# CE MARKING PROCESS & NOTIFIED BODIES

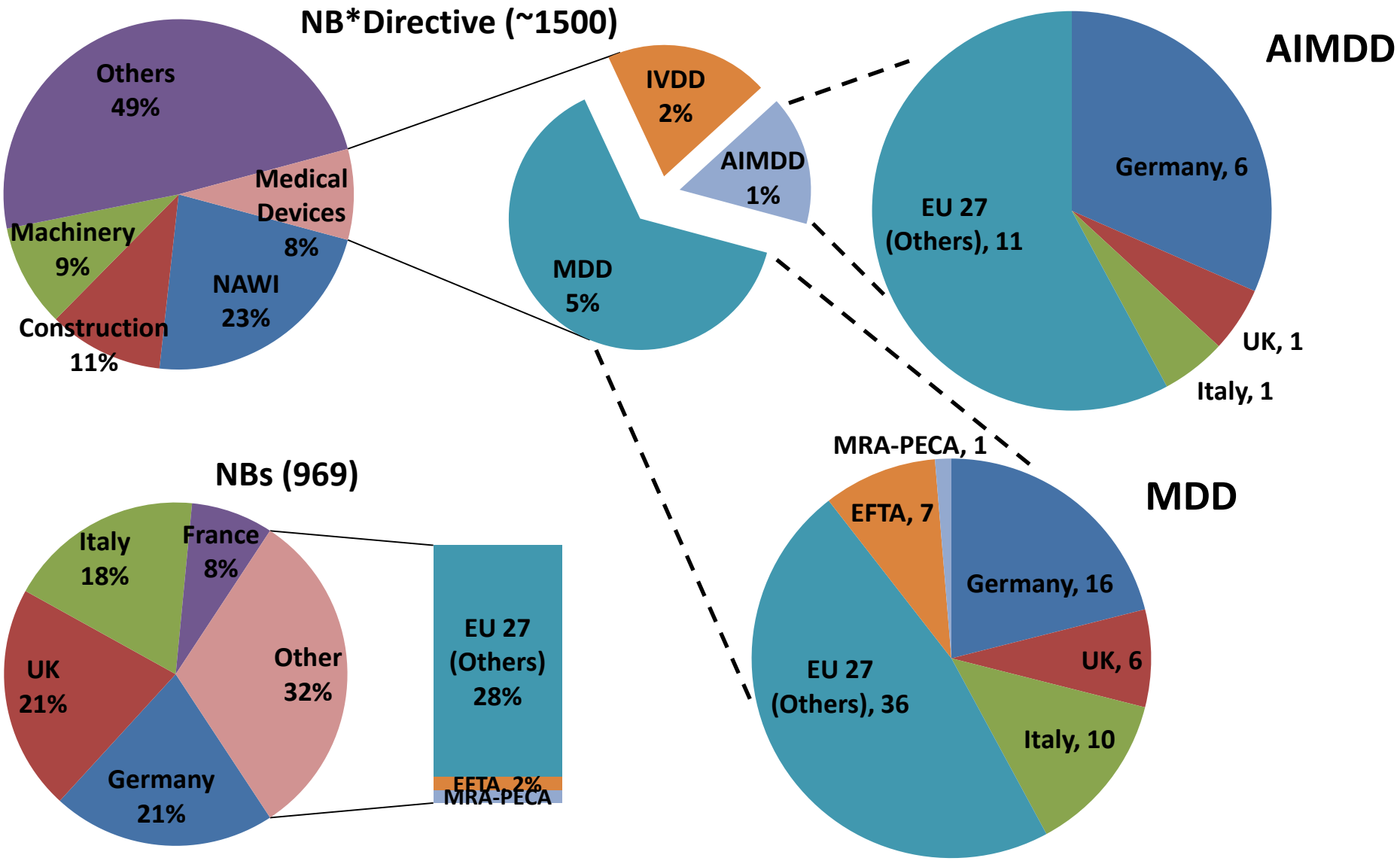
*GLOBAL BIODESIGN*

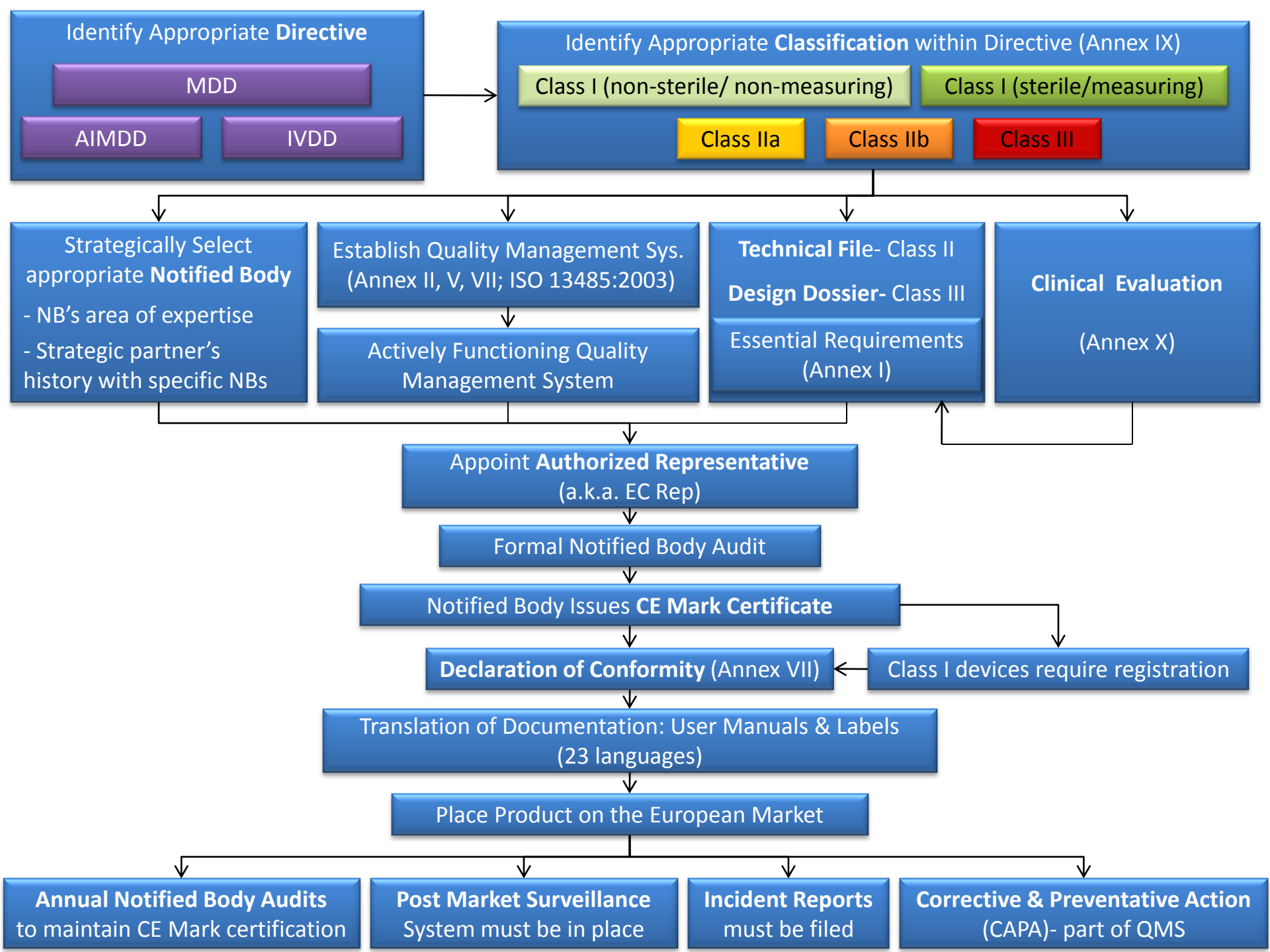
STANFORD UNIVERSITY

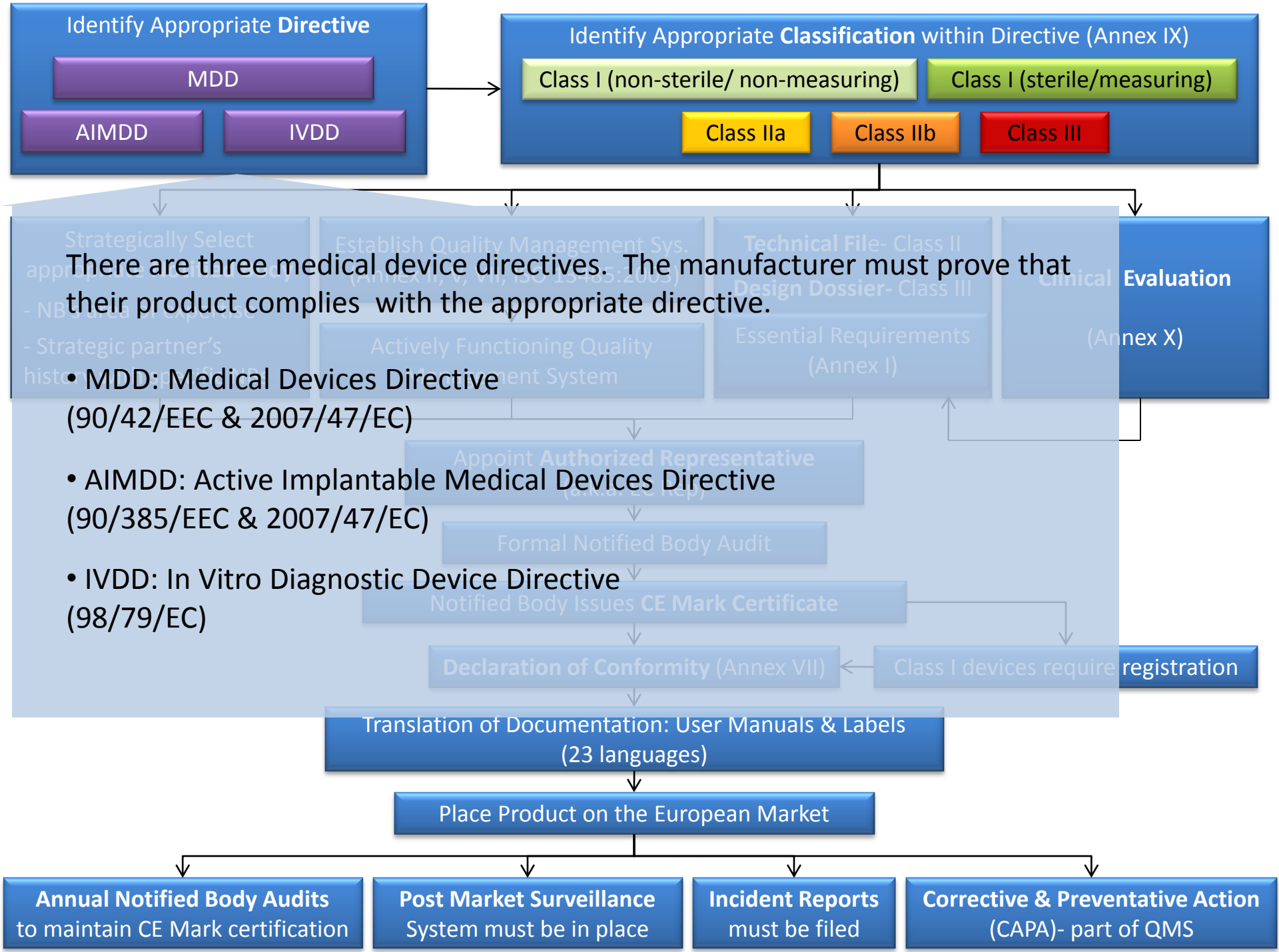
Ellis Garai
Ramin Miri

Spring 2011

# Notified Bodies Industrial and Geographical Distribution

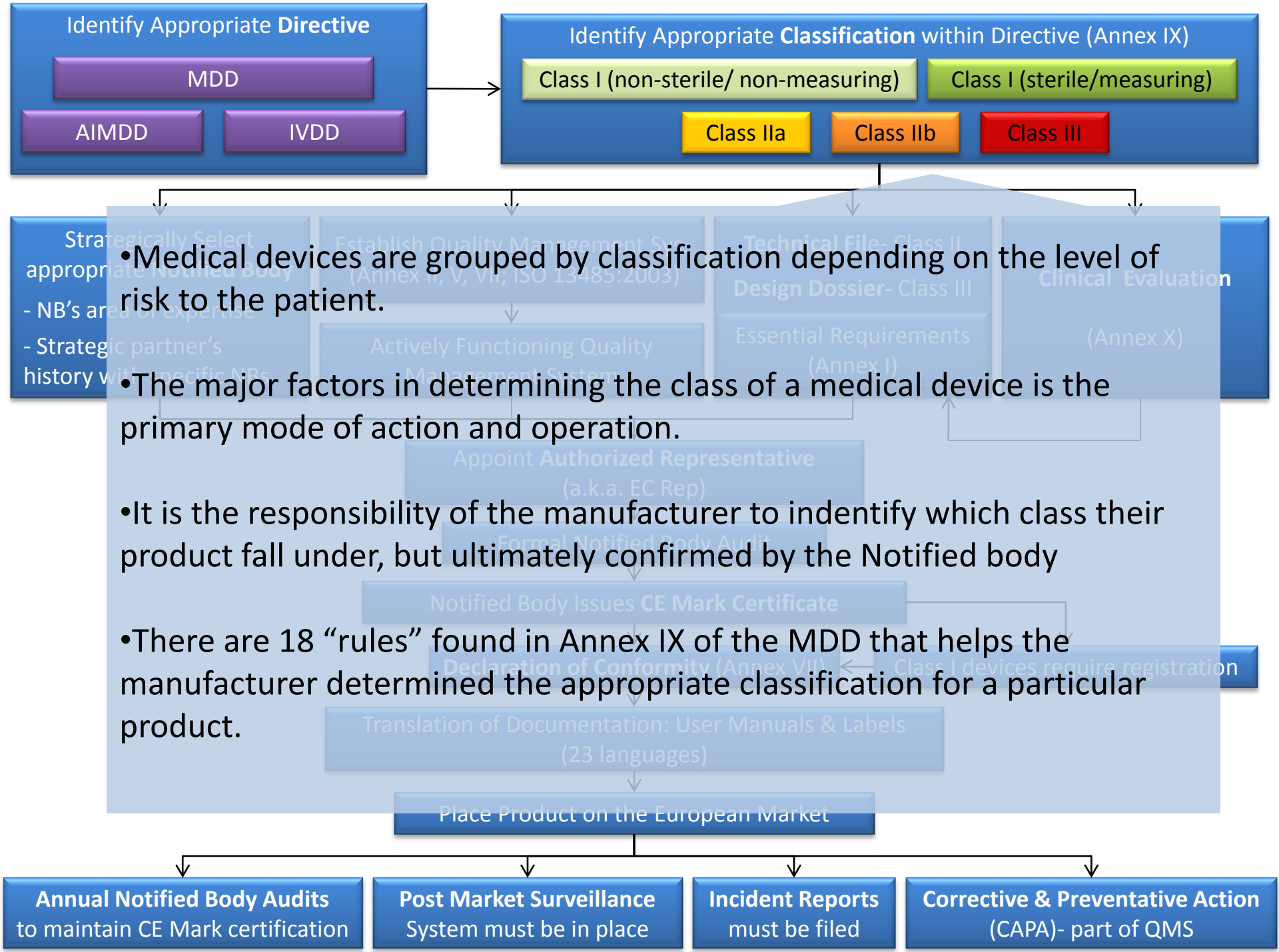



Identify Appropriate **Directive**
MDD
AIMDD
IVDD
Identify Appropriate **Classification** within Directive (Annex IX)
Class I (non-sterile/ non-measuring)
Class I (sterile/measuring)
Class IIa
Class IIb
Class III
Strategically Select appropriate **Notified Body**
- NB's area of expertise
- Strategic partner's history with specific NBs
Establish Quality Management Sys. (Annex II, V, VII; ISO 13485:2003)
Actively Functioning Quality Management System
**Technical File**- Class II
**Design Dossier**- Class III
Essential Requirements (Annex I)
**Clinical Evaluation**
(Annex X)
Appoint **Authorized Representative** (a.k.a. EC Rep)
Formal Notified Body Audit
Notified Body Issues **CE Mark Certificate**
**Declaration of Conformity** (Annex VII)
Class I devices require registration
Translation of Documentation: User Manuals & Labels (23 languages)
Place Product on the European Market
**Annual Notified Body Audits** to maintain CE Mark certification
**Post Market Surveillance** System must be in place
**Incident Reports** must be filed
**Corrective & Preventative Action** (CAPA)- part of QMS

