

Medical Device Requirements in Europe (MDD – 93/42/EEC)

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Session 1

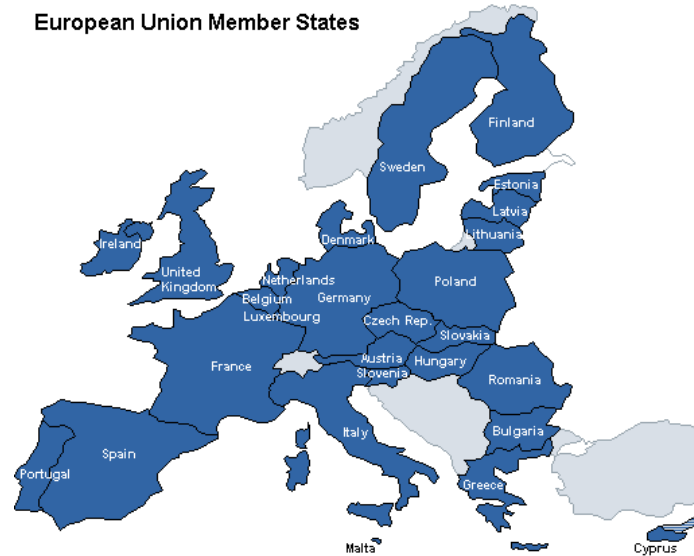
This session covers :

- Overview of the EU
- Background to the “ New Approach”
- Principles of CE marking

What is the European Union?

- A unique economic and political partnership between 27 democratic European countries.
- EU- 27 Countries, 23 languages with over 492 million citizens
- EFTA- 4 Countries
 - Iceland, Norway, Licht, Switz

European Union Member States



Belgium
France
Italy
Luxembourg
Netherlands
Germany
Denmark
Ireland Ireland
United Kingdom
Greece
Portugal
Spain
Austria
Finland
Sweden
Cyprus
Czech Republic
Estonia
Hungary
Latvia
Lithuania
Malta
Poland
Slovakia
Slovenia
Bulgaria
Romania

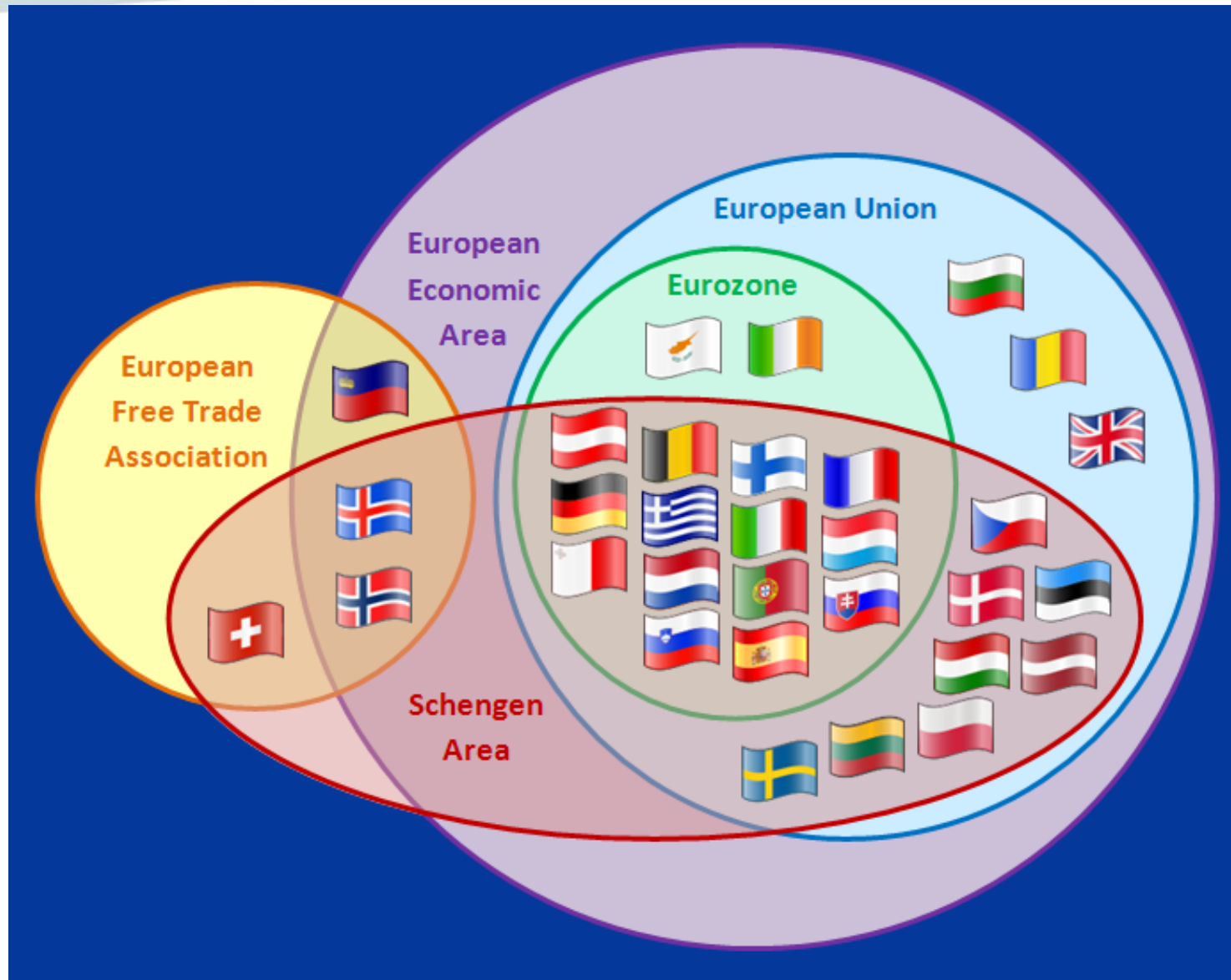


European Union map



http://europa.eu/abc/european_countries/eu_members/index_en.htm

Supranational European Bodies





Ten historic steps

1951: The European Coal and Steel Community is established by the six founding members

1957: The Treaty of Rome establishes a common market

1973: The Community expands to nine member states and develops its common policies

1979: The first direct elections to the European Parliament

1981: The first Mediterranean enlargement

1993: Completion of the single market

1993: The Treaty of Maastricht establishes the European Union

1995: The EU expands to 15 members

2002: Euro notes and coins are introduced

2004: Ten more countries join the Union



What are its aims ?

To create a single market to guarantee freedom of movement of:

- People
- Goods
- Services
- Capital

between member states



Creation of a single market

Could not have been achieved without :

- A new regulatory technique that set down only the general “ Essential Requirements”
- Use of quality assurance and other modern conformity assessment techniques
- Move to “qualified majority voting” within the Council rather than unanimity



“New Approach” Concept

- Free movement of goods is a cornerstone of the single market
- Mechanisms based on :
 - ✓ Prevention of new barriers to trade
 - ✓ Mutual recognition
 - ✓ Technical harmonization



Key principles of the “New Approach” (1)

- Based on New Approach Directives
- Limited to **Essential Requirements** that products placed on the Community market must meet if they are to benefit from free movement
- Technical Specifications supporting the ERs are laid down in **harmonized standards**
- Application of harmonized or other standards remains **Voluntary**.



Key principles of the “New Approach” (2)

- Product manufactured in compliance with harmonized standards benefit from “**Presumption of Conformity**” with the corresponding ERs
- Manufacturers may choose between different conformity assessment procedures provided for in the applicable Directive
- Provides for **CE marking**



Key principles of the “New Approach” (3)

- Detailed local technical provisions
 - ✓ Removed
 - ✓ Placed in harmonised standards instead
- Essential Requirements
 - ✓ Included
 - ✓ Products MUST comply
 - ✓ Legally binding
 - ✓ Enforceable



Key principles of the “New Approach” (4)

- Harmonised standards
 - ✓ Not listed, but
 - ✓ “Presumption of Conformity” applies

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

- Compliant product allowed free circulation

New Approach Directives (provide for CE Marking)

- Active Implantable (AIMDD) - 90/385/EEC
- Medical Devices (MDD) – 93/42/EEC
- In-Vitro Diagnostics (IVDD) – 98/79/EC
- Machinery Safety - 2006/42/EC
- Personal Protective Equipment - 89/686/EEC
- Low Voltage - 2006/95/EC
- Electromagnetic Compatibility- 2004/108/EC

