

Medical Device Classification

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Speaker Biography

- Dan O’Leary
 - Dan O’Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.
 - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.
 - He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.
- Ombu Enterprises, LLC
 - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

Outline

- The Concepts Of Medical Device Risk
- Classification in the US (FD&CA)
- Classification in the EU (MDD)
- Classification in Canada (CMDR)
- GHTF Guidance
- Summary and Conclusions
- Questions

The Concepts of Medical Device Risk

Factors That May Affect Risk

- Design
 - Device design should incorporate the principles of inherent safety
- Manufacture
 - Manufacturing processes must be well planned and under control
 - Validated process ensure conforming output and reduce the compromise to safety

Factors That May Affect Risk

- Intended Use
 - This is the objective intent of the manufacturer on how the device will be used.
 - The intended use will define the “scope” of use, and, in particular, places where the device is **not** intended for use
- User experience, education, and training
 - Define the anticipated user
 - Identify the expected user’s skill level
 - Home use devices should be simple to operate
 - Complex devices may require higher levels of training

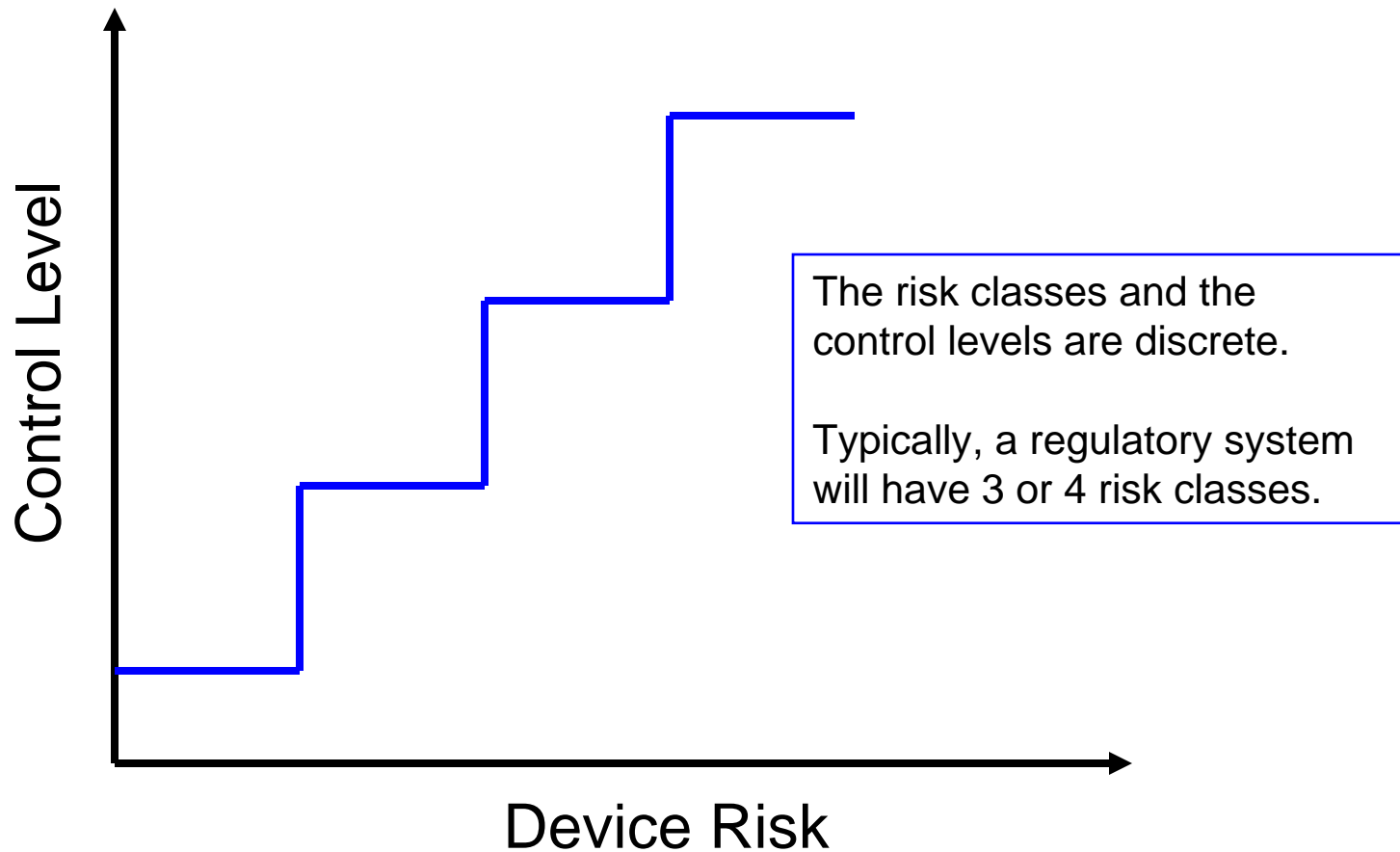
Factors That May Affect Risk

- Device should not compromise
 - The clinical condition of patients
 - The safety of patients
 - Safety or health of users
- Acceptable risks
 - Risks are acceptable when weighed against patient benefits
 - Compatible with a high level of health and safety
- Risk/benefit analysis
 - X-rays are inherently dangerous
 - X-ray machines have a benefit in diagnosis
 - The benefit of imaging outweighs the exposure risk

Regulatory Controls

- Regulators ensure public health and safety
 - Regulations try to match the level of control with the risk
 - The overarching goal is appropriate control commensurate with risk!
- The methods to approach regulatory controls differ by geographic market
- Controls follow the market, not the manufacturing location
 - Product marketed in the EU and manufactured in the US must follow EU regulations

Concept of Control v. Risk



Classification in the US

Devices Classes

- Device classes (and controls) in the US are defined by law
- The Food, Drug, and Cosmetic Act (FD&CA) defines the classes as:
 - Class I, General Controls
 - Class II, Special Controls
 - Class III, Premarket Approval

