Study Group 1

Conformity Assessment

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Aim of Conformity Assessment

- Provide Objective evidence that a manufacturer has established effective and adequate procedures to demonstrate compliance with Essential Principles of safety and performance of a medical device
  - (Doc SG 1/N41)

Aim of Conformity Assessment (cont'd)

- Ensures a manufacturer has an effective quality management system commensurate with the risk classification of the device
  - Classification SG1/N045 (draft)

- Conformity assessment and classification, as principles, are co-dependent
  - Risk classification
  - Level of documentation
  - Type of quality system
  - Extent of review by 3rd party

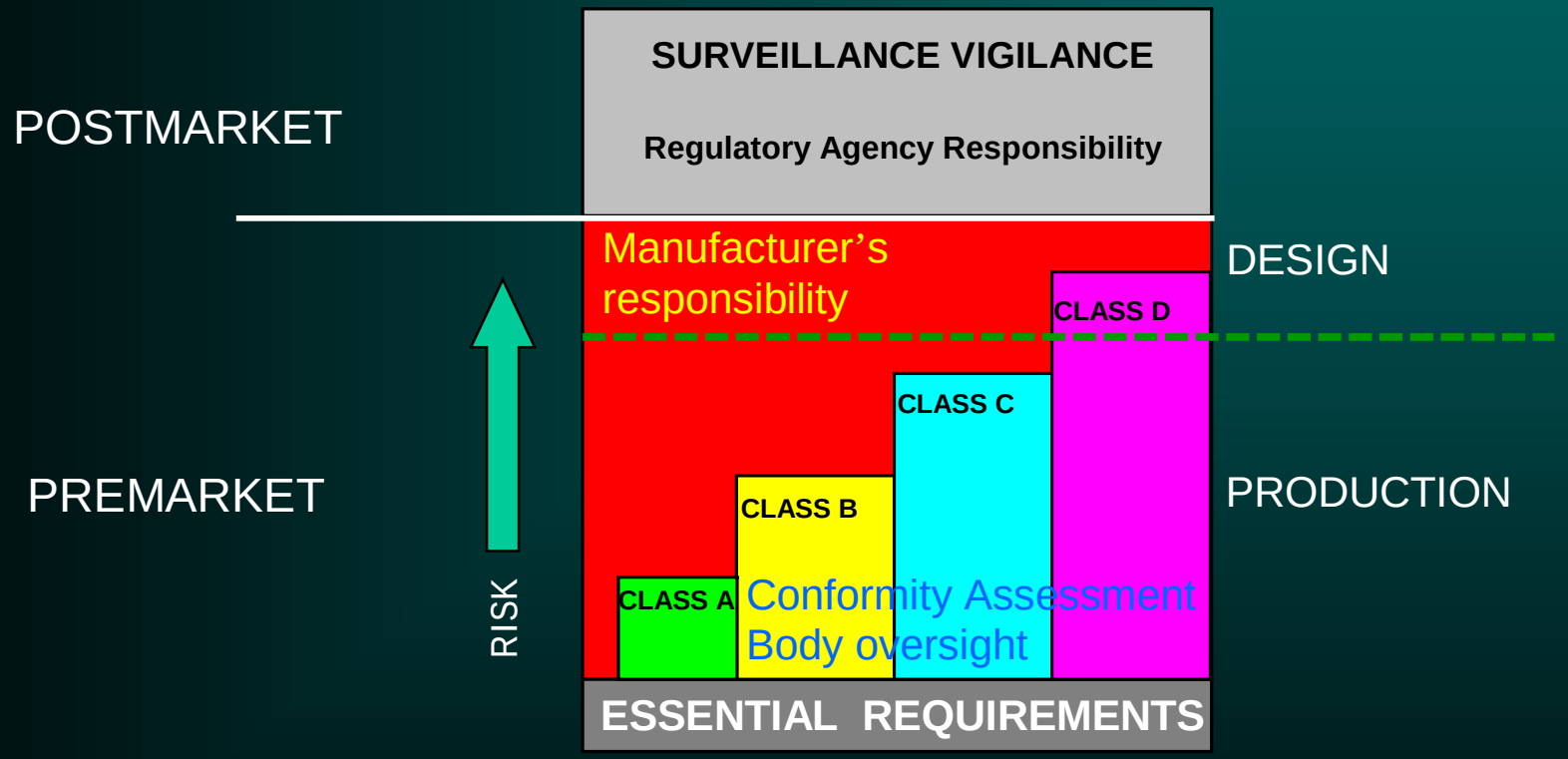
Classification

- According to risk to patient, user, environment
  - Class D – High Risk
  - Class C – Moderate to high risk
  - Class B – Moderate Risk
  - Class A – Low risk

Documentation

Type of Quality System

- ISO 13485 Full quality system with design Control
- ISO 13485 Full Quality system **except** design control
- Type examination
- Batch verification
- Device verification
- Self declaration


SURVEILLANCE VIGILANCE
Regulatory Agency Responsibility
POSTMARKET
Manufacturer's responsibility
DESIGN
CLASS D
CLASS C
CLASS B
CLASS A
PREMARKET
PRODUCTION
RISK
Conformity Assessment Body oversight
ESSENTIAL REQUIREMENTS

Conformity Assessment

- Considerations
  - Public health protection priorities
  - Proportionality of methods to public health benefits
  - Access to market