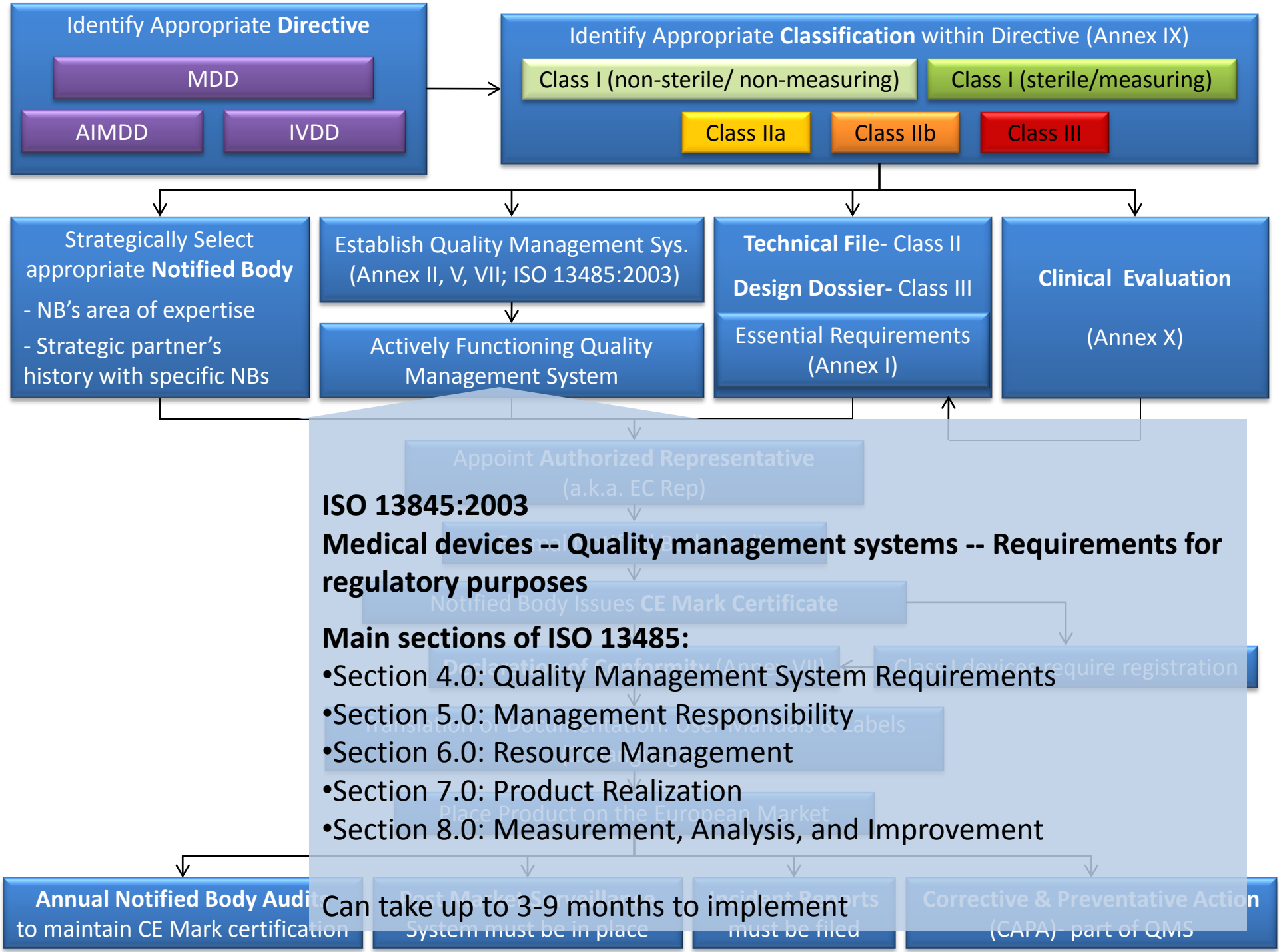



There are three medical device directives. The manufacturer must prove that their product complies with the appropriate directive.

- MDD: Medical Devices Directive (90/42/EEC & 2007/47/EC)
- AIMDD: Active Implantable Medical Devices Directive (90/385/EEC & 2007/47/EC)
- IVDD: In Vitro Diagnostic Device Directive (98/79/EC)




- Medical devices are grouped by classification depending on the level of risk to the patient.
- The major factors in determining the class of a medical device is the primary mode of action and operation.
- It is the responsibility of the manufacturer to indentify which class their product fall under, but ultimately confirmed by the Notified body
- There are 18 "rules" found in Annex IX of the MDD that helps the manufacturer determined the appropriate classification for a particular product.