New Approach Directives

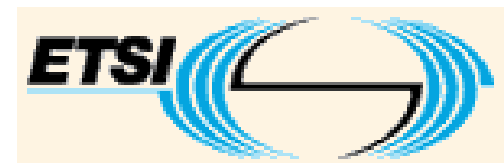
90/396/EEC	Appliances burning gaseous fuels	93/42/EEC	Medical devices: General
2000/9/EC	Cableway installations designed to carry persons	98/79/EC	Medical devices: In vitro diagnostic
89/106/EEC	Construction products	92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)
2004/108/EC	Electromagnetic compatibility	90/384/EEC	Non-automatic weighing instruments
94/9/EC	Equipment and protective systems in potentially explosive atmospheres	94/62/EC	Packaging and packaging waste
93/15/EEC	Explosives for civil uses	89/686/EEC	Personal protective equipment
95/16/EC	Lifts	97/23/EC	Pressure equipment
2006/95/EC	Low voltage equipment	1999/5/EC	Radio and telecommunications terminal equipment
98/37/EC	Machinery safety	94/25/EC	Recreational craft
2004/22/EEC	Measuring instruments	87/404/EEC	Simple pressure vessels
90/385/EEC	Medical devices: Active implantable	88/378/EEC	Toys safety

Essential Requirements (ERs)

- The ERs at Annex I of each of the New Approach Directives :
 - Lay Down the **necessary elements** for protecting the public interest
 - Are **mandatory**. Only products complying with the ERs may be placed on the market and put into service
 - Must be applied as a function of the hazards inherent in a given product

The Role of Standards

- To fill in the Technical Detail missing from Directives
- To Enable manufacturers to demonstrate conformity
- To enable Notified Bodies to assess conformity



Hierarchy of Standards

1st Harmonised Standards

2nd Other European Standards

3rd Other Member State Standards

4th International Standards

5th Other published Documents (AAMI,ASTM,*etc*)

6th In-house Specifications



The Role of Notified Body

- A **Notified Body**, in the [European Union](#), is an organisation that has been accredited by a [Member State](#) to assess whether a product meets certain preordained standards.
- Assessment can include inspection and examination of a product, its design and manufacture.

Accreditation Body, Notified Body & Certification Body

• AB



083



• NB



(New Approach Notified and Designated Organisations)



Principles of CE marking

CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer

CE marking affixed to products is a declaration by the responsible person (manufacturer or EU AR) that :

- The product conforms to all applicable Community provisions
- The appropriate conformity assessment procedures have been completed

European Union Compliance summary

- The need for CE Marking
- New Approach Directives
 - Eliminate differences in laws therefore remove non-tariff barriers to trade
 - Prescribe the Essential Health, Safety, and Performance Requirements
 - Member states transpose directives and harmonized standards into their national requirements
 - Manufacturer Self Declaration
 - Voluntary Use of Standards
 - CE Label as the indication of compliance



Session 2

This session covers :

- The European Medical Device Directive (93/42/EEC) as a subset of the “ New Approach”

The 3 European Medical Device Directives

1. Active Implantable Medical Device Directive 90/385/EEC
 - Powered implantable devices e.g. pacemakers, etc
 - Transition period : started 1 Jan 93; ended 1 Jan 95
2. Medical Device Directive (MDD) 93/42/EEC
 - Transition period : started 1 Jan 95; ended 14 Jun 98
3. In-vitro Diagnostic Med.Dev Dir (IVD) 98/79/EC
 - Transition period : started 27 Oct 98; ended 27 Oct 2003

Structure & Content

- Recitals
 - Define the scope of Directive in legal terms
- Articles
 - Contain key definitions and important information relating to the application of the Directive ,e.g. how to demonstrate compliance and principles of classification of devices
- Annexes
 - Contain more technical detail; in each Directive
Annex 1 defines the Essential Requirements which devices must meet

Articles

- ✓ The scope of the Directive
- ✓ The EEC vigilance structure
- ✓ The role of the Standards
- ✓ The role of the Competent authority
- ✓ The role of the Notified Body

Annexes

- ✓ The Essential Requirements (Annex 1)
- ✓ How to control the conformity. The “ Routs”
(Annex 2 to 8)
- ✓ The Classification rules (Annex 9)
- ✓ Clinical Evaluation (Annex 10)
- ✓ Notified Bodies (Annex 11)

What is a Medical Device ?

European Directive definition (from 93/42/EEC) :

A medical device is : ‘any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended **by the manufacturer** to be used **for human beings** for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which **does not** achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means’

Classification of Devices (1)

Based on perceived risk and nature and duration of contact with patient

Duration of contact:

< 60 minutes	Transient
< 30 days	Short term
> 30 days	Long term

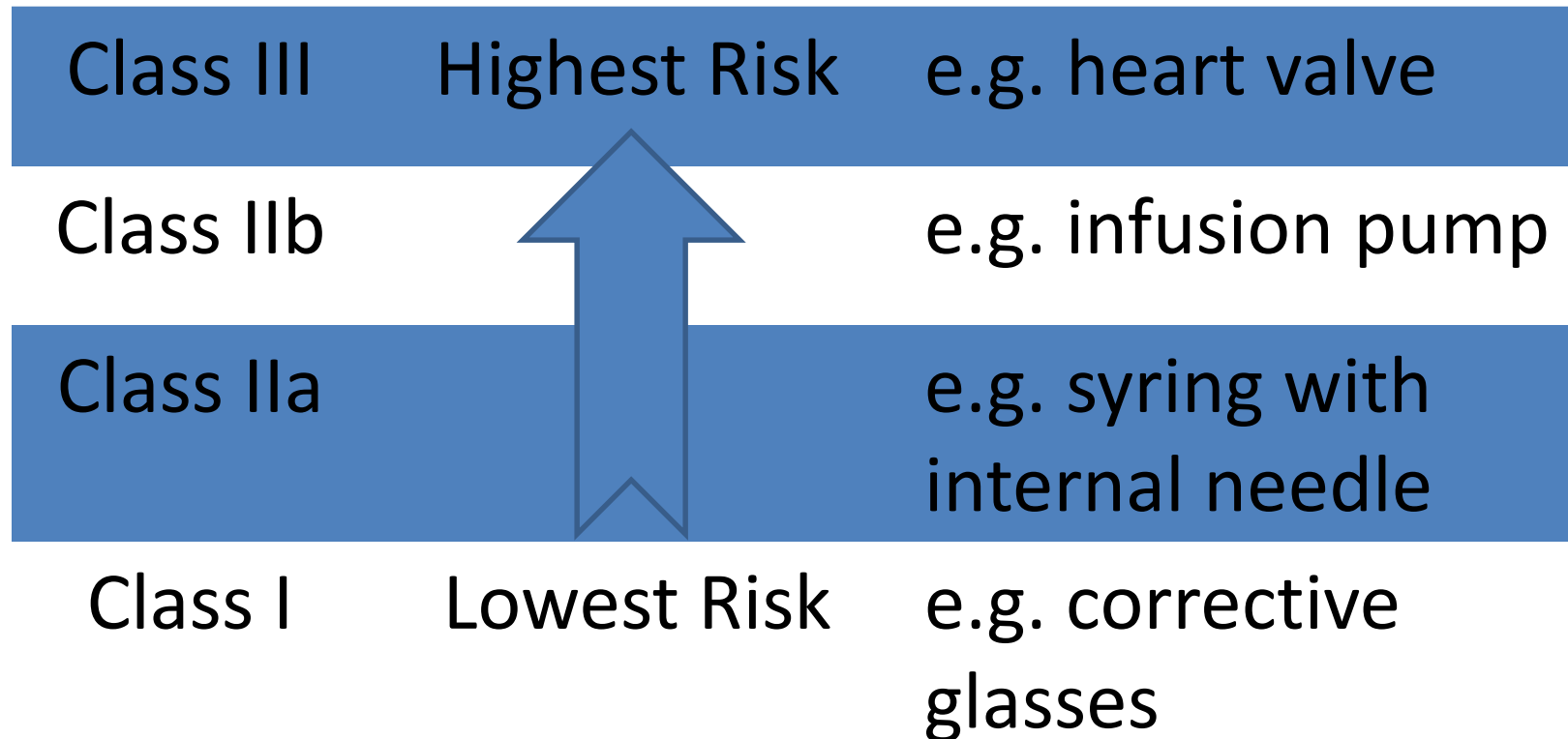


Degree of invasiveness:

- Application to body surface or into body orifice
- Surgically invasive
- Implantable

Classification of Devices (2)

- Medical Device Directive – 4 Classes



* Further subdivided on basis of Sterility or Measuring function

Classification of Devices (3)

- Medical Device Directive
 - Classification Criteria and Rules in Annex IX
- European Commission guidance
 - MEDDEV 2.4/1 Rev 8 (July 2001)
 - “ Guidelines for the Classification of Medical Devices”

Essential Requirements (1)

- Article 3

‘The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned’.