  - Risk / Benefit provides safety
  - Resources
    - Funding
    - Expertise
    - Efficient use
    - Timeliness (eg - impact on market viability)

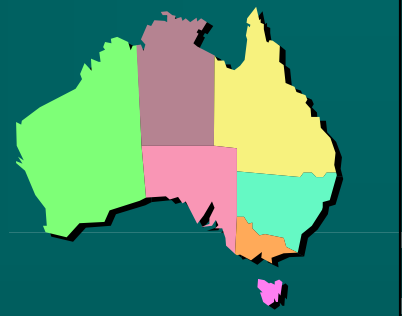
Conformity Assessment

- Considerations (cont'd)
  - Transparency of process
    - Standards
      - Essential principles
      - Classification
      - Quality systems
  - Predictability of decisions
      - Consistency
      - No surprises !!

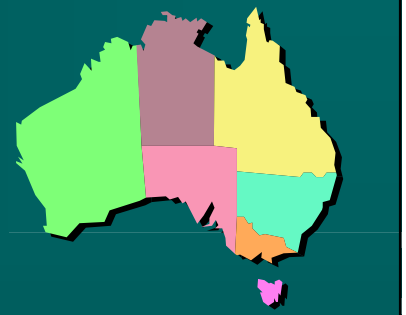
Conformity Assessment

- Options
  - Registration of manufacturer's and Importers
  - Premarket Conformity assessment review
    - Design Dossier
    - Technical File
    - Regulatory File (STED)
    - Quality System (including documentation and records)
    - Clinical Evidence
  - Premarket notification
  - Self certification
  - Postmarket responsibilities
  - Postmarket Audits

Conformity Assessment in Australia

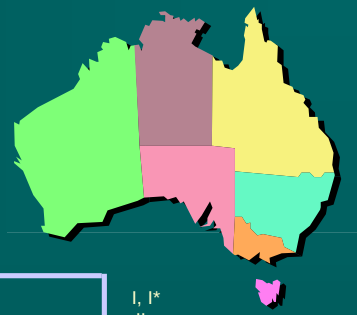


- Obligations on the manufacturer relating to:
  - Use of a quality management system
  - Certification of a quality management system
  - Compliance with the Essential Principles
  - Notification and assessment of changes
  - Declarations of conformity
  - Ongoing surveillance of a QMS
  - Performance monitoring
  - Corrective action
  - Keeping of records



- The procedure chosen by the manufacturer will determine the type of audit and the assessment process
- After audit, opportunity provided to correct non-conformities
- Certification
  - Subject to ongoing surveillance
  - Contractual requirement to report changes