General Controls

- The FD&CA lists the General Controls as references to sections of the law.
- In general, they are:
 - Cannot be adulterated (must follow the regulations)
 - Cannot be misbranded (must have accurate labels and labeling)
 - The firm must register with the FDA
 - The firm must list its devices with the FDA
 - Cannot be a banned device (unreasonable and substantial risk of illness or injury)
 - Not subject to recall (or similar action)
 - The firm must maintain certain records and reports
 - The firm must apply good manufacturing practices

Special Controls

- General controls are not sufficient, by themselves, to provide reasonable assurance of the safety and effectiveness of the device
- Special controls include:
 - performance standards
 - postmarket surveillance
 - patient registries
 - guidelines (including clinical data in premarket notification)
 - other appropriate actions

Premarket Approval

- General controls and Special controls are not know to be sufficient to ensure the safety and efficacy of the device.
- Application for premarket approval include:
 - Reports of investigations to show whether or not such device is safe and effective
 - a statement of the components, ingredients, and properties and of the principle or principles of operation, of the device
 - a description of the methods, facilities, and control for the manufacture, processing, packing, and installation of the device
 - Reference to any relevant performance standards and the device ability to meet the performance standard
 - Sample of the device and components
 - Proposed labeling
 - Certification related to clinical trials
 - Other relevant information the FDA may require

The Controls

- For each device, the FDA determines the Class.
 - Class I devices require general controls
 - Class II devices require general control and special controls
 - Class III devices require general controls, special controls, and premarket approval
- There are exceptions and exemptions for certain devices

Who Classifies Devices

- The law requires a recommendation from panels based on medical specialties
- The current panels are:
 - Anesthesiology
 - Cardiovascular
 - Clinical Chemistry and Clinical Toxicology
 - Dental
 - Ear, Nose, and Throat
 - Gastroenterology and Urology
 - General and Plastic Surgery
 - General Hospital and Personal Use
 - Hematology and Pathology
 - Immunology and Microbiology
 - Neurology
 - Obstetrical and Gynecological
 - Ophthalmic
 - Orthopedic
 - Physical Medicine
 - Radiology

The Panels

- The panel examines the device type
- The panel classifies the device as I, II, or III.
- The panel can exempt certain parts of the regulations:
 - Premarket notification
 - Good manufacturing practices
- When accepted, the panel's recommendations are published as regulations

Two Dimensional Classification

- In the US, every device is classified along two dimensions:
 - Each device is assigned a panel
 - The panel determines the Class and other controls and exemptions
- The outcome is a regulation that specifies the class, special controls, exemptions, *etc.*
- All of the information is available on the FDA website.

Classification Example #1

- **Blood pressure cuff**
- Regulation Description: Blood pressure cuff
- Definition: A blood pressure cuff is a device that has an inflatable bladder in an elastic sleeve (cuff) with a mechanism for inflating the bladder. The cuff is used to determine a subject's blood pressure.
- Regulation Medical Specialty: Cardiovascular
- Review Panel: Cardiovascular
- Product Code: DXQ
- Submission Type: 510(k)
- Regulation Number: 870.1120
- Device Class: 2
- GMP Exempt? No
- Recognized Consensus Standards
 - AAMI SP10:2002 Manual, electronic or automated sphygmomanometers
- Guidance Document
 - Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final
- Third Party Review: Eligible for Accredited Persons Program

Classification Example #1 (cont.)

Sec. 870.1120 Blood pressure cuff.

- (a) Identification. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.
- (b) Classification. Class II (performance standards).

Classification Example #2

- **Infant Heel Warmer**

- Device: Infant heel warmer (chemical heat pack)
- Regulation Description: Hot or cold disposable pack.
- Regulation Medical Specialty: Physical Medicine
- Review Panel: Physical Medicine
- Product Code: MPO
- Submission Type: 510(k)
- Regulation Number: 890.5710
- Device Class: 1
- GMP Exempt? No
- Guidance Document
 - Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices
- Third Party Review: Eligible for Accredited Persons Program

Classification Example #2

(cont.)

Sec. 890.5710 Hot or cold disposable pack

- (a) Identification. A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

- (b) Classification. Class I (general controls). Except when intended for use on infants, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 890.9.

Notice that the device class remains constant, but the regulatory requirements change with the intended use (adult or infant).

Classification Example #3

- Device: Stent, coronary
- Definition: This device is a metal scaffold placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen.
- Review Panel: Cardiovascular
- Product Code: MAF
- Submission Type: PMA
- Device Class: 3
- GMP Exempt? No
- Recognized Consensus Standards
 - ASTM F2079-02 Standard Test Method for Measuring Recoil of Balloon-Expandable Stents
 - ASTM F2129-06 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
 - ASTM F2081-06 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
- Guidance Document
 - Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems - Guidance for Industry and FDA Staff
- Third Party Review Not Third Party Eligible

Premarket Notification

- Many device types require Premarket Notification.
 - Typically, these are Class II devices
 - Section 510(k) of the FD&CA created this approach, so they are typically called a 510(k)

Substantial Equivalence

- One approach in the premarket notification submission (510(k)) demonstrates the device is "substantially equivalent" to a legally marketed device.
- Substantially equivalent means:
 - the same intended use as the predicate device
 - the same technological characteristics as the predicate device, or
 - has different technological characteristics but is as safe and effective as a legally marketed device, and
 - does not raise different questions of safety and effectiveness than the predicate device

Basic Control

	General Controls	Special Controls	Premarket Approval
Class I	YES		
Class II	YES	YES	
Class III	YES	YES	YES

Note: Some specific devices may be exempt from the requirements shown here. Always check the regulation for the device type.

US Summary

- Three device classes (I, II, and III)
- Classification determined by the FDA
- Controls depend upon the classification
- For “existing” devices, Premarket Notification establishes a chain of predicate devices
- For “new” devices, Premarket Approval demonstrates the device is safe and effective.

Classification in the EU (MDD)

Product Directives

- The EU uses a system of product directives.
- Each directive applies to a particular kind of product.
- The manufacturer must determine the applicable directives.

Directives Related to Medical Devices

- The EU has three directives that apply to medical devices.
 - Active Implantable Medical Devices are controlled by the AIMDD
 - In Vitro Diagnostic Devices are controlled by the IVDD
 - All other medical devices are controlled by the MDD
- We will discuss the MDD only

MDD Revisions

- A revision of the MDD goes into effect at the end of March 2010.
- Our presentation is based on the revised version.
- The same general principles apply to both versions.

