



Elements of the Regulatory Framework for Medical Devices

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The T'asman Market

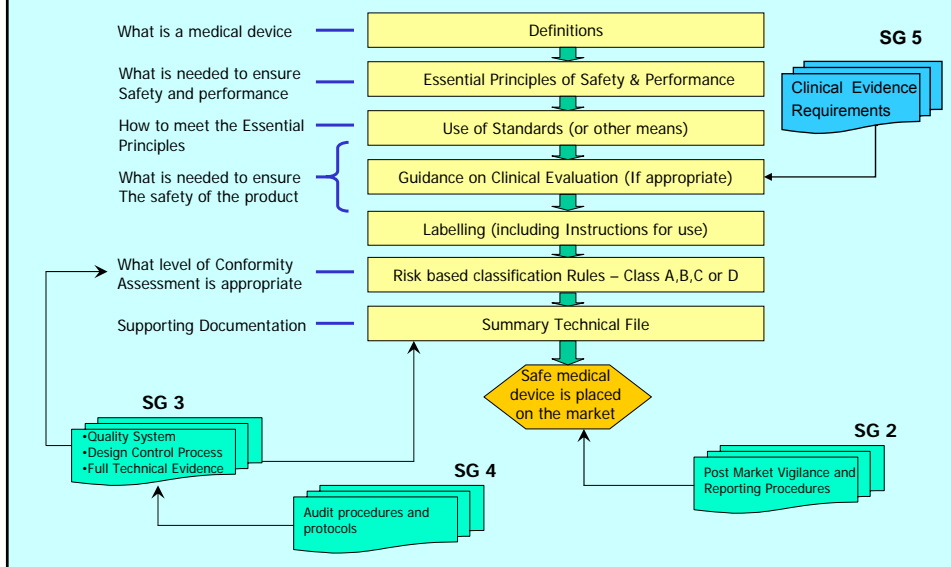
- ~2100 suppliers
- ~38,000 different devices
 - between 400 - 600,000 catalogue items
- >85% of devices are imported
- <10% of devices could be classified as high risk
- Australia and New Zealand approximately 2% of world market

The Model

- Based on the recommendations of the Global Harmonisation Task Force
- Mutual Recognition Agreements with the European Union

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Study Group 1 – Pre-market Technical Requirements





The Participants –

- Manufacturer
 - has an obligation to show that products conform to safety and performance principles
 - GHTF Essential Principles
 - has an obligation to follow an assessment procedure
 - to ensure the initial and on-going conformity to the Essential Principles
 - includes quality management system requirements
 - includes post-market monitoring, investigation and reporting requirements
 - similar to the EU Conformity Assessment Procedures

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The Participants –

- Sponsor
 - certifies that a manufacturer has met their obligations
 - ensures information flows to and from the manufacturer
 - accepts the responsibility for the supply of product
 - assists the manufacturer to comply with the obligations on the manufacturer
 - submits the manufacturer's evidence of conformity to the Agency
 - applies for an entry for the manufacturer's product on the Agency Product Licence Register.

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The Participants –

- The Regulator
 - the Agency
 - performs selected full pre-market assessment
 - performs selected short pre-market assessments
 - performs post-market vigilance and investigation



Key Definitions



Intended Purpose

- The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.



- The purpose for which the manufacturer of a medical device intends it to be used, as stated in
 - the information provided with the device; or
 - the instructions for use of the device; or
 - any advertising material applying to the device.
- Used to determine
 - if the device is a medical device
 - classification



Medical Device

- Any article **intended by the manufacturer** to be used for a medical purpose.
 - Principal action not pharmacological, immunological or metabolic
- At a stage of manufacture ready to be supplied to the final user
 - Products may be finished products but still require some assembly or preparation by the user.
- **Accessories** are medical devices, and are treated as medical devices for conformity assessment purposes

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'Medical device' means

- any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
 - diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
 - investigation, replacement, modification, or support of the anatomy or of a physiological process,
 - supporting or sustaining life,
 - control of conception,
 - disinfection of medical devices,
 - providing information for medical 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.

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Contrast with

Current NZ - Medical Device.....

Any device, instrument, apparatus, or contrivance including components and accessories thereof, that is manufactured imported sold or supplied for a therapeutic purpose...

- treating or preventing disease
- diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or
- effecting contraception; or
- inducing anaesthesia; or
- altering the shape, size, structure, size or weight of the human body; or
- otherwise preventing or interfering with the normal operation of the physiological function



Accessories

- Accessories intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself.