Conformity Assessment Procedures



Design

Production

Active Implants
III

IIb
IIa

Active Implants
III
IIb

I, I*
IIa

Part 1
Declaration of Conformity
+
Examination of the Product Design (Part 1.6)

Full Quality Assurance System

(ISO 13485)

Evaluation by the CAB

Surveillance

Part 1
Declaration of Conformity

Full Quality Assurance System

(ISO 13485)

Technical document checked during audit

Evaluation by the CAB

Surveillance

Part 2
Type Examination

Examination by the CAB

I* - Sterile
- Measuring Function

Active Implants
III
IIb
IIa
I* (meas)

III
IIb
IIa
I* (meas)

Active Implants
III
IIb
IIa
I* (meas/ster)

IIb
IIa
I* (meas)

Part 3
Device Verification

Statistical Verification

Examination and Testing by the CAB

Part 3
Device Verification

100% Verification

Examination and Testing by the CAB

Part 4
Device Declaration of Conformity

Production Quality Assurance (ISO 13485 without Design control)) Evaluation by the CAB

Surveillance

Part 5
Device Declaration of Conformity

Production Quality Assurance (ISO9003) Evaluation by the CAB

Surveillance

Part 6
Declaration of Conformity

Class I* sterile products and measuring devices

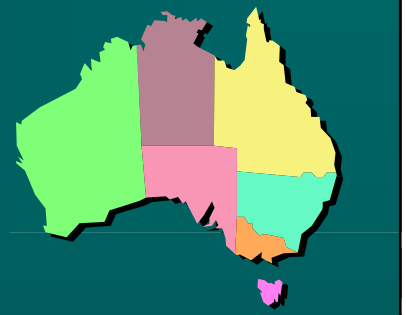
Self Certification with Documentation available.

TGA Surveillance

Entry on ARTG

Entry on ARTG

In practice

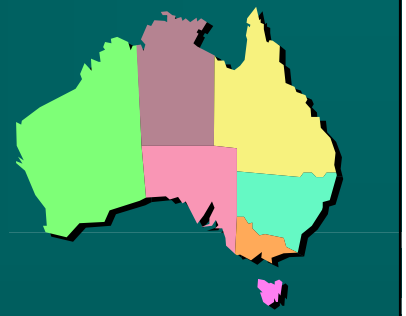


- Class D
  - Examination of Design Dossier
  - Full quality system (including Design Control)

OR

  - Type Examination PLUS
  - Production quality system (excluding Design Control) OR
  - Statistical verification of batch or device

In practice

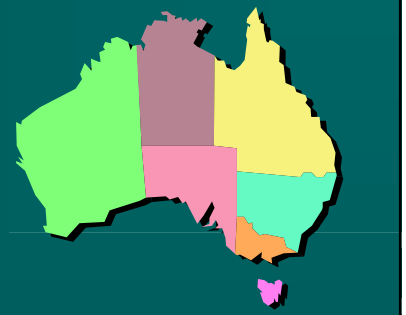


- Class C
  - Full quality system (Including Design Control)
  - Content of Technical File checked during audit

OR

  - Type Examination PLUS
    - Production Quality system (excluding design control), OR
    - Statistical verification by batch or device, OR
    - Finished product testing of each device

In practice

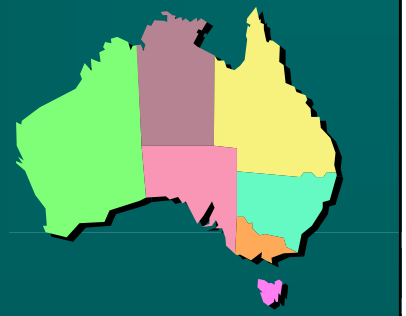


- Class B
  - Full quality system (Design Control optional)
  - Content of Technical File checked during audit

OR

  - Self Declaration of Design PLUS
    - Quality system (excluding design control), OR
    - Statistical verification by batch or device, OR
    - Finished product testing of each device