The Notified Body

- The EU does not have a government organization equivalent to the FDA.
- Devices are put on the market following conformity assessment methods.
- Conformity assessment is risk based, using device classification, and may involve a Notified Body.
- A Notified Body is a private company that you, as the manufacturer, hire.
- Notified Bodies are accredited by organizations in the Member States.

Basic Definitions

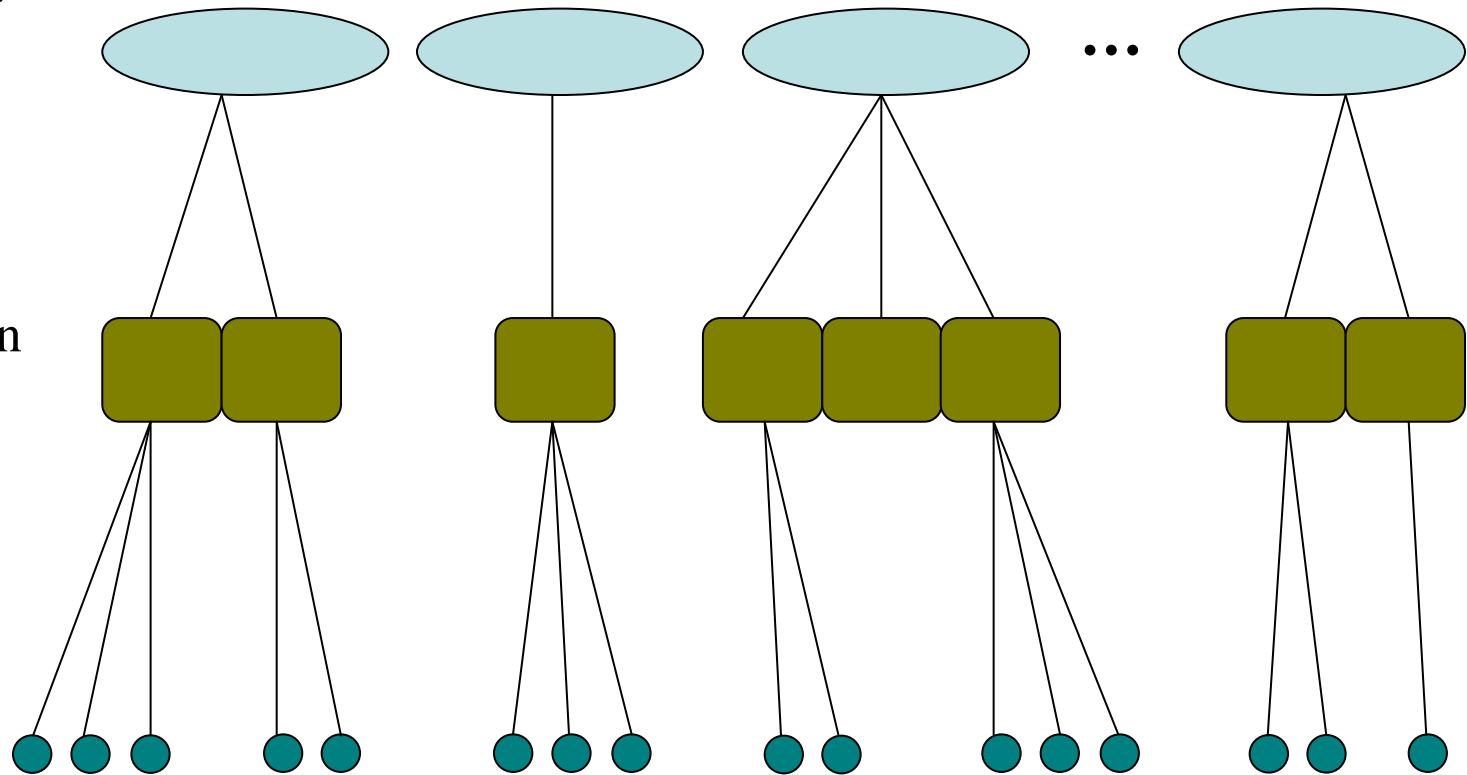
- *Notification* – An act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State.
- *Notified Body* – Certification, inspection, or testing body designated by the Notifying authority of a EU Member State to perform the Attestation of Conformity of products within the scope of a New Approach Directive.

