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Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

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4-8 December, 2017 I New Delhi

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Grouping of Medical Devices: CAB Role and Grouping – A balance between Regulatory Controls and Processes with the Economics of MD Industry

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Senior Product Specialist
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Grouping of Medical Devices:

All statements , positions and expressions in this presentation are my own opinions.

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Grouping of Medical Devices: Part 1: The industry perspective

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Preamble:

- No such thing as one size fits all.
- Variants are necessary due to needs and expectations of end users or consumers….in order for the device to function effectively….meets intended use

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Industrial realities in device availability:

Examples of necessary variables:

a. Geriatric, adult, paediatric and neonatal models
b. Sizes (length and/or width)
c. Product features
d. Shapes

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Premarket approvals/registrations for groups of medical devices including:

- Different Fr sizes of urinary catheters
- Procedure packs of medical devices and non medical devices

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Uncertainties in group approvals

- Heterogeneity
- Non representative test data
- Unsupported decisions to add new members
- Subjectivity across the regulatory spectra

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Grouping of Medical Devices: Part 2: The Regulatory perspective

Benefit of approving a group vs individual medical devices

- Removal of redundancies in application, reviews approval, renewal, amendment.

Example of Regulatory oversight:

Canadian Medical Devices Regulations SOR/98-282

Medical Devices Deemed Licensed:

`Collective approvals' (the Speaker's own term) for Systems, Test Kits, Medical device groups, Medical device group families

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Canadian Medical Devices Regulations

SOR/98-282

Medical Devices Deemed Licensed:

For Example:

30 If a medical device or a medical device group is licensed and forms part of a medical device family or a medical device group family, as the case may be, all other medical devices or medical device groups in the family are deemed to have been licensed.

Canadian Medical Devices Regulations

SOR/98-282

Medical Devices Deemed Licensed:

Medical device family means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Canadian Medical Devices Regulations

SOR/98-282

Medical Devices Deemed Licensed:

Legal definitions include:

Test Kit

System

Medical device group

Example of Regulatory oversight:

European Medical Device Regulations

- Risk based approach to assessment of variants i.e. different models configuration, sizes
- Conformity assessment route i.e.
  - Type testing
  - Design dossier review for Class III devices
  - Conformity assessment for non class III devices

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European Medical Device Regulations

- Sampling Plan for Technical documentation for Class IIa and IIb
- Listing of variants in the list of CE marked devices

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Grouping of Medical Devices: Part 3: Controls (or Best Practices) in addressing uncertainties

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Example of controls:

Use of references and databases:

EUDAMED Database
List of CE Marked devices

Example of controls:

Use of Classification to ensure conservation risk based assessment:

Examples:

e.g. variation in degree of invasiveness, duration of use

Combination with drugs

Example of controls:

Use of state of the art

Examples of device standards which

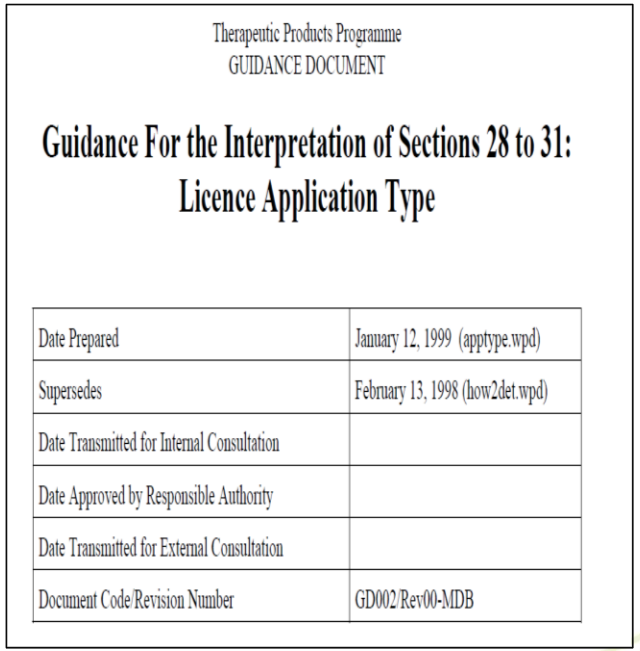
- ISO 10555-1 for Intravascular catheters
- EN 455 series for gloves
- ISO 4074 for condoms

Example of controls:

Use of guidance documents

For example:

Canada: GD002/RevDR-MDB DRAFT



Therapeutic Products Programme
GUIDANCE DOCUMENT

Guidance For the Interpretation of Sections 28 to 31: Licence Application Type

Date Prepared	January 12, 1999 (apptype.wpd)
Supersedes	February 13, 1998 (how2det.wpd)
Date Transmitted for Internal Consultation	
Date Approved by Responsible Authority	
Date Transmitted for External Consultation	
Document Code/Revision Number	GD002/Rev00-MDB

Example of controls:

Use of guidance documents

For example:

Singapore: GN-12-1 Revision 2.1 November 2017
Guidance of Product Grouping for Product Registration – General Grouping Criteria

Example of controls:

Use of guidance documents

For example:

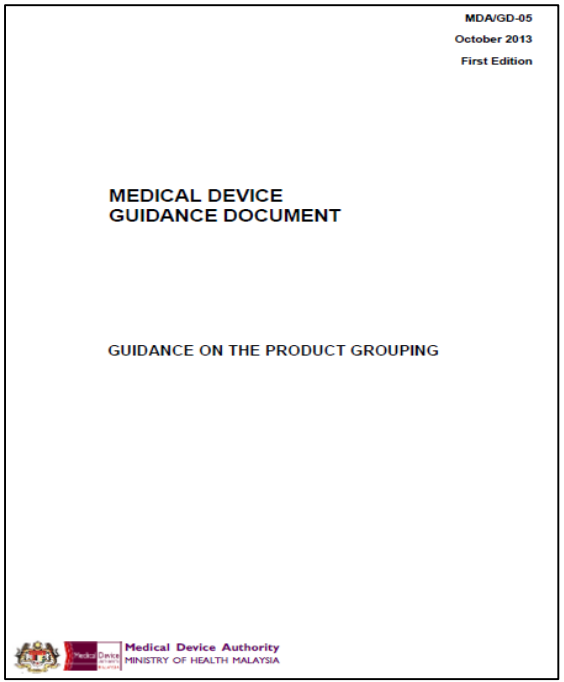
Singapore: GN-12-2 Revision 1.1 November 2017
Guidance of Product Grouping for Product Registration – Device Specific Grouping Criteria

Example of controls:

Use of guidance documents

For example:

Malaysia: MDA/GD-05 Oct 2013



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How do guidance documents help:

1) Clarification
2) Definition
3) Flowcharts
4) Negation (e.g. what cannot be a family)
5) Device specific grouping e.g. IVF Fertilisation Media

(Singapore: GN-12-2 Revision 1.1 November 2017)

Example of controls:

Change Notification system (a.k.a. license amendment)

- Ensures that expansion of families / groups are notified

Example of controls:

- Assessment of variant technical documentation using a sampling plan (NBOG)
  - qualified personnel
  - training matrix
  - evaluation program

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Summary on Grouping based device approvals:

1. Real world nature for medical devices to exist in groups
2. Grouping facilitates approval and other regulatory processes but uncertainties and risks abound
3. Controls (and best practices) are available to address uncertainties and risks

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Thanks and questions?

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