What is NOT a medical device

- **Intermediate products** or components not supplied to the final user are not medical devices.
- **Spare parts** are not medical devices



Manufacturer

- Person **responsible** for design, production, packaging and labelling regardless of whether these operations are actually carried out by the person.
- Person who assembles, packages, processes, fully refurbishes and/or labels one or more 'ready made' products and/or assigns to a ready made product an intended purpose



A person is **not** the manufacturer if

- the person assembles or adapts the device for an individual patient; and
- the device has already been supplied by another person; and
- the assembly or adaptation does not change the purpose intended for the device

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Key elements

- 14 Essential Principles for safety and performance
- 22 Rules of Classification based on Risk to user and/or patient
- Quality Systems – eg - ISO 13485
- Independent Assessment and on-going surveillance of Quality Systems
- Postmarket Surveillance

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Essential Principles



Essential Principles

General

- Risks vs benefits are acceptable
- Take account of generally acknowledged state of the art
- Apply the following principles when selecting design solutions -
 - inherent safe design
 - fail safe mechanisms
 - document the residual risk



Essential Principles

General (cont'd)

- must achieve the intended performance
- must not be adversely affected by normal conditions of use
- must not be adversely affected by transport and storage
- undesirable side effects must be acceptable when weighed against the intended performance



Essential Principles

Specific

- Chemical, physical & biological properties
- Infection & microbial contamination
- Construction and environmental function
- Protection against radiation



Essential Principles

Specific (cont'd)

- Devices with a measuring function
- Devices supplied sterile
- Medical devices connected to or equipped with an energy source
- Information supplied by the manufacturer
- Clinical data



Design and construction of medical devices to conform with safety principles

- The solutions adopted by the manufacturer for the design and construction of a medical device **must conform with safety principles**, having regard to the generally acknowledged state of the art.
- Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to **minimise any risks** associated with the use of the device, the manufacturer must:
 - first, **identify hazards and associated risks** arising from the use of the device for its intended purpose, and **foreseeable misuse of the device**; and
 - second, **eliminate, or reduce, these risks as far as possible** by adopting a policy of inherently safe design and construction; and
 - third, if appropriate, ensure that **adequate protection measures** are taken, **including alarms if necessary**, in relation to any risks that cannot be eliminated; and
 - fourth, **inform users of any residual risks** that may arise due to any shortcomings of the protection measures adopted.



Essential Principles

- Devices labelled either as sterile, or as having a special microbiological state, should have been processed, manufactured and, if applicable, sterilized by an appropriate validated methods
- Devices intended to be sterilized should be manufactured in appropriately controlled (eg environmental conditions)



Essential Principles

Clinical Evidence

- Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles.



Classification



Classification

- Defines the level of pre-market assessment
- Based on the manufacturer's intended use
- Based on risk criteria
- Rules for classification based on the relationship of the device and its application to the body
- Rules accommodate new technology



Classification

Diminishing Level of Risk

- III & AIMD - High Risk
- IIb - Medium Risk
- IIa - Medium Risk
- Im & Is - Low Risk, but sterile or measuring function
- I - Low Risk



22 Rules for classification based on

- **Duration of use**
 - transient < 1 hour
 - short term < 30 days
 - long term > 30 days
- **Invasiveness**
 - non-invasive
 - through body orifices
 - surgically invasive
 - implantable



Active medical devices — general

- An active medical device is classified as **Class IIa**, unless the device is classified at a higher level under another clause.

Active medical devices for therapy

- An active medical device for therapy that is intended by the manufacturer to be used to administer energy to a patient, or exchange energy to or from a patient, is classified as **Class IIa**.



Active devices for therapy

- All active devices intended to administer or remove medicines, body liquids or other substances to or from the body are in **class IIa**: unless
- this is done in as potentially hazardous manner taking into account the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are **class IIb**



Devices incorporating tissues

- Devices containing material of animal origin, rendered non-viable, are Class III. (Devices containing material of human origin and viable animal origin will be regulated under the proposed framework for cellular therapies)



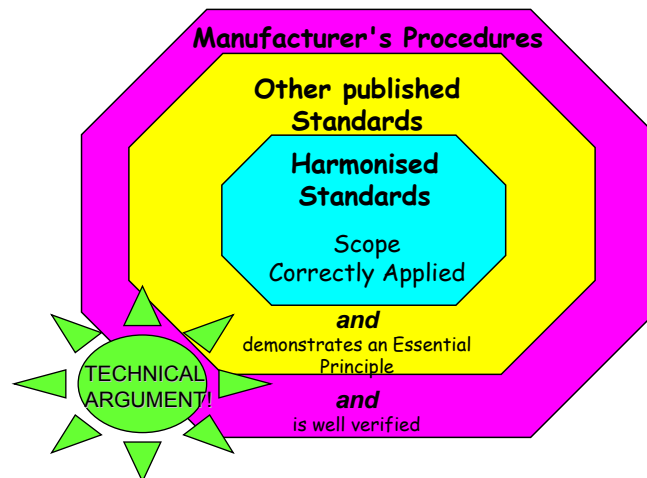
8 Special rules

- | | |
|--|------------|
| – incorporating a medicinal product | class III |
| – contraceptive or for prevention of STD's | class IIb |
| – disinfecting or cleaning contact lenses | class IIa |
| – ...non active.. For recording X-ray images | class IIa |
| – ...animal origin | class III |
| – blood bags | class IIb |
| – Active Implants | Class AIMD |