A Simplified Picture

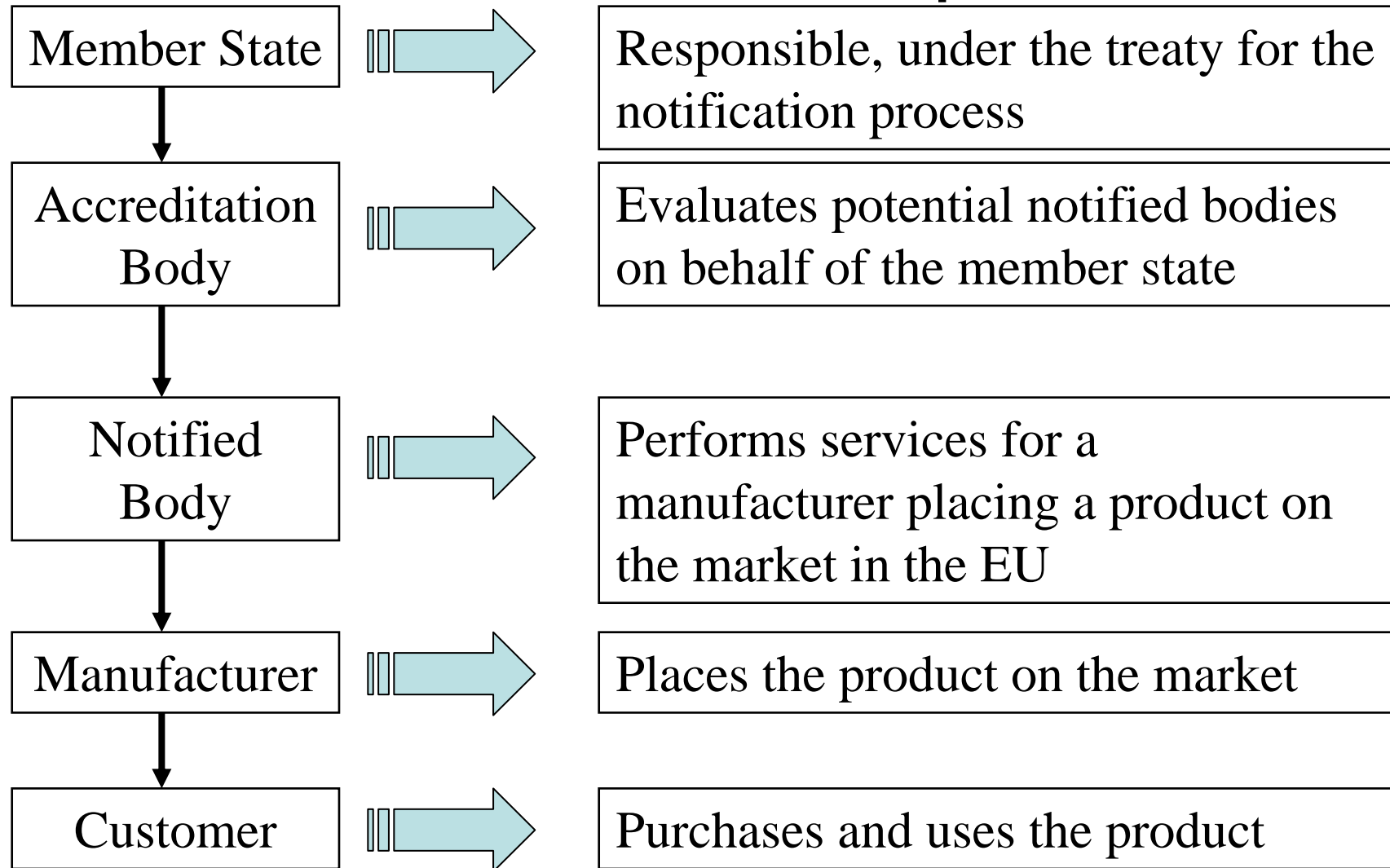
EU Member States (27)

Accreditation Bodies

Notified Bodies



The Relationships



Modules

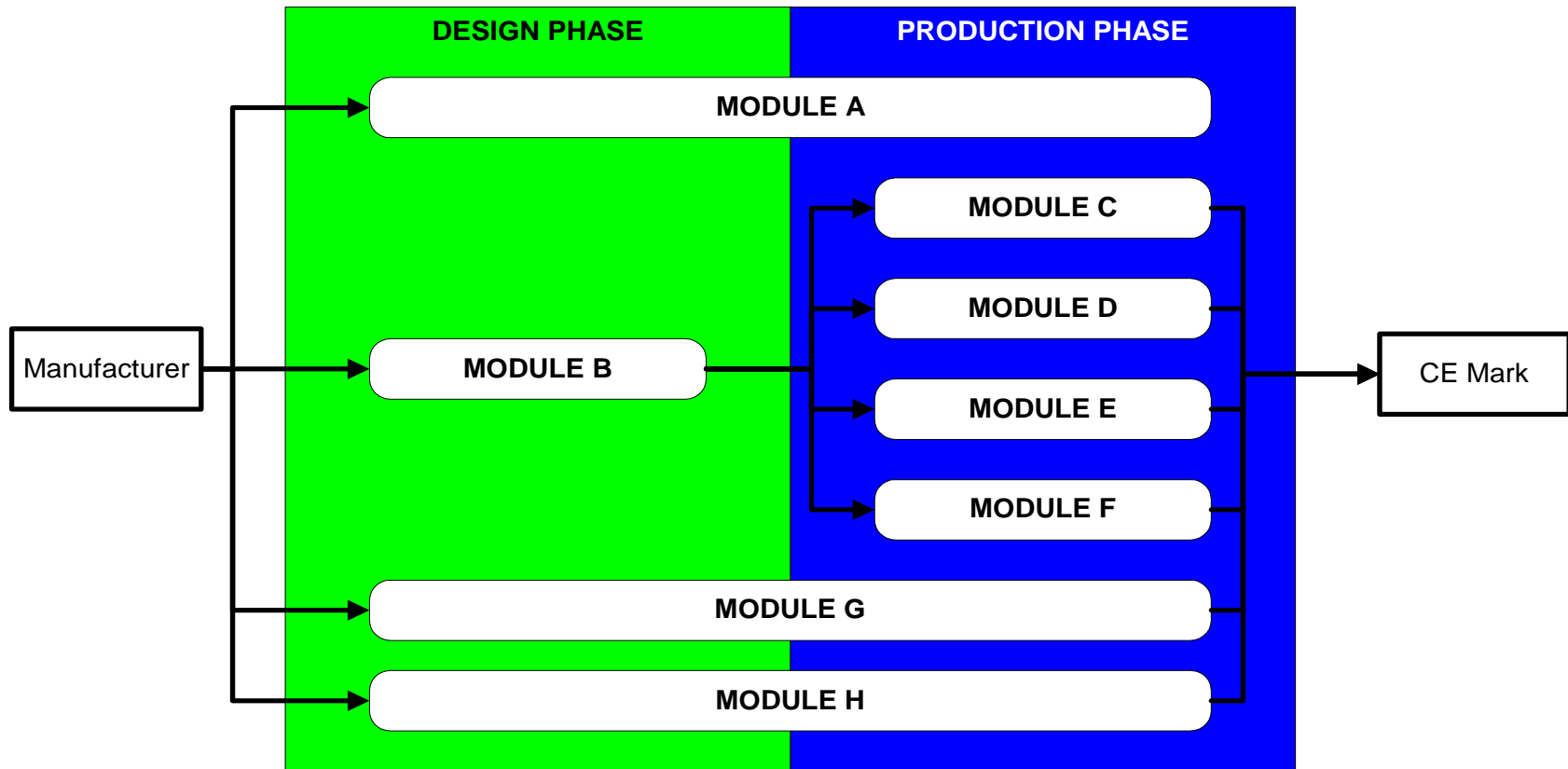
- The conformity paths are based on the concept of modules
- Each directive implements the appropriate methods based on the directive.