- Annex I : format

1. General Requirements (**always apply**)

2. Particular Requirements :

Requirements regarding Design and Construction
(only some apply to particular devices)

Essential Requirements (2)

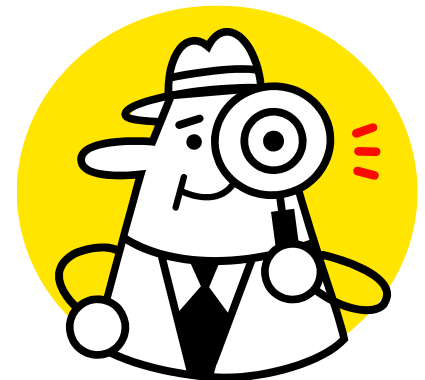
- General
- Particular
 - Chemical and physical properties
 - Infection and microbial contamination
 - Construction and environmental properties
 - Aspects of measurement
 - Protection against energy risks
 - Protection against mechanical and thermal risks
 - Risks posed by energy sources/ substances
 - Information supplied by manufacturer
 - Clinical data

CE marking process

- **Step 1**- Ensure device falls within scope of MDD
- **Step 2**- Identify the applicable ERs
- **Step 3**- Identify the corresponding Harmonised Standards
- **Step 4**- Ensure the device meets the Harmonised Standards
- **Step 5**- Classify the device
- **Step 6**- Decide an appropriate conformity assessment procedure
- **Step 7**- Choose a Notified Body (if device is not basic Class I)
- **Step 8**- Undergo the conformity assessment
- **Step 9**- Make Declaration of Conformity and apply CE Marking

Basic Terms of Compliance

- Risk assessment
- Notified Body
- Authorized Representative and Competent Authority registration
- Vigilance system
- CE Marking
- Declaration of Conformity



Risk Assessment

ISO 14971:2007 is used to:

- Identify the **product** and describe the **intended use**
- Characteristics which could affect **safety**
- Identify possible **hazards**
- **Estimate** the risk, and...

FMEA (Failure Modes & Effects Analysis) for <Process or Product>

Responsible: <name> Prepared by: <name>
Original date: <date> Revised: <date>

Systems2win
Templates and Training
for Continuous Improvement

Process Step / Input	Potential Failure Mode	Potential Failure Effects	Severity	Potential Causes	Occurrence	Current Controls	Detection	Risk P/N	Actions Recommended	Res. p.	Actions Taken	Severity	Occurrence	Detection	Risk P/N
Add milk to cake mix	Wrong amount of milk	Cake too dry or too soggy	6	Small marks on measuring cup	10	None	6	100	Use large print measuring cups.	JV	Replaced measuring cups	5	1	1	5
			5	Faded marks on measuring cup	5	Visual inspection	3	75	Replace faded measuring cups	JV	Replaced cups & retrained inspectors (not get complete)	5	1	2	11
			5	Milk spilled	6	None	100	100	Train bakers	HH	Changed SOP & improved training program	5	3	5	75
			5	Employee carelessness	5	Training (apparently ineffective)	9	100	Change Standard Operating Procedure, and improve training program	HH		6	1	4	24
			6	Employee carelessness	2	Training	9	100							

Some people like to split into two columns: Process step and specific input.

Notice that there can be several failure modes per step, and several effects and causes per failure mode.

Risk Priority Number (RPN) = Severity x Occurrence x Detection.
Notice that RPN is calculated both before and after corrective action.

Plan both:
Preventative actions and
Contingent actions (how to
limit damage if it happens)

Purpose of Failure Modes & Effects Analysis
(Also known as Error Modes & Effects Analysis)
To anticipate problems and take actions to minimize risks.

When to use FMEA:

- * To design or change any system, product, or process
- * To define risks
- * To prioritize attention to key process input variables
- * To assess the effectiveness of attempts to control variability

FMEA Ranking Scale

FMEA Ranking Scale is:

Click here for On-line Help: Tips

Click here for On-line Training

Important: Any document created using a company or division must be in a non-editable format.

Editing Tips for this I
These Tips are meant to supplement, not replace, the instructions in the FMEA worksheets.

Notified Body

- **Third party** organization appointed by a Member State to undertake prescribed activities
- **Commercial contracts** with manufacturers
- Who is **responsible**?

30.4.2001 EN Official Journal of the European Communities C 129/73

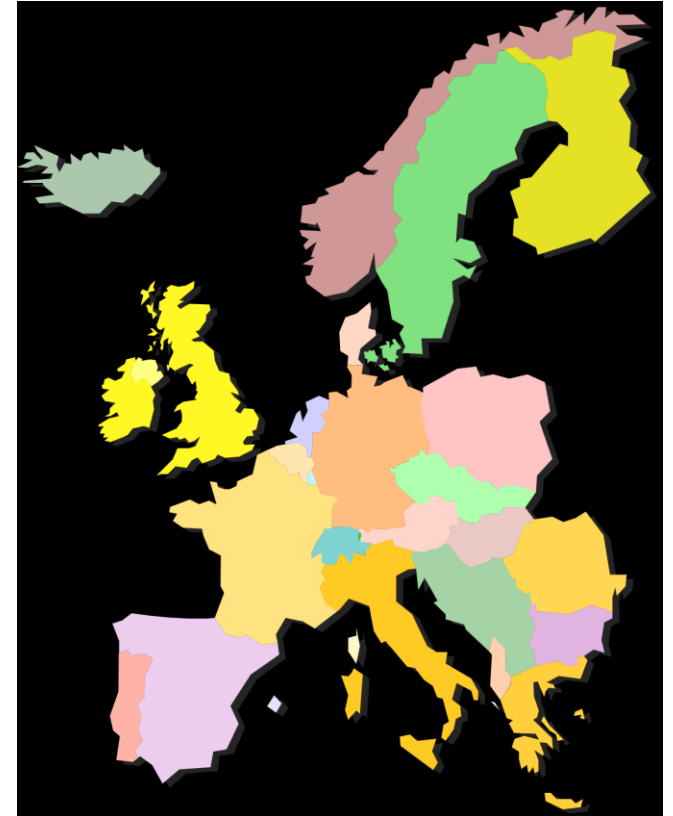
LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC

MEDICAL DEVICES

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures/modules	Annexes/articles of the directives
TUV HANNOVER/SACHSEN-ANHALT e.V. TÜV CERT-ZERTIFIZIERUNGSSTELLE Am TÜV 1 D-30565 Hannover	0032	Active medical devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
TUV ANLAGENTECHNIK GmbH UNTERNEHMENSGRUPPE TÜV RHEINLAND/BERLIN- BRANDENBURG Am Grauen Stein D-51105 Köln	0035	Active medical devices: — equipment for infusions — anaesthesia devices, respirators and oxygen therapy equipment — vital-parameter monitoring and plotting devices — surgical equipment and ancillary surgical equipment — stimulation devices — ophthalmological devices — dental equipment — prostheses and rehabilitation devices — disinfection and sterilisation equipment — radiotherapy equipment with non-ionising radiation — medical supply units — patient storage and transport equipment — imaging equipment: — with ionising radiation — with non-ionising radiation	EC type-examination EC verification	Annex III Annex IV
RWTVV e.V.	0044	Non-active medical devices: — — — — —	Full quality assurance system	Annex II

Authorized Representation (1)

- Authorized Representative for **Europe** in the event the manufacturer is **not established** within the EEA
- Who is **responsible**?



Authorized Representation (2)

- Listed on the **label** and/or **packaging**
- Name of the manufacturer and the device **must be notified** to the Competent Authority
- Keeps the **Technical File** available for review by Competent Authorities
- Plays an essential role in **vigilance procedures** and **Post-market Surveillance**

Post Marketing Surveillance

- Required for **all devices**
- **Review** of market, field data, complaints, investigation, corrective actions
- Systematic records kept



Vigilance

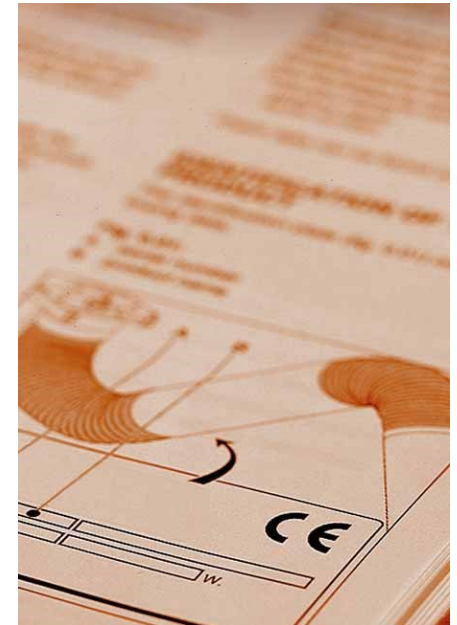
Vigilance, MEDDEV 2.12.1, Rev. 5

The manufacturer must:

- Institute and keep up to date a **systematic procedure** to review experience gained from devices in the post-production phase and;
- Implement appropriate means to apply any necessary **corrective actions**

CE Marking

- **Implies conformance** with European Directives
- Inspection Authorities
- Preempts all other marks for same requirements
- **Not a quality mark!**
- Measurement
- Affixing
- Labeling



Declaration of Conformity

- **Product** identification
- Identification of the **manufacturer**
- **Directives** complied with Standards used
- **Signature** by authorized person
- Language requirements

Product name :
Brand :
Cat. Number :
Batch/Serial Nr. :

Name :
Address :

Country :
Tel :
Fax: :

Name :
Address :

Country :
Tel :
Fax : :

[COMPANY NAME] declares that the products listed have been classified as Class I, Annex IX, Rule ... and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC.