Guidance Documents on Classification

- MEDDEV 2.4/1 Rev 8 Guidelines on the Classification of Medical Devices - European Commission, DG enterprise
- Principles of Medical Device Classification - Study Group 1, GHTF - www.ghtf.org
- Australian Medical Device Guidance Document 25 - Classification of Medical Devices - TGA - www.tga.gov.au

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Standards

- Standards will no longer be mandatory
 - Except –
 - ISO 13485 – Quality Systems
(and even then, not strictly so !!!!)
 - 14 Essential Principles

Standards

Standards are not mandatory

- But they are the foundation of the framework
- Manufacturers will use more standards in product development, not less !!
- Harmonised standards
- Compliance with harmonised standard deems compliance with relevant elements of EP's



The Rules

- ▶ Impose certain **obligations** on manufacturers of medical devices
- ▶ These obligations are known as Conformity Assessment Procedures
- ▶ These obligations must be met by Australian, New Zealand and overseas manufacturers before a Sponsor may supply a product in Australia/NZ



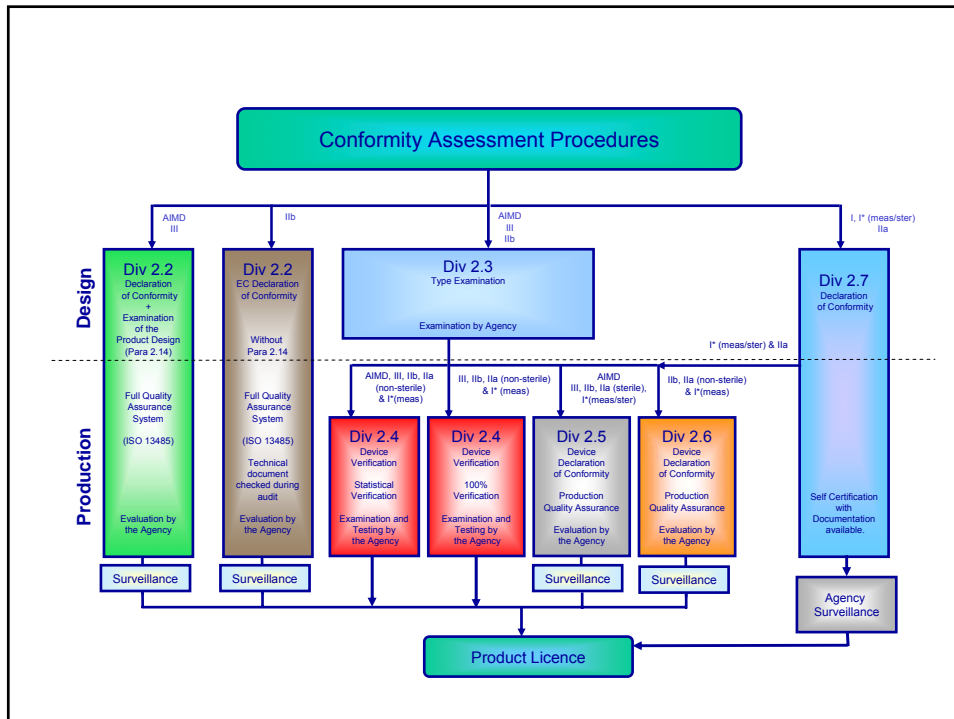
Obligations relate to:

- ▶ Use of a Quality Management System for manufacturing medical devices
- ▶ Demonstrating compliance of medical devices to Essential Principles
- ▶ Manufacturer's Declaration of Conformity
- ▶ Notify the Agency of changes to QMS (including scope)
- ▶ Post market monitoring of devices
- ▶ Keeping records

Selection of Conformity Assessment Procedure -

- Manufacturer selects conformity assessment procedure(s)
- Legislation specifies minimum conformity assessment procedures for each device class
- Manufacturer may choose conformity assessment procedure(s) more onerous than the minimum!

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Declaration of Conformity

- Format is specified in the Rule
- A statement that:
 - Manufacturer has followed the selected conformity assessment procedure
 - The product complies with the applicable essential principles
- May be prepared for a range or category of devices
- Must identify the range, lot, batch or serial numbers of devices included in scope of certificate