Module Content

Module	Description
A – Internal control of production	Covers internal design and production control. Does not require a notified body to take action.
B – EC type-examination certificate	Covers design, and must be followed by a production phase module. A notified body issues the EC type-examination certificate
C – Conformity to type	Follows module B. Provides for conformity with the type as described in the EC type examination certificate. Does not require a notified body to take action.
D – Production quality assurance	Follows module B. A notified body approves the quality system for production, and for final product inspection and test.
E – Product quality assurance	Follows module B. A notified body approves the quality system for final product inspection and test.
F – Product verification	Follows module B. A notified body controls conformity to type as described in the EC type examination certificate and issues a certificate of conformity.
G – Unit verification	Each individual product is examined by a notified body who issues a certificate of conformity.
H – Full quality assurance	A notified body approves the quality system for design, manufacture, and final product inspection/test.

Note: The structure aligned with the, now superseded, ISO 9001, 9002, & 9003 model.

Module Scheme



A Look at the MDD

Where to obtain the Directives

- The best place is the European Commission site
 - <http://ec.europa.eu>
 - Click EN (for English)
 - Search "List of references of harmonised standards" (with quotation marks and the British spelling)
- This site contains the directives that require CE Mark, and other useful information.
 - The text of directive and amendments
 - Consolidated version of directive
 - Lists of references of harmonized standards

Consolidated Version

- The site has the following entries for the MDD
 - Each of the entries has a hyperlink to the documents
 - The subject hyperlinks to the Harmonized Standards list
 - The MDD has been modified, so there is a consolidated version

Text of directive and amendments	Consolidated version of directive	Subject (short title of directive)
93/42/EEC 98/79/EC 2000/70/EC 2001/104/EC 2007/47/EC	93/42/EEC	Medical devices

The Device Class

- The manufacturer determines the device class following the rules in Annex IX
- Determine if the device is invasive or not
 - An invasive device, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body
- Determine if the device is active
 - An active device depends on a source of electrical energy (or any source of power other than that directly generated by the human body or gravity) and acts by converting this energy
- Determine if any special rules apply
- When multiple rules could lead to different classification, use the highest risk class.

Conformity Paths

- The rules lead to multiple paths to demonstrate conformity
- The device class determines the available options
- Some of the options require a Notified Body

The Annexes

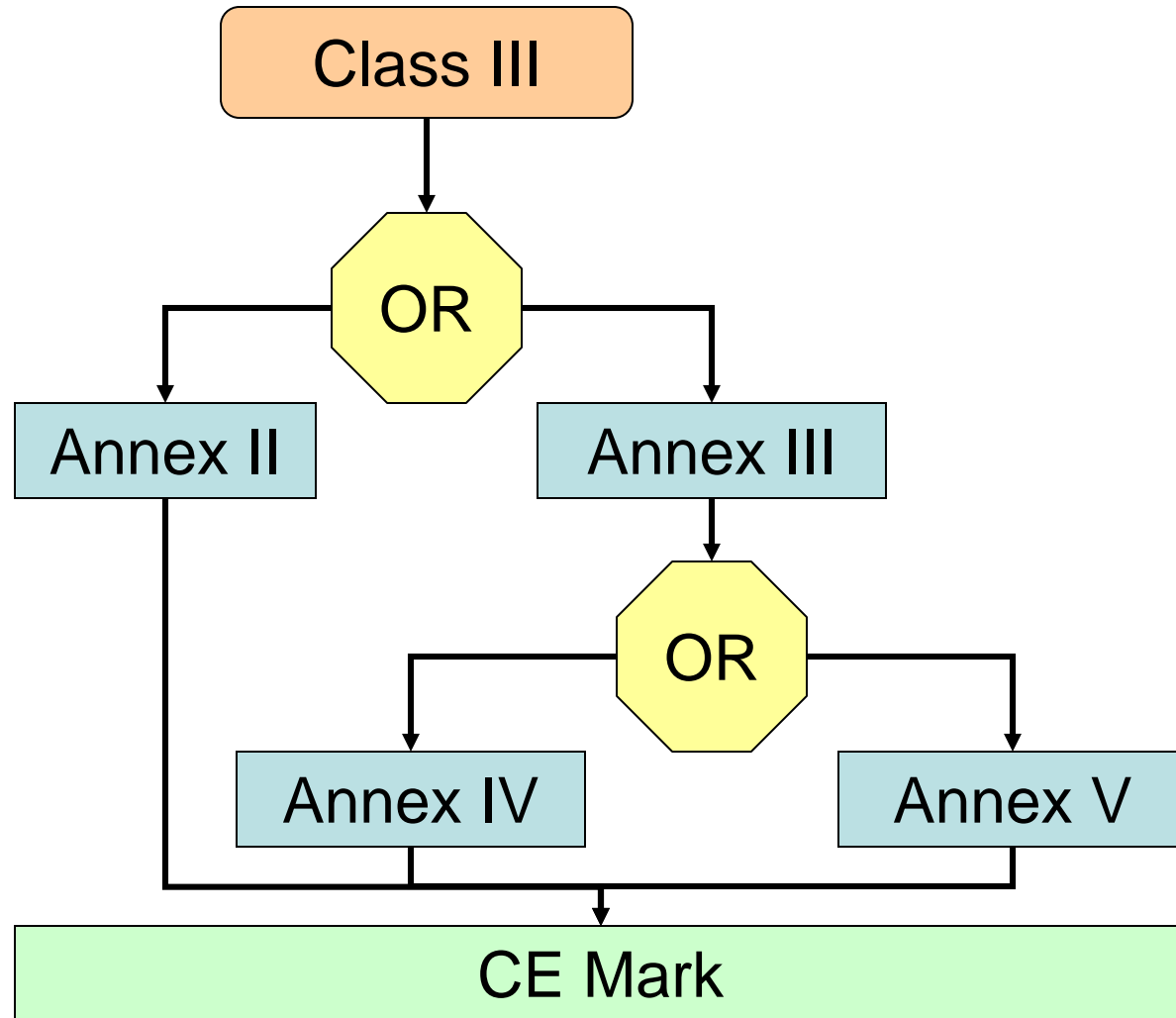
- Annex II EC Declaration Of Conformity
 - The manufacturer applies the quality system approved for the design, manufacture and final inspection of the products concerned
- Annex III EC Type-examination
 - A notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of the Directive
- Annex IV EC Verification
 - The manufacturer (or authorized representative) ensures the products conform to the type described in the EC type-examination certificate and meet the requirements of the Directive which apply to them