In practice



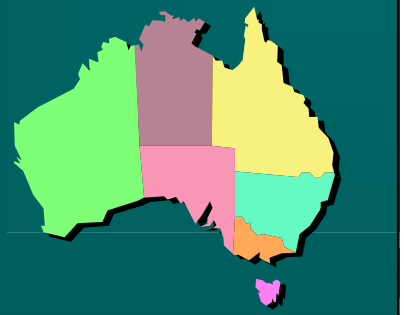
- Class A
  - Self Declaration by the manufacturer

Unless supplied sterile or with a measuring function –

- Quality system , OR
- Statistical verification by batch or device, OR
- Finished product testing of each device

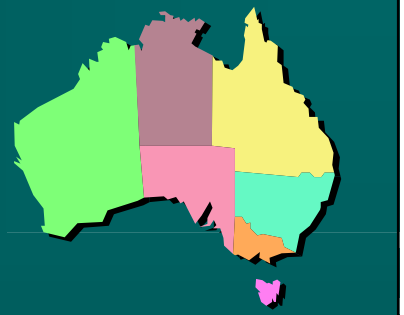
To verify sterility, or accuracy of the measuring function

The Declaration of Conformity



- States that it is a Declaration of Conformity made under the relevant regulatory framework
- Name and address of manufacturer
- Information on the devices to which it applies (eg classification, GMDN code)
- Specifies which devices it applies to
- States that the devices comply with the
  - Essential Requirements of Safety and Performance
  - Is correctly classified according to the Classification Rules
  - The correct Conformity Assessment Procedure has been applied
  - Lists standards used in the Conformity Assessment Procedure
- Dated and signed by manufacturer (appropriately senior personnel)

Surveillance Audits



- Quality systems is not like passing an exam
- It is continual assessment
  - To ensure on-going operation and compliance of the quality system
- Audit frequency based on risk and level of compliance found
  - Generally 12 – 18 months
  - May be unannounced

But what if such a process has already been applied elsewhere –

Provided the Conformity Assessment Procedures are equivalent to Australia -

- > 95% of devices are authorised for marketing without further assessment by the TGA

- For most of the other 5% -
  - **Application audit**

  Rather than

  - Conformity Assessment

What does the Application Audit provide ….

- Intended to confirm that the appropriate Conformity Assessment Procedure has been applied
- is the application effective?
  - made in the approved form?
  - Prescribed fee paid?
  - Correct certificates held?
  - False or misleading information
- presence of Declaration of Conformity
- Are the matters certified by the applicant correct?

The process is ……

- Mandatory for High risk devices
  - Class III and AIMD (GHTF Class D)
- Applied randomly to other categories to validate compliance levels of manufacturers

Documentation provided for Audit ….

- Original or notarised copy of the manufacturer's Declaration of Conformity (to Australian requirements)
- Original or notarised copies of manufacturer's evidence (Quality System, Design examination, or Type Examination certificates, as relevant)
- Copies of information accompanying the device (labels, instructions for use, advertising material)
- Copy of manufacturer's risk analysis
- Documentary evidence to support the manufacturer's certificates
  - audit report (original certification or re-certification)
  - most recent surveillance audit report
  - evidence of close out of non-conformities

Documentation provided for Audit …. (cont'd)

- Summary of clinical evidence (including an Expert Report and evidence to support the expertise of the author)
- essential principles checklist
- design examination or type examination report, as applicable
- validation reports for "special processes" eg sterilisation

Is this documentation looking familiar ……

- The Application Audit picks up
  - The key elements from the Summary Technical Document (STED)
    - Essential principles checklist
    - Device Description (Labelling & IFU)
    - Risk analysis
    - Clinical evidence
    - Special Process validations
  - Evidence of quality systems assessment by a recognised third party Conformity Assessment Body
-

The process delivers ……

- Efficient utilisation of review resources
  - Funding
  - Technical expertise
- Lower compliance costs for the manufacturer
- Timeliness to market
- Balance of risk / benefit (a select group of **extremely** high risk devices are not eligible)
- Transparency
- Very few surprises !!

But most important of all ……..

It does away with re-inventing the wheel …..

by recognising, where possible, equivalent assessments undertaken in other market economies.

Thank you