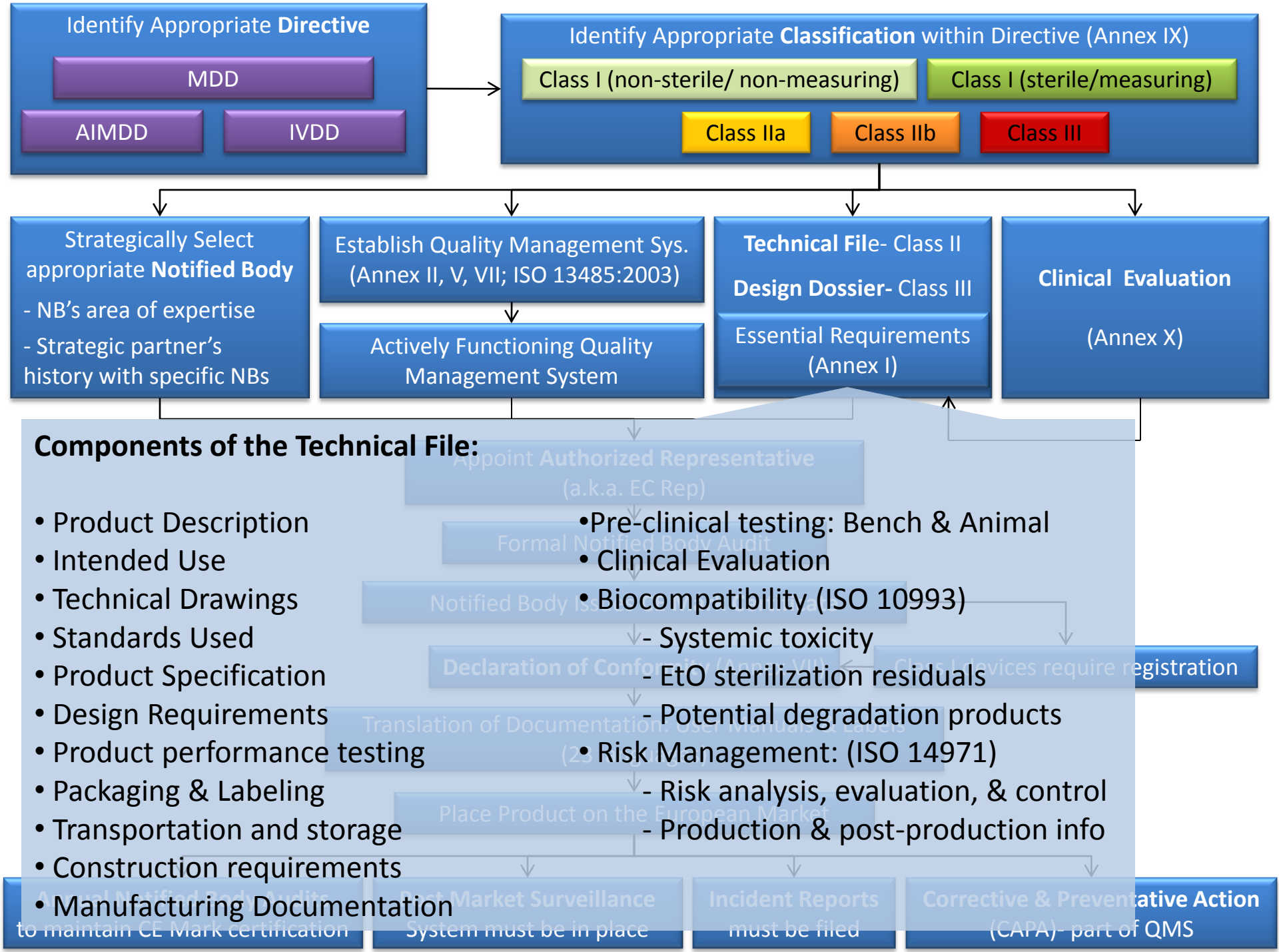



**ISO 13845:2003**
**Medical devices -- Quality management systems -- Requirements for regulatory purposes**

**Main sections of ISO 13485:**

- Section 4.0: Quality Management System Requirements
- Section 5.0: Management Responsibility
- Section 6.0: Resource Management
- Section 7.0: Product Realization
- Section 8.0: Measurement, Analysis, and Improvement