Place and date :
Signature :
Name : :

[PRINTED ON ORIGINAL COMPANY LETTERHEAD]

[SAMPLE]

Declaration of Conformity

Product identification

Manufacturer

Authorized Representative in Europe

Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
(+31) (0) 70 362 4896
(+31) (0) 70 346 7299

Means of conformity

Signature

[Name and Signature of authorized person]

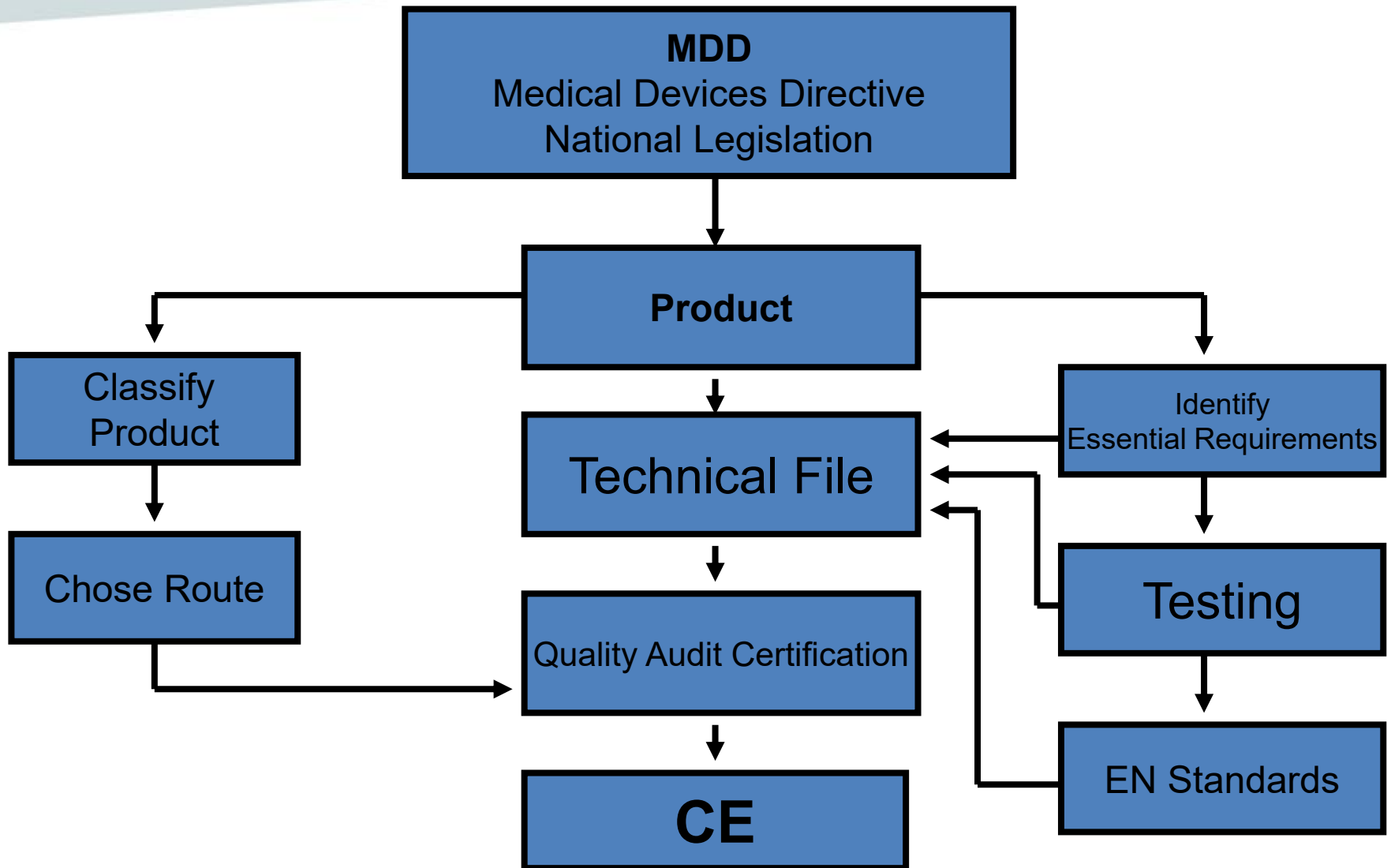


Session 3

This session covers :

- Conformity assessment under the New Approach
- The Conformity assessment Annexes of the Medical Device Directive