The Annexes

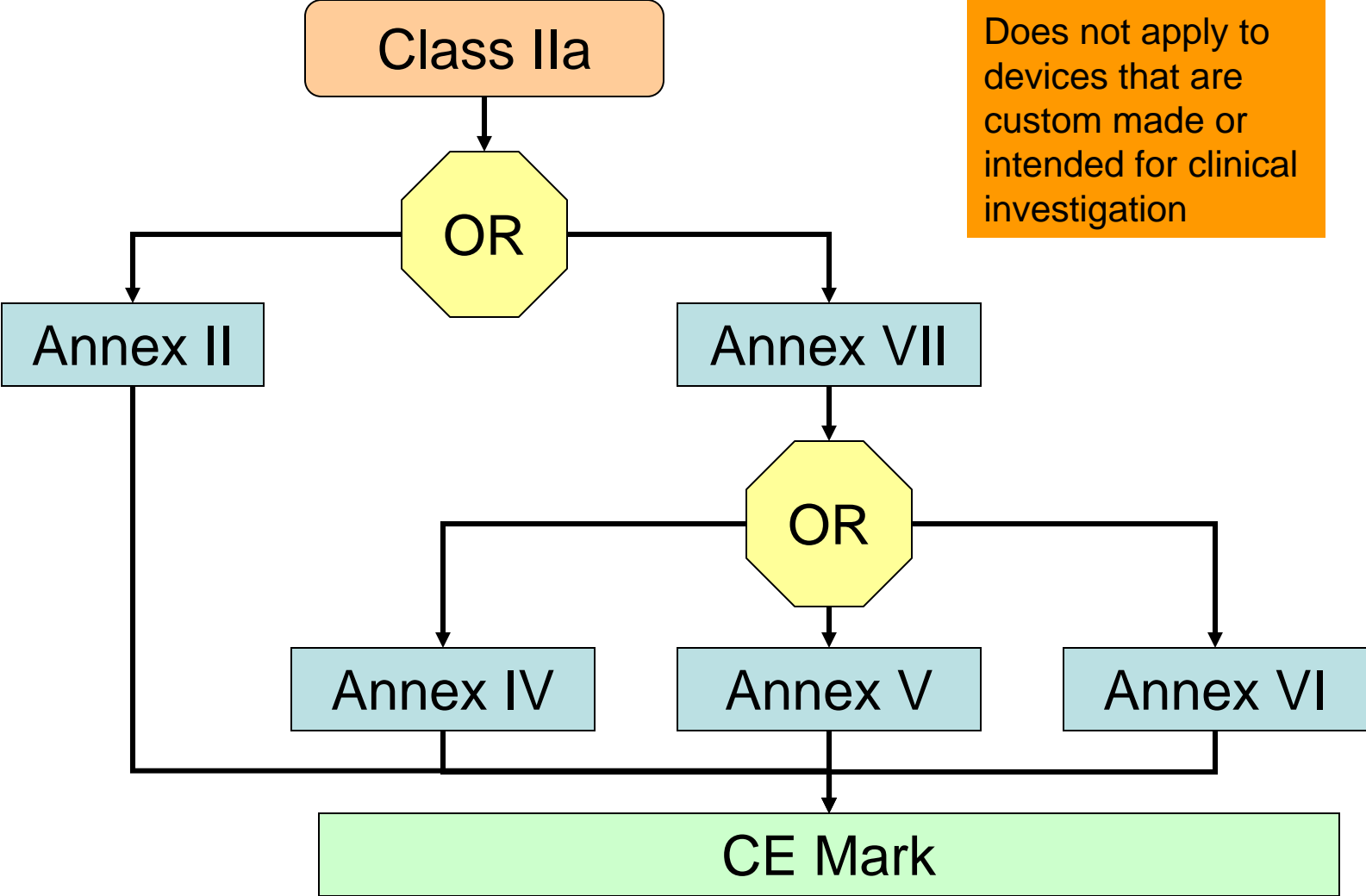
- **Annex V EC Declaration Of Conformity**
 - The manufacturer ensures application of the quality system approved for the manufacture of the products concerned, carries out the final inspection, and is subject to surveillance
- **Annex VI EC Declaration Of Conformity**
 - The manufacturer ensures application of the quality system approved for the final inspection and testing of the product and is subject to surveillance
- **Annex VII EC Declaration Of Conformity**
 - The manufacturer (or authorized representative) prepares technical documentation.
 - This annex has special provisions for sterile devices and devices with a measuring function