Can take up to 3-9 months to implement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Components of the Technical File:
• Product Description
• Intended Use
• Technical Drawings
• Standards Used
• Product Specification
• Design Requirements
• Product performance testing
• Packaging & Labeling
• Transportation and storage
• Construction requirements
• Manufacturing Documentation
•Pre-clinical testing: Bench & Animal
• Clinical Evaluation
• Biocompatibility (ISO 10993)
- Systemic toxicity
- EtO sterilization residuals
- Potential degradation products
• Risk Management: (ISO 14971)
- Risk analysis, evaluation, & control
- Production & post-production info
Appoint Authorized Representative (a.k.a. EC Rep)
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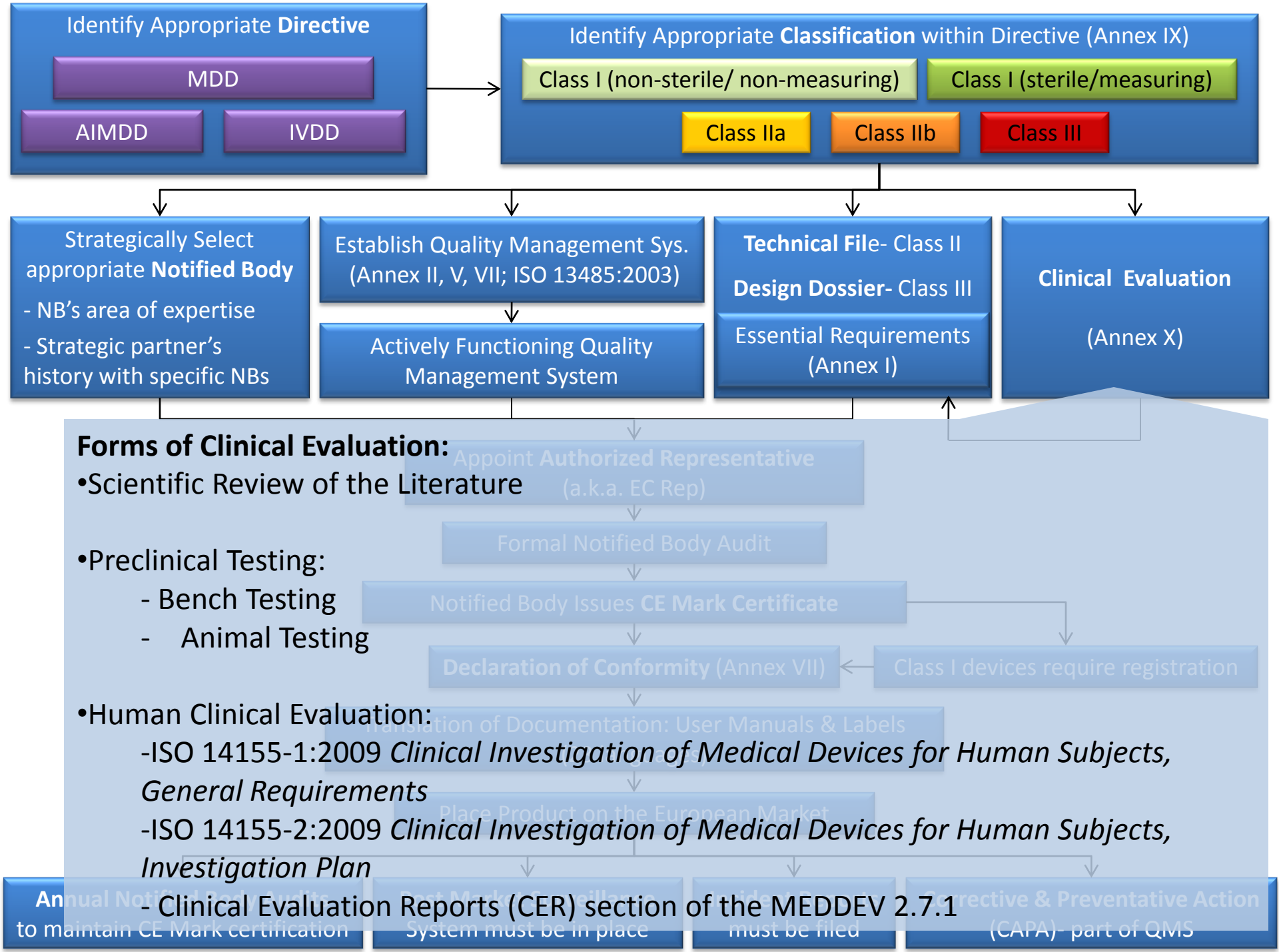
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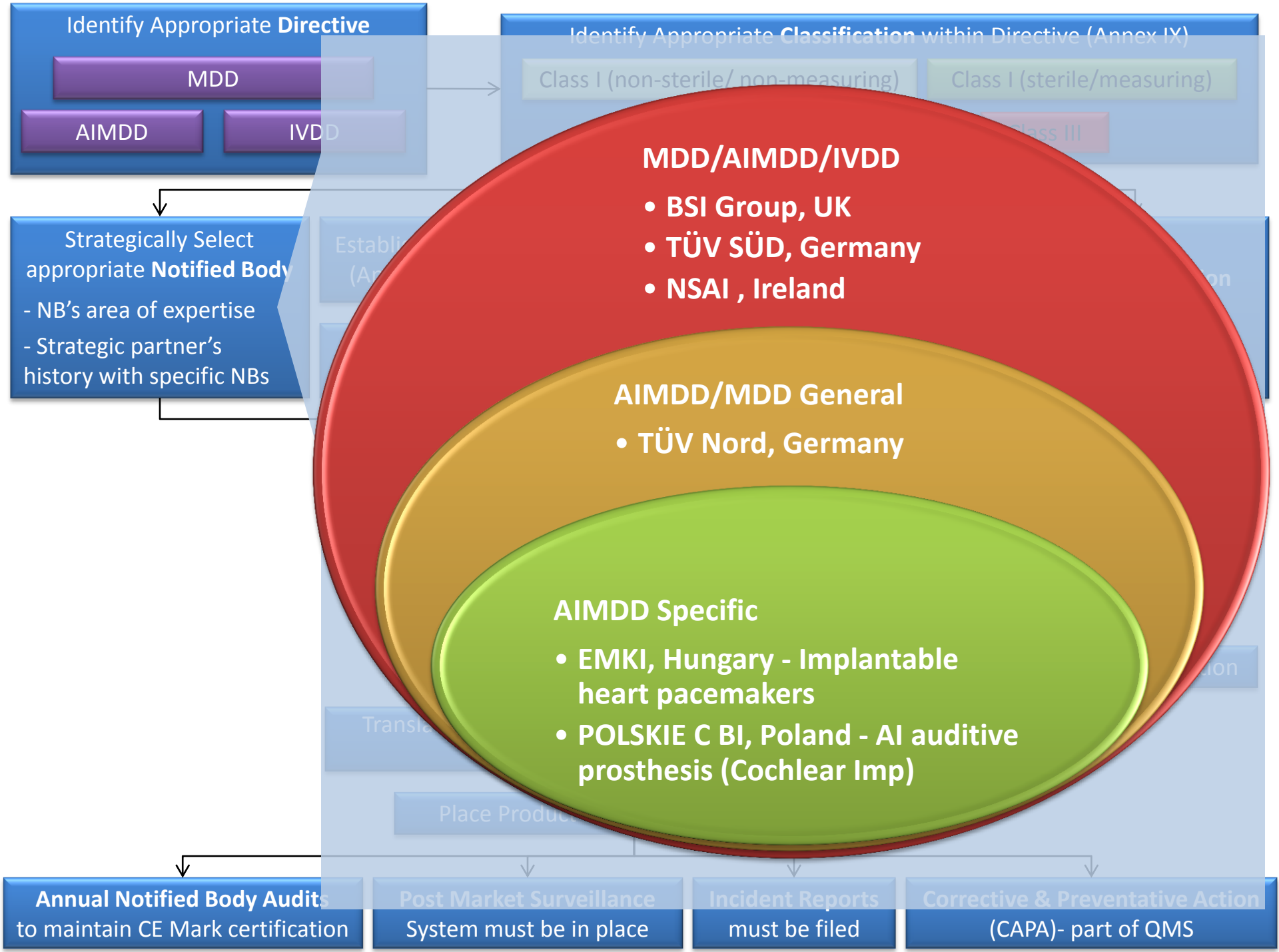
(Annex X)