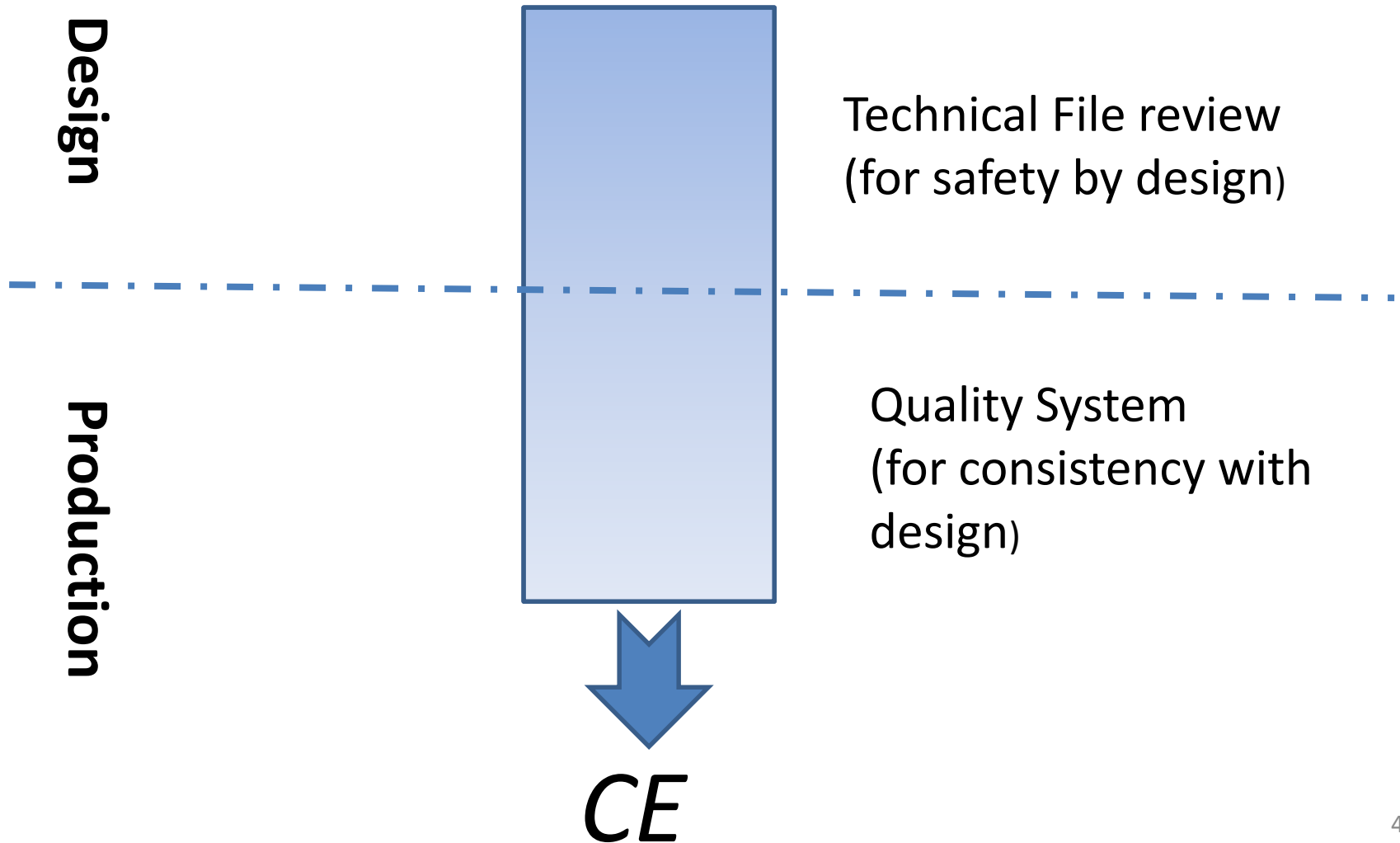
Enforcement of the Directive



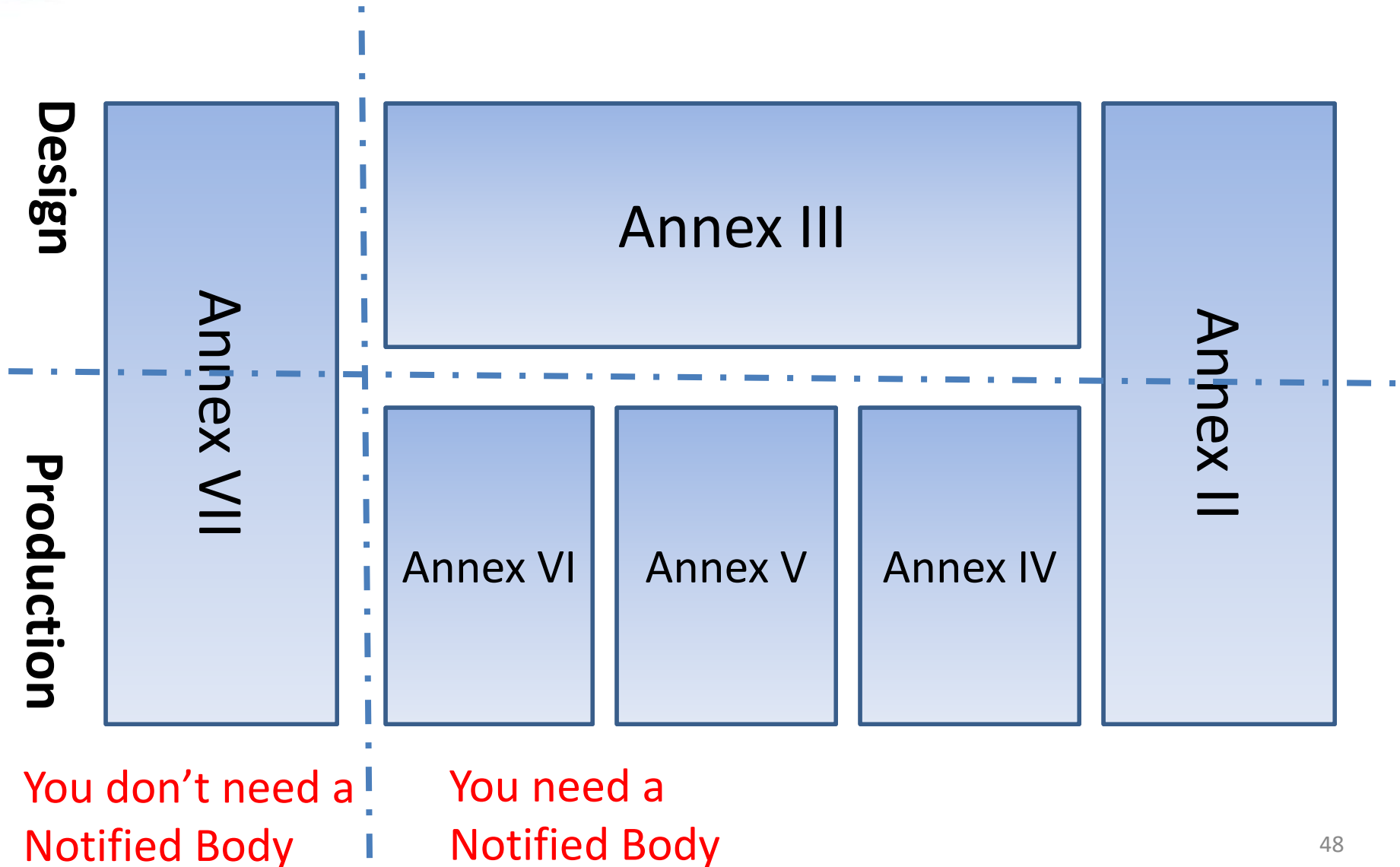
Conformity assessment procedures

- Based on modular approach
- Intervention of :
 - A first party (manufacturer)
 - A third party (Notified Body)
- Relates to :
 - Design phase
 - Production phase
 - Or both above
- Each Directive uses an appropriate selection from the available modules

Modular approach (1)



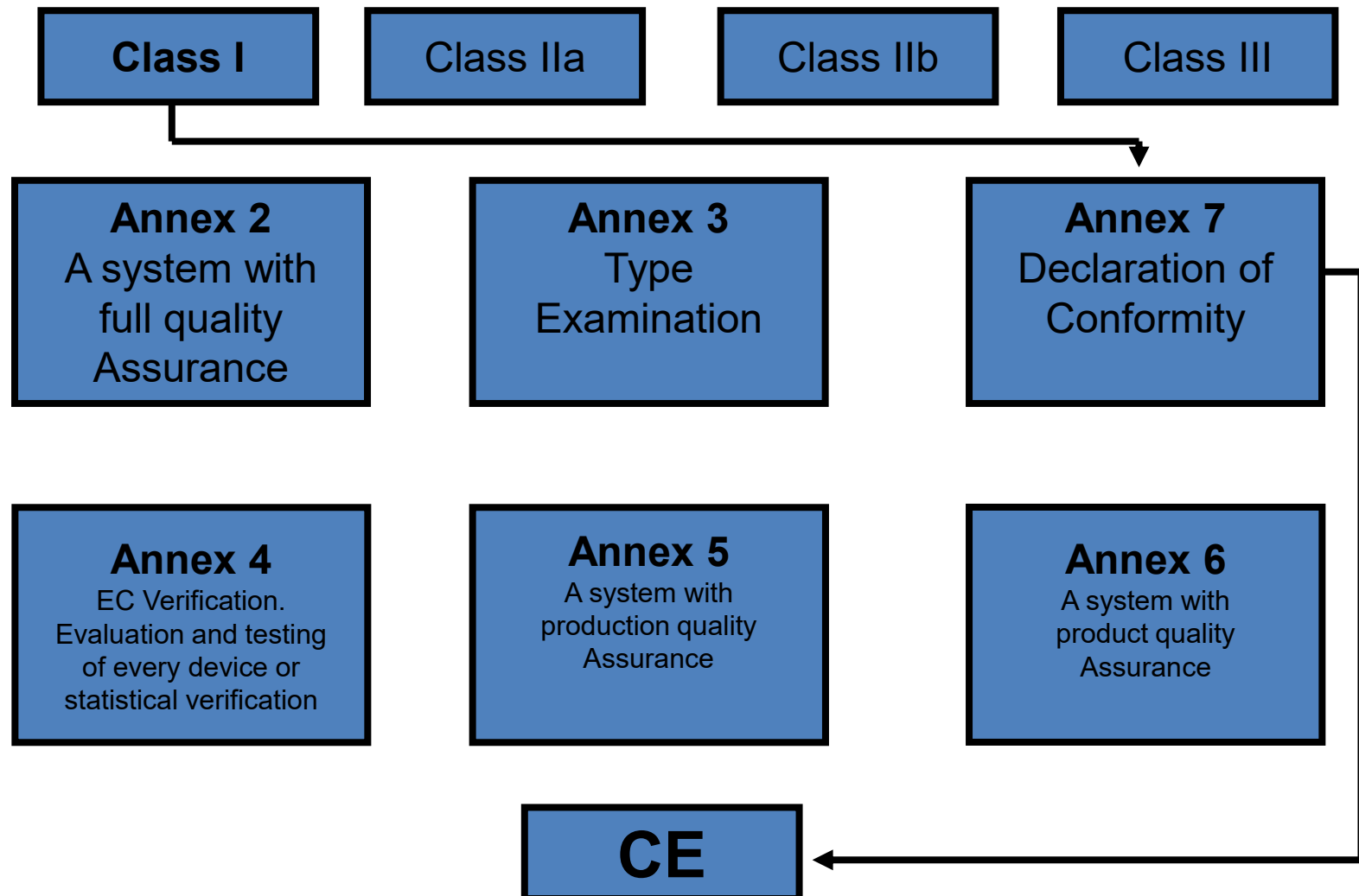
Modular approach (2)