Class III Devices

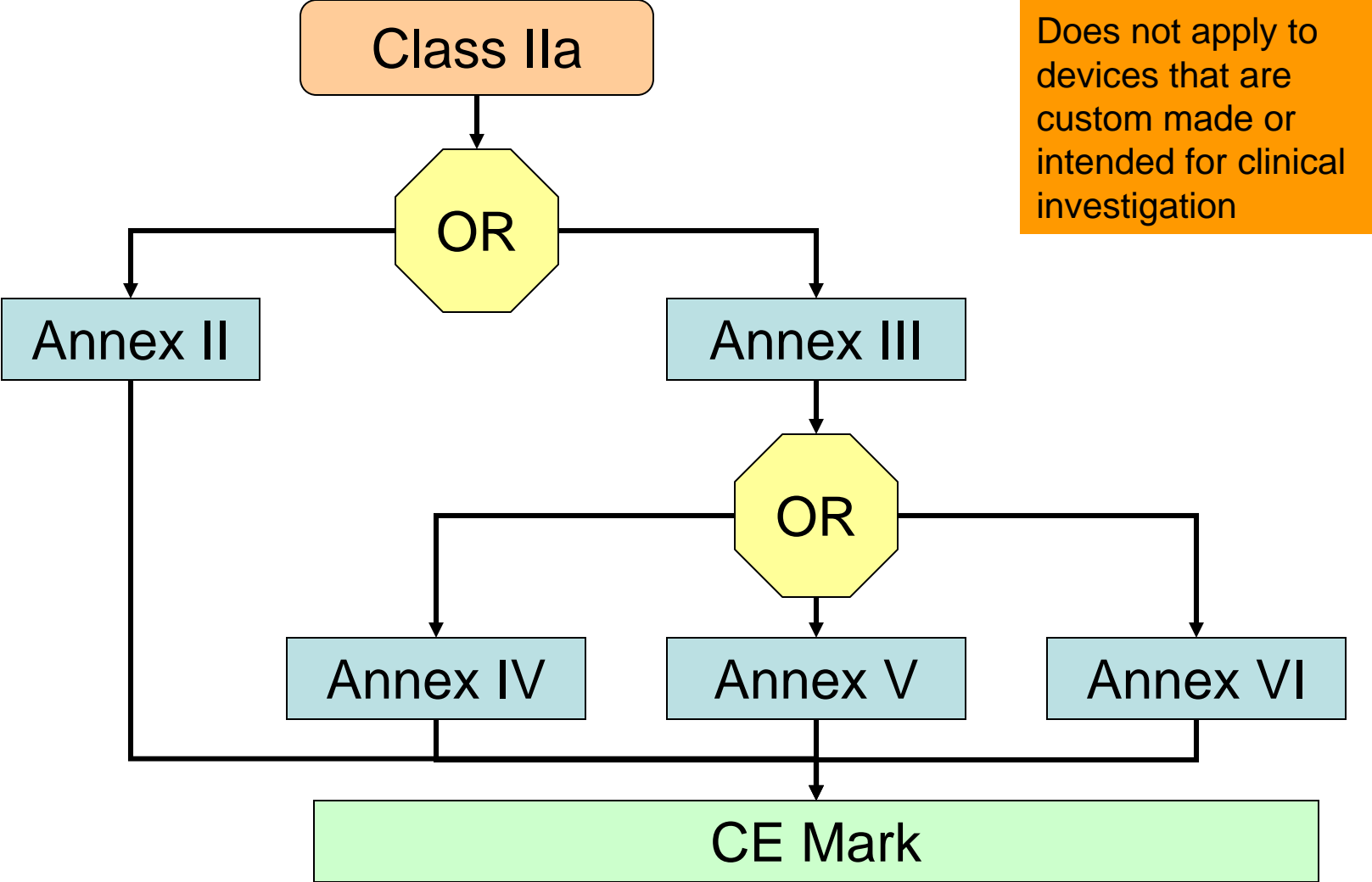
Does not apply to devices that are custom made or intended for clinical investigation



Class IIa Devices



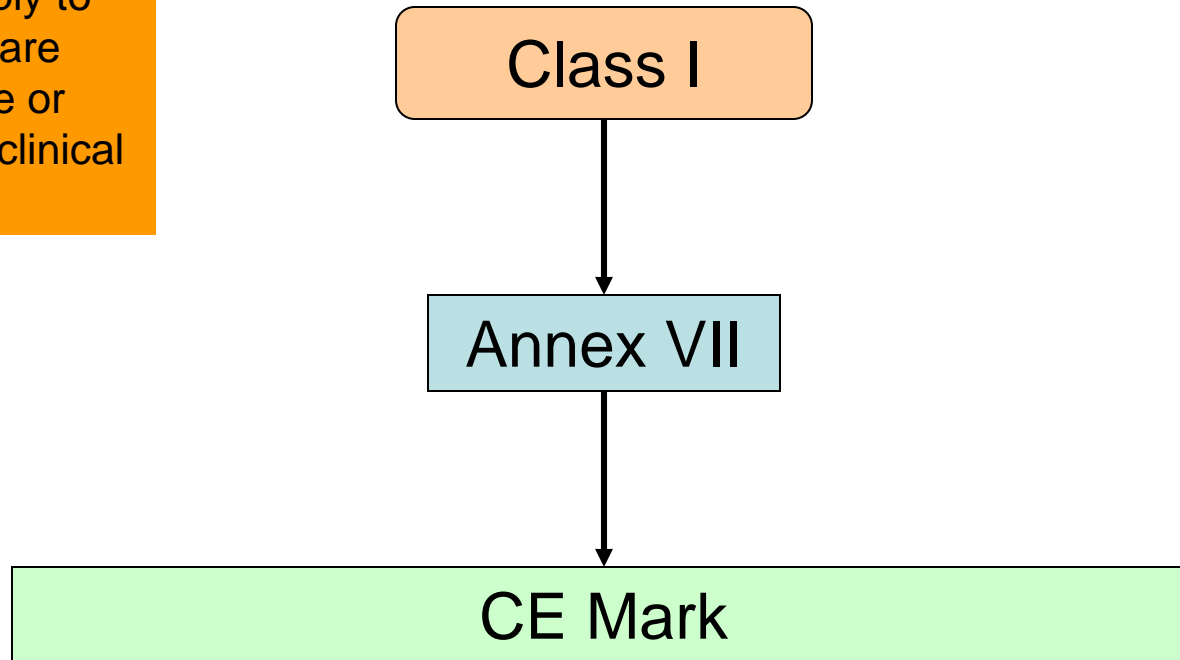
Class IIb Devices



Does not apply to devices that are custom made or intended for clinical investigation

Class I Devices

Does not apply to devices that are custom made or intended for clinical investigation



Classification Example #1

- **Blood pressure cuff**
- Invasive or non-invasive: non-invasive
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
 - Doesn't come into contact with injured skin
- Not an active device
- No special rules apply
- Class I by Rule 1

Classification Example #2

- **Infant Heel Warmer**
- Invasive or non-invasive: non-invasive
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
 - Doesn't come into contact with injured skin
- Not an active device
- No special rules apply
- Class I by Rule 1

Classification Example #3

- **Coronary Stent**
- Invasive or non-invasive: Invasive
 - Duration: Long term (Normally intended for continuous use for more than 30 days)
 - Implantable (intended to be totally introduced into the body by surgery)
- Class III by Rule 8 Point 2 (An implantable device in direct contact with the central circulatory system.)