Forms of Clinical Evaluation:
•Scientific Review of the Literature
•Preclinical Testing:
- Bench Testing
- Animal Testing
•Human Clinical Evaluation:
-ISO 14155-1:2009 Clinical Investigation of Medical Devices for Human Subjects, General Requirements
-ISO 14155-2:2009 Clinical Investigation of Medical Devices for Human Subjects, Investigation Plan
- Clinical Evaluation Reports (CER) section of the MEDDEV 2.7.1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MDD/AIMDD/IVDD
• BSI Group, UK
• TÜV SÜD, Germany
• NSAI , Ireland
AIMDD/MDD General
• TÜV Nord, Germany
AIMDD Specific
• EMKI, Hungary - Implantable heart pacemakers
• POLSKIE C BI, Poland - AI auditive prosthesis (Cochlear Imp)
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to maintain CE Mark certification
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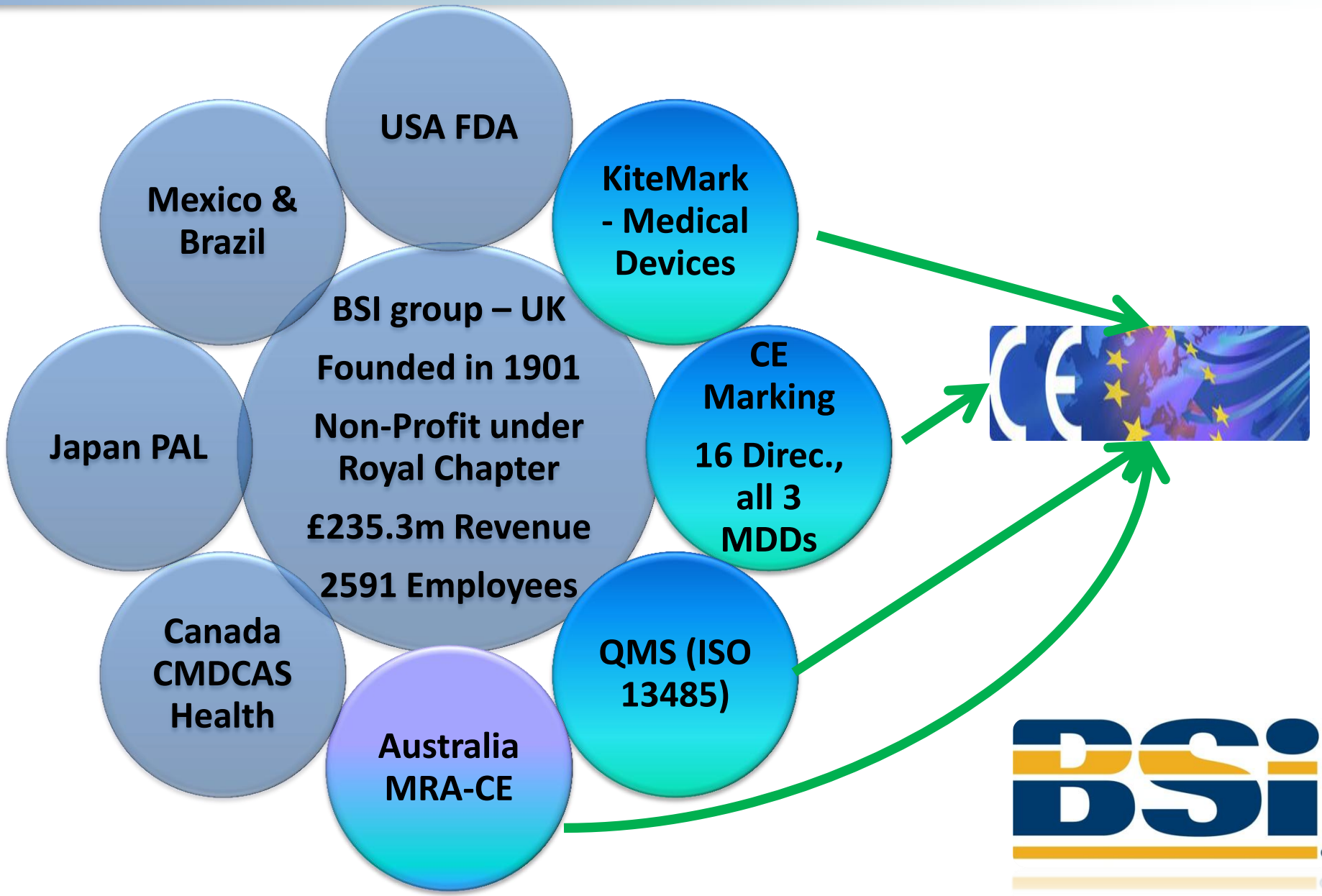
# General NBs in Medical Devices