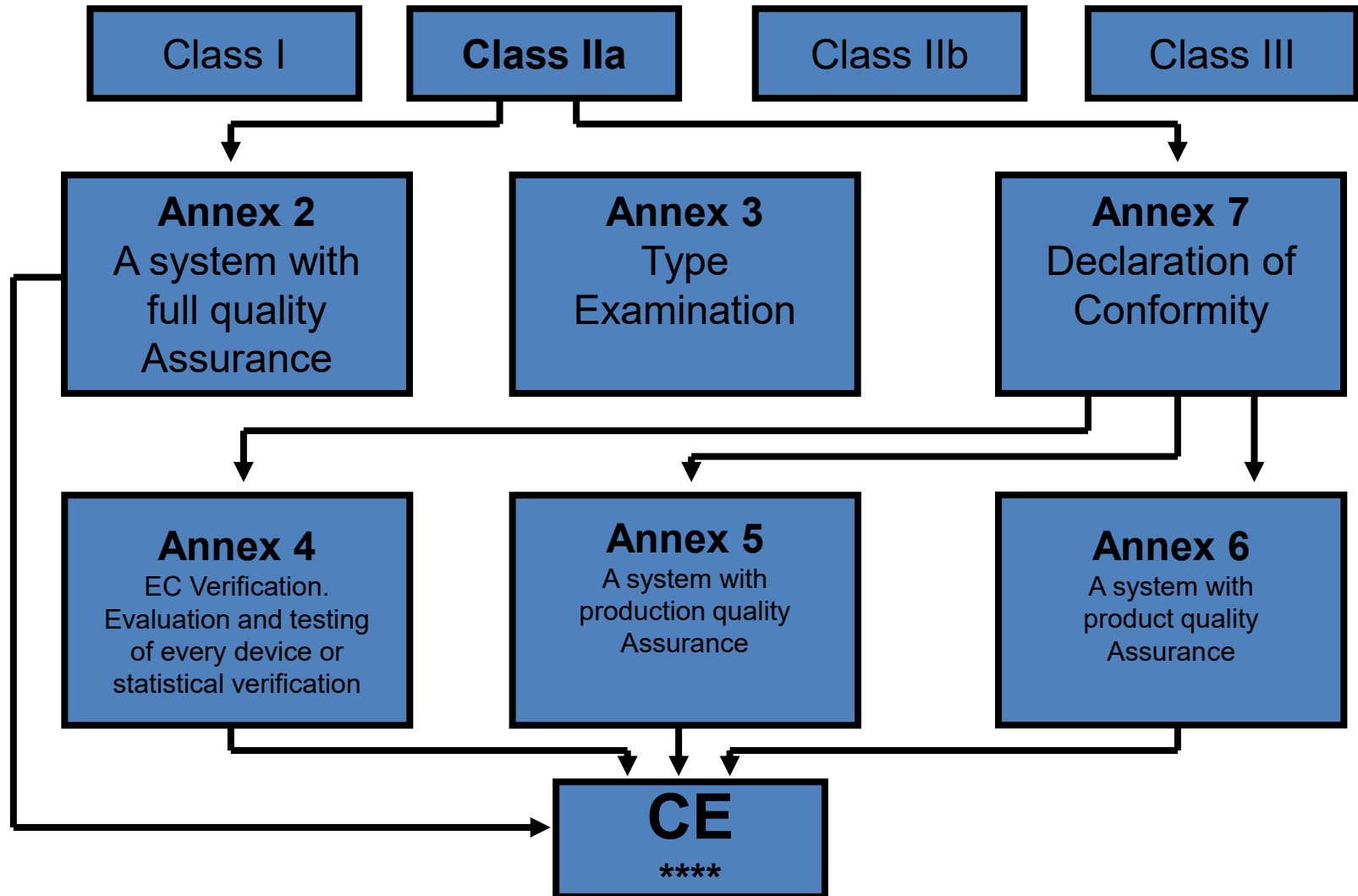
Classification Vs Conformity Assessment

Class	Type	Conformity Assessment
I	Low risk	Manufacturer
IIa	Medium risk	Notified Body at production
IIb	High risk	Notified Body at design and production
III	High risk	Notified Body at design / production + verification of design dossiers

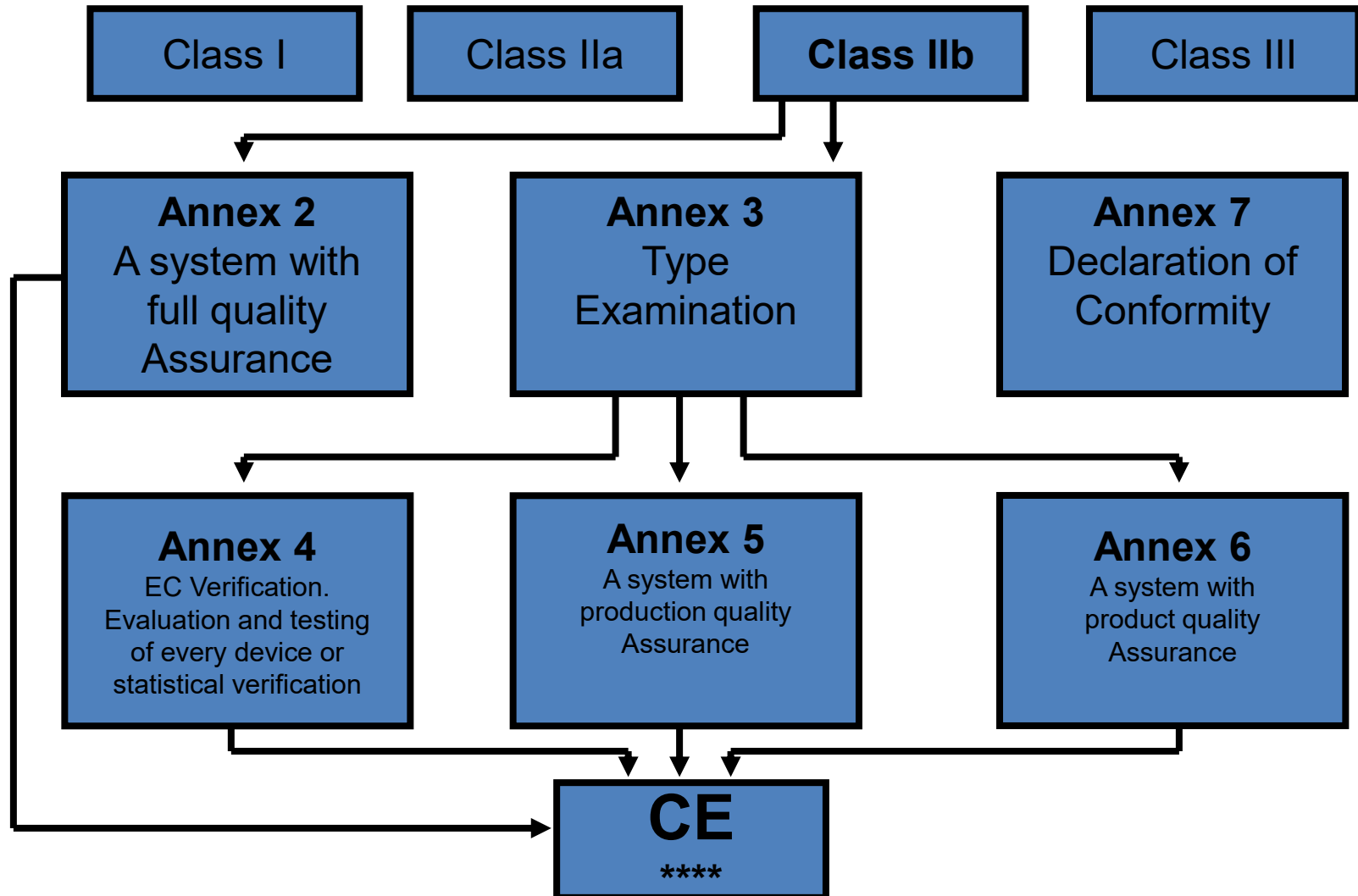
MDD Compliance Process (Conformity Assessment Procedure)



