collection of two or more medical devices, assembled together as one package to perform a certain procedure by a manufacturer, for a common intended use.

## **DENTAL GROUPING TERM (DGT)**







Similar dental devices used for a similar intended purpose that falls under a generic dental term defined by the regulatory authority (e.g. dental cement, orthodontic appliance)

## **SCOPE**

Generic device categories defined by the regulatory authority (EU)



# BUNDLING CRITERIAS COMPARISON

	SAUDI ARABIA 	EU 	CANADA 	USA 	SINGAPORE 	MALAYSIA 
SINGLE	✓		✓	✓	✓	✓
FAMILY	✓		✓	✓	✓	✓
IVD TEST KIT	✓		✓	✓	✓	✓
SYSTEM	✓		✓	✓	✓	✓
SYSTEMS GROUP	✓				✓	✓
IVD CULSTER	✓			✓	✓	
GROUP	✓		✓	✓	✓	✓
DENTAL GROUPING TERM	✓				✓	
SCOPE		✓				

\*The terminology used here is for purpose of presentation and may vary across respective guidance

# Best Practices

**Best Practices Identified was mostly from Canada, Singapore, Malaysia and Saudi Arabia Grouping system:**

- Comprehensive grouping criteria
- Multiple routes for medical devices grouping, which gives flexibility to manufacturers to select the most convenient and lower cost routes.
- Recent medical devices grouping criteria (Attempted to overcome grouping challenges faced by older grouping criteria).

**Thank You**