# Full Spectrum NB



# AIMDD NBOG Codes

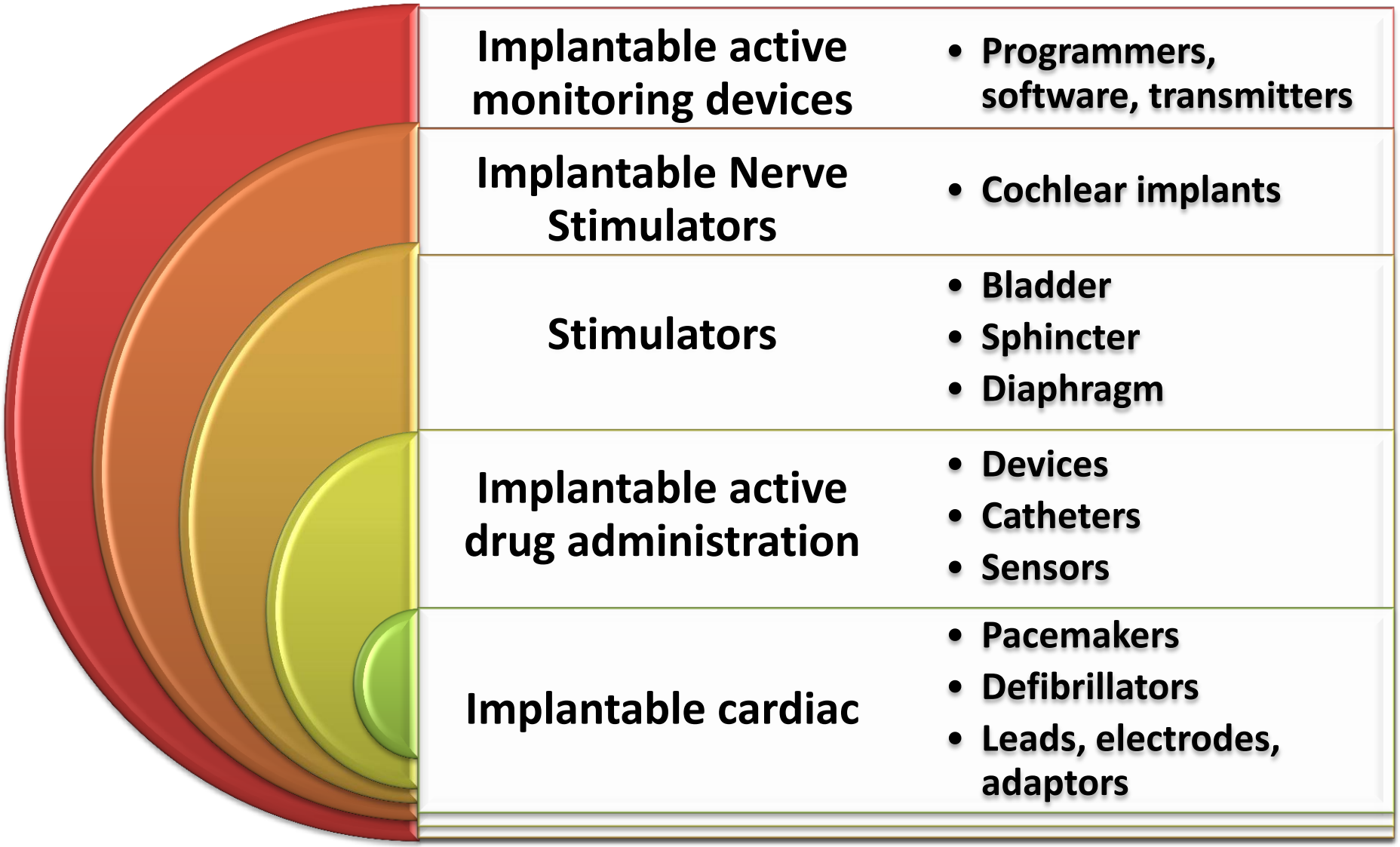
**AIMDs Product Categorization**

- **0100: General AIMDDs**
- 0101: AIMDs for stimulation / inhibition
- 0102: AIMDs delivering drugs or other substances
- 0103: AIMDs substituting or replacing organ functions

**MDD & AIMDD SCOPE EXPRESSIONS, ADDITIONS**

- MDS 7000: **MDD / AIMDD Specifics**
- MDS 7004: MDDs referencing the Directive 2006/42/EC on machinery
- MDS 7005: MDDs referencing the Directive 89/686/EEC on personal protective equipment (PPE)
- MDS 7006: MDDs in sterile condition

# AIMDD (90/385/EEC) Products



# Specific AIMDD NB

**EMKI – Hungary**
**MDD/AIMDD/IVDD**

**But only implantable heart pacemakers in AIMDD directive**
**Specialized in pacemakers**

- Preparation and exchange information, and Pre-evaluating group
- Classification of C.A. scope (NBGO), and Calculating the time interval of C.A. procedures
- Designating the members of C.A. group, and making a bid
- Planning, performing, & Closure of C.A. procedure, and Decision about Conformity
- Issuing, modifying, or supplementing certificates
- Suspending, withdrawing, or constraining certificates
- Transparency and reproducibility of C.A. procedure

Conformity Assessment

# Specific AIMDD NB

**EMKI – Hungary**
**MDD/AIMDD/IVDD**

**But only implantable heart pacemakers in AIMDD directive**
**Specialized in pacemakers**