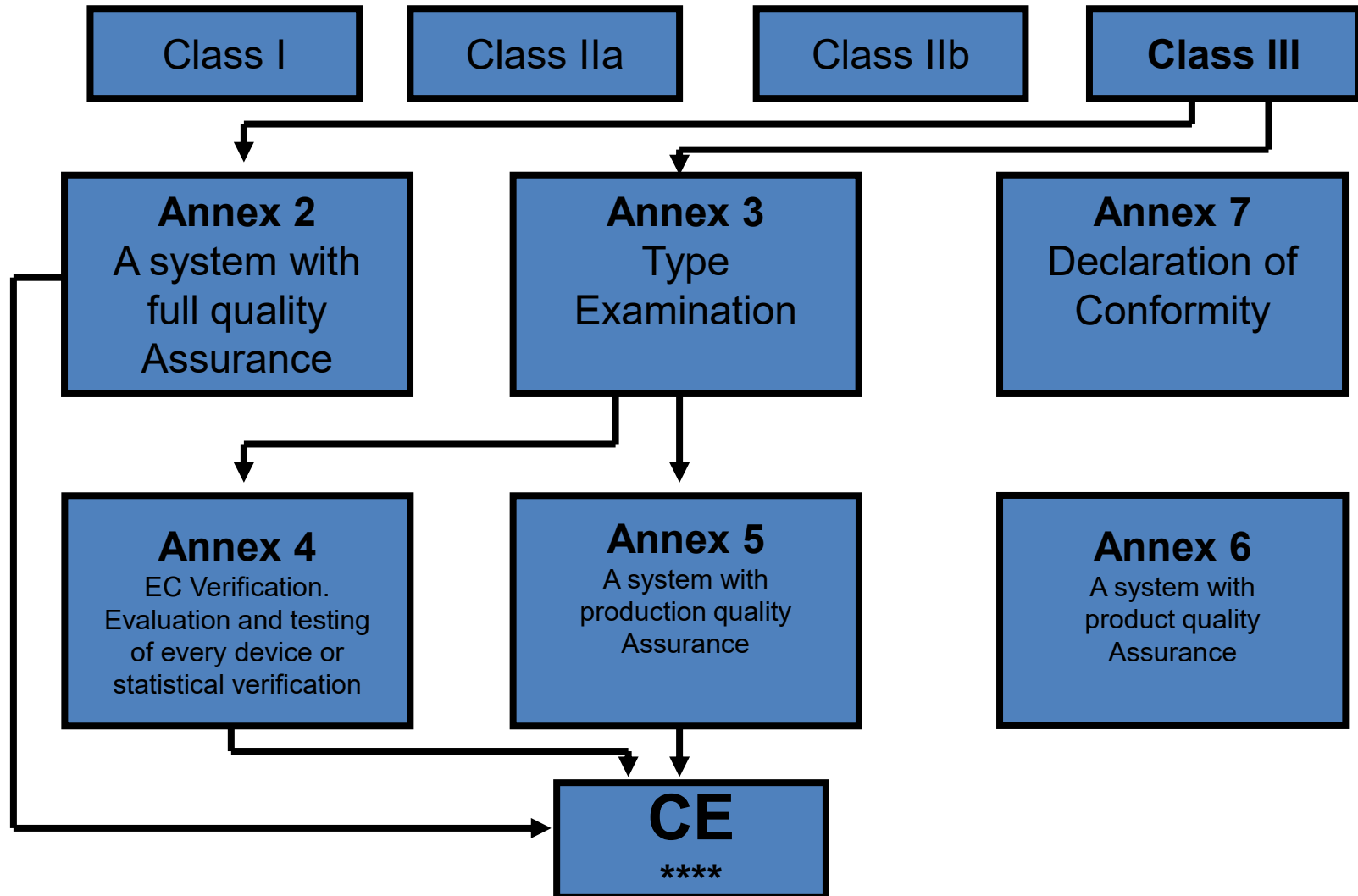
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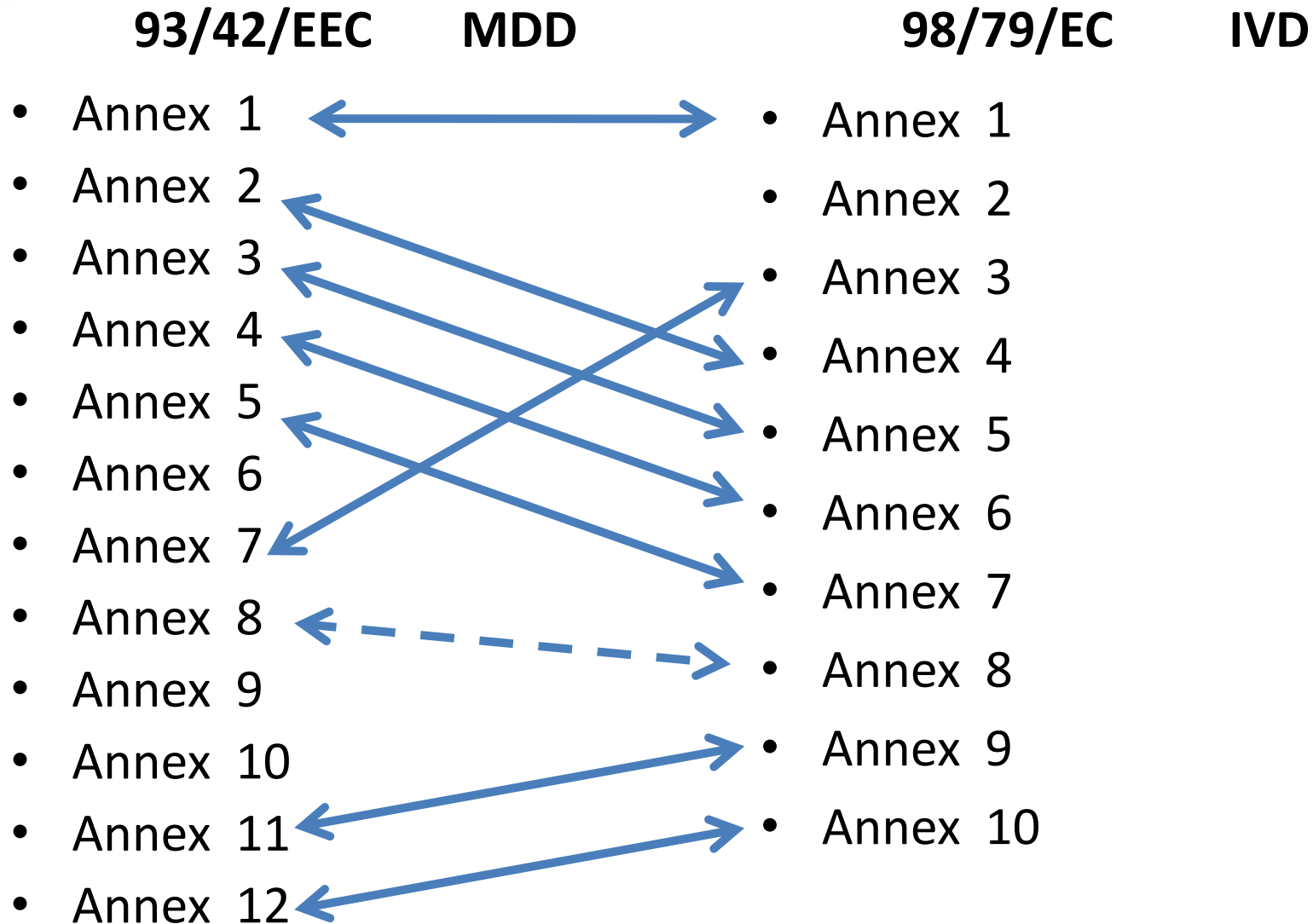
MDD Compliance Process (Conformity Assessment Procedure)



MDD Compliance Process (Conformity Assessment Procedure)



93/42/EEC (MDD) Vs. 98/79/EC (IVD)