MDD Summary

- Four device classes (I, IIa, IIb, and III)
- Classification determined by the manufacturer following a rule based approach in Annex IX
- Controls depend upon the classification
 - Implemented using modules to define the conformity assessment system
- No distinction between “existing” devices and “new” devices

Canadian Medical Device Regulations

Canadian Medical Device Regulations

- The regulations are available on the Health Canada website
 - <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>
 - Click on Legislation and Guidelines
 - Follow the links to the Justice Canada website

Medical Device Classes

- Four device classes (I, II, III, or IV)
- Class I represents the lowest risk and Class IV represents the highest risk
- The classification rules are in SOR/98-282 Schedule 1
 - If a medical device can be classified into more than one class, the class representing the higher risk applies.

Schedule 1

Part 1 Non-IVDs

- Invasive devices
- Non-invasive devices
- Active devices
- Special rules

Part 2 IVDs

- Use with respect to
Transmissible Agents
- Other Uses
- Special Rules

Regulatory Requirements

- Class II, III, or IV devices require a license
- The required information for a license changes with the device class

Classification Example #1

- **Blood pressure cuff**
- Invasive or non-invasive: non-invasive
 - Doesn't come into contact with injured skin
 - Not intended as a mechanical barrier
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
- Not an active device
- No special rules apply
- Class I by Rule 7, subrule (1)

Classification Example #2

- **Infant Heel Warmer**
- Invasive or non-invasive: non-invasive
 - Doesn't come into contact with injured skin
 - Not intended as a mechanical barrier
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
- Not an active device
- No special rules apply
- Class I by Rule 7, subrule (1)

Classification Example #3

- **Coronary Stent**
- Invasive or non-invasive: Invasive
 - “surgically invasive device” means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids.
- Class III by Rule 1 Subrule (3) (A surgically invasive device normally intended to remain in the body for at least 30 consecutive days.)

CMDR Summary

- Four device classes (I, II, III, and IV)
- Classification determined by the manufacturer following a rule based approach in Schedule 1 Part 1
- Controls depend upon the classification
 - Implemented through different licensing requirements based on the device class
- No distinction between “existing” devices and “new” devices

Global Harmonization Task Force Guidance

GHTF Overview

- The Global Harmonization Task Force (GHTF) was conceived in 1992 in an effort to respond to the growing need for international harmonization in the regulation of medical devices.
- GHTF has been comprised of representatives from five founding members (European Union, United States, Canada, Australia and Japan) grouped into three geographical areas: Europe, Asia-Pacific and North America.
- Beginning in 2006, membership expanded to include three Liaison Body members:
 - Asian Harmonization Working Party (AHWP),
 - International Organization for Standardization (ISO), and
 - International Electrotechnical Commission (IEC).

GHTF Guidance

- The GHTF web site
 - www.gh tf.org
- The GHTF is organized into Study Groups
 - SG 1 - Premarket Evaluation
 - SG 2 - Post-Market Surveillance/Vigilance
 - SG 3 - Quality Systems
 - SG 4 - Auditing
 - SG 5 - Clinical Safety/Performance
- SG 1 issued GHTF/SG1/N:15:2006 *Principles of Medical Devices Classification*

The Classification Structure

The document recommends four classes (A, B, C, and D)

Class	Risk Level	Device Examples
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

The Classification Structure

- The guidance offers a rule based approaches
- The rules are divided into:
 - Non-invasive Devices
 - Invasive Devices
 - Active Devices
 - Additional Rules
- The guidance document includes decision trees that help navigate the rule structure

Conformity Assessment

- GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*
- The each device class the document has a table that defines the activities in:
 - Conformity assessment of the QMS
 - Conformity assessment of device safety & performance
 - Registration
- It also defines the responsibility of
 - The manufacturer
 - Regulatory Authority or Conformity Assessment Body

Classification Example #1

- **Blood pressure cuff**
- Invasive or non-invasive: non-invasive
 - Doesn't come into contact with injured skin
 - Not intended as a mechanical barrier
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
- Not an active device
- No special rules apply
- Class A by Rule 4

Classification Example #2

- **Infant Heel Warmer**
- Invasive or non-invasive: non-invasive
 - Doesn't come into contact with injured skin
 - Not intended as a mechanical barrier
 - Doesn't channel or store fluids for eventual infusion
 - Doesn't modify blood or other body fluids
- Not an active device
- No special rules apply
- Class A by Rule 4

Classification Example #3

- **Coronary Stent**
- Invasive or non-invasive: Invasive
 - Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
 - Long term duration: Normally intended for continuous use for more than 30 days.
- Class C by Rule 8

GHTF Summary

- Four device classes (A, B, C, and D)
- Classification determined by the manufacturer following a rule based approach supplemented with decision trees.
- Does not discuss controls, but refers to GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*
- No distinction between “existing” devices and “new” devices

Quality Management Systems

QMS Requirements

Region	Required QMS
US	21 CFR Part 820 <i>Quality System Regulation</i>
EU	EN ISO 13485:2003/AC:2007 <i>Medical devices - Quality management systems - Requirements for regulatory purposes</i>
Canada	CAN/CSA-ISO 13485:03 <i>Medical devices - Quality management systems - Requirements for regulatory purposes</i>

Summary & Conclusions

Summary

- Each region (US, EU, and Canada) has a system for classification of medical devices
- The device classification determines the conformity assessment scheme
- In the US, the FDA determines the device class using medical specialty panels
- In the EU and Canada, the manufacturer applies a rule based system to determine the class.
- The three systems are not the same, *i.e.*, any given device could be in a different risk class in a different system

Summary

- The GHTF has an approach to standardize the classification and regulatory system.
 - GHTF/SG1/N15:2006 *Principles of Medical Devices Classification*
 - GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*

Conclusions

- A manufacturer will often sell devices in multiple markets.
- The classification and conformity systems differ in the various markets
 - A manufacturer must conform to systems where the device is marketed



QUESTIONS