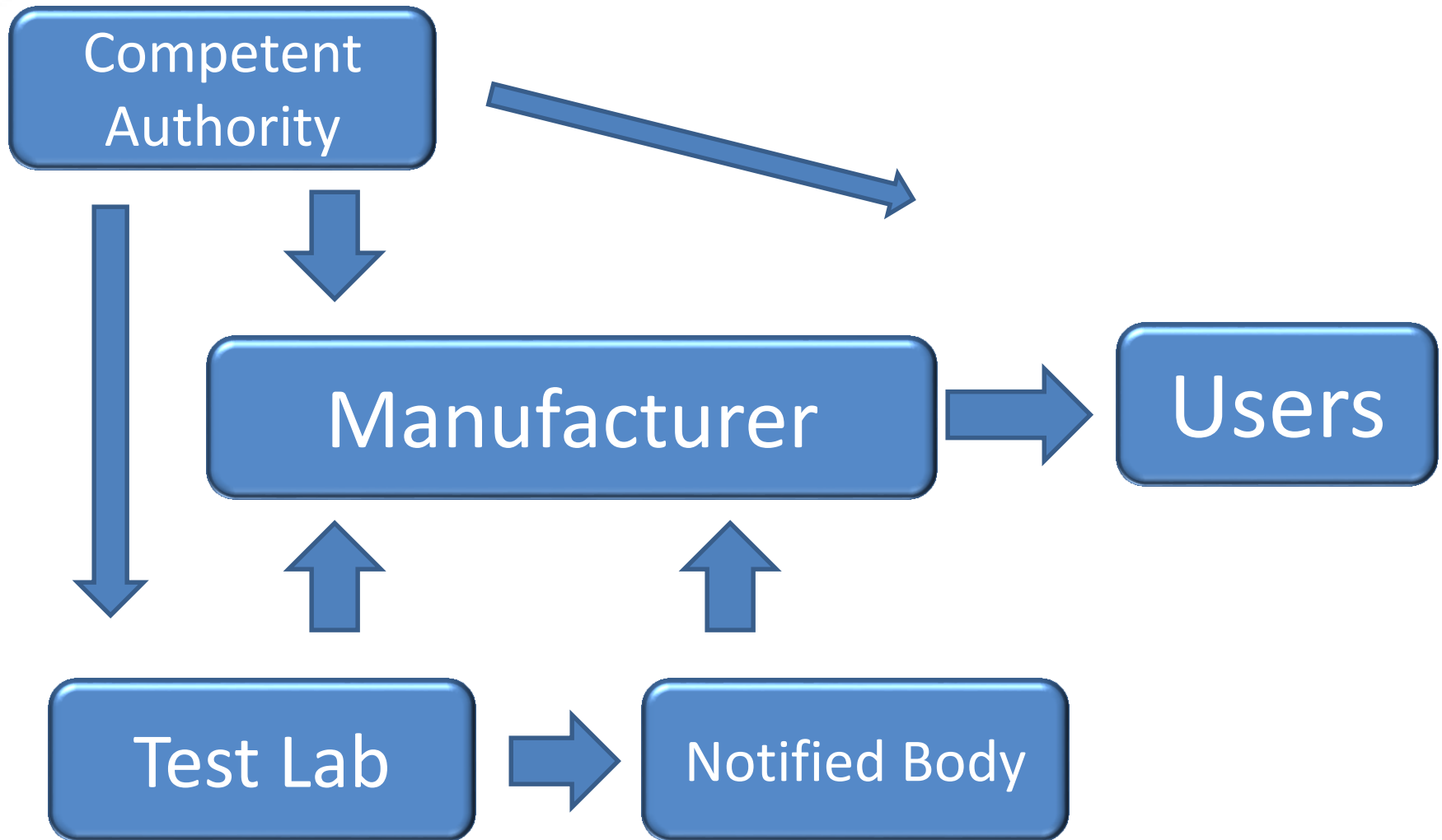


Session 4

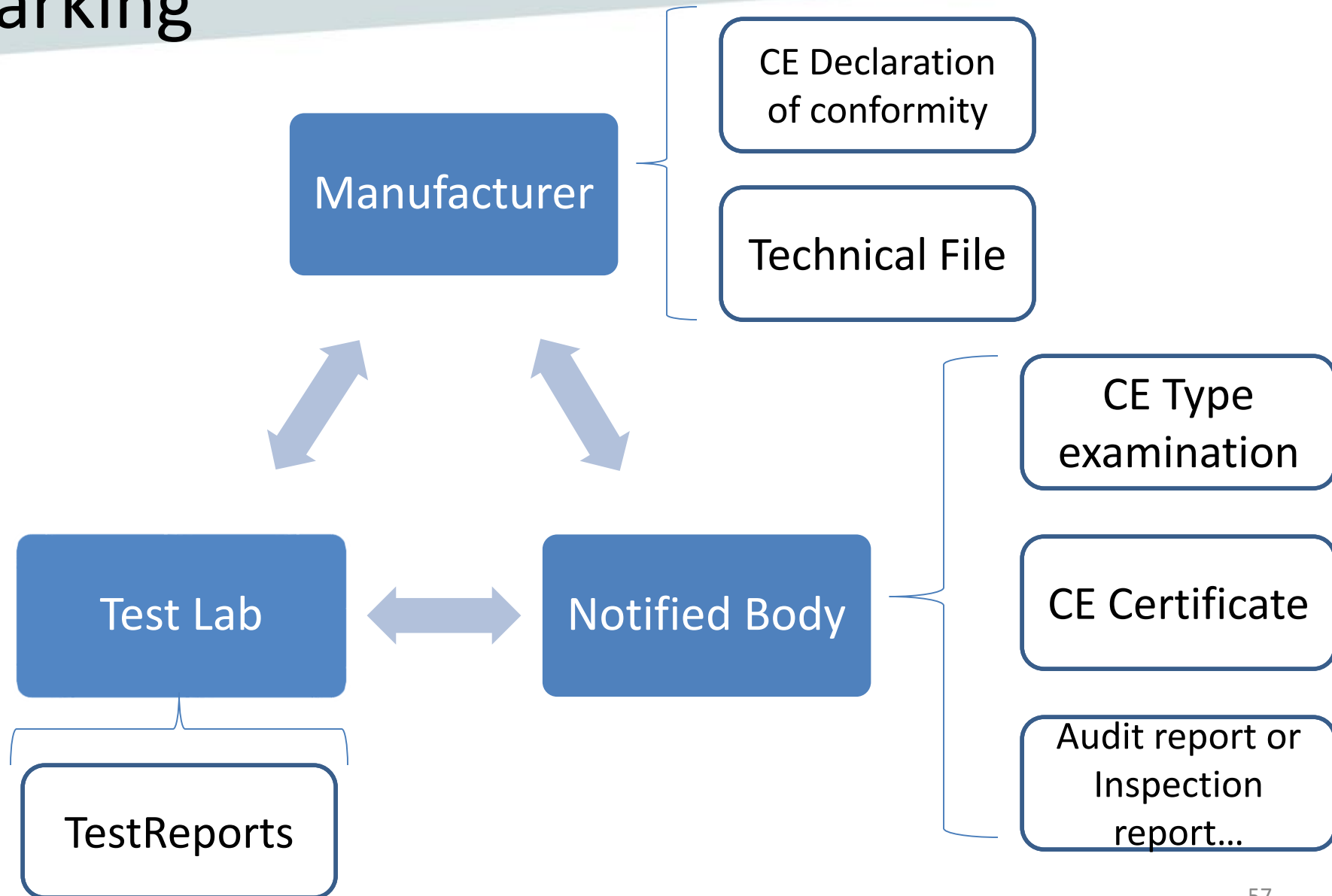
This session covers :

- Documents associated with CE marking
- Technical File & Design Dossier

Main players of CE marking

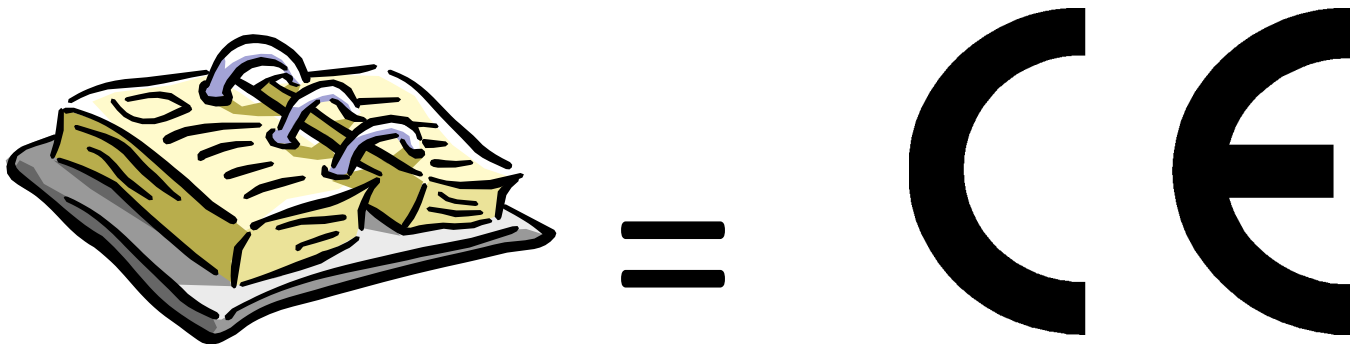


Documents associated with CE marking



Technical File & Design Dossier

Contains all the **relevant** information to demonstrate that the product meets the **Essential Requirements** of the Directive



Technical File (1)

Typical contents :

- Index
- Name and address of the manufacturer
- Classification with rationale
- Description of the device and variants
- Specifications :
 - *Raw materials*
 - *Packaging components*
 - *Finished products*

Technical File (2)

- Test methods
- Labels, Packaging specification, IFU, *etc.*
- Design verification data (history, *etc.*)
- Risk Analysis
- Essential Requirements checklist referencing standard used

Technical File (3)

- Sterilisation method, validation and routine control (where relevant)
- Clinical Data
- Manufacturing records
- Records of post-market surveillance and vigilance leading to any design changes
- Declaration of conformity

Technical File (4)

- Statements about specifics
 - *Connection to other devices*
 - *Animal materials*
 - *Incorporation of medicinal substances, etc.*
- Description of quality system and cross reference to relevant procedures

Design Dossier

- Required for high risk products
- Reviewed by NB – EC Examination Certificate
- Similar to Technical File but more details of design history
- NO STANDARD PRO-FORMA EXISTS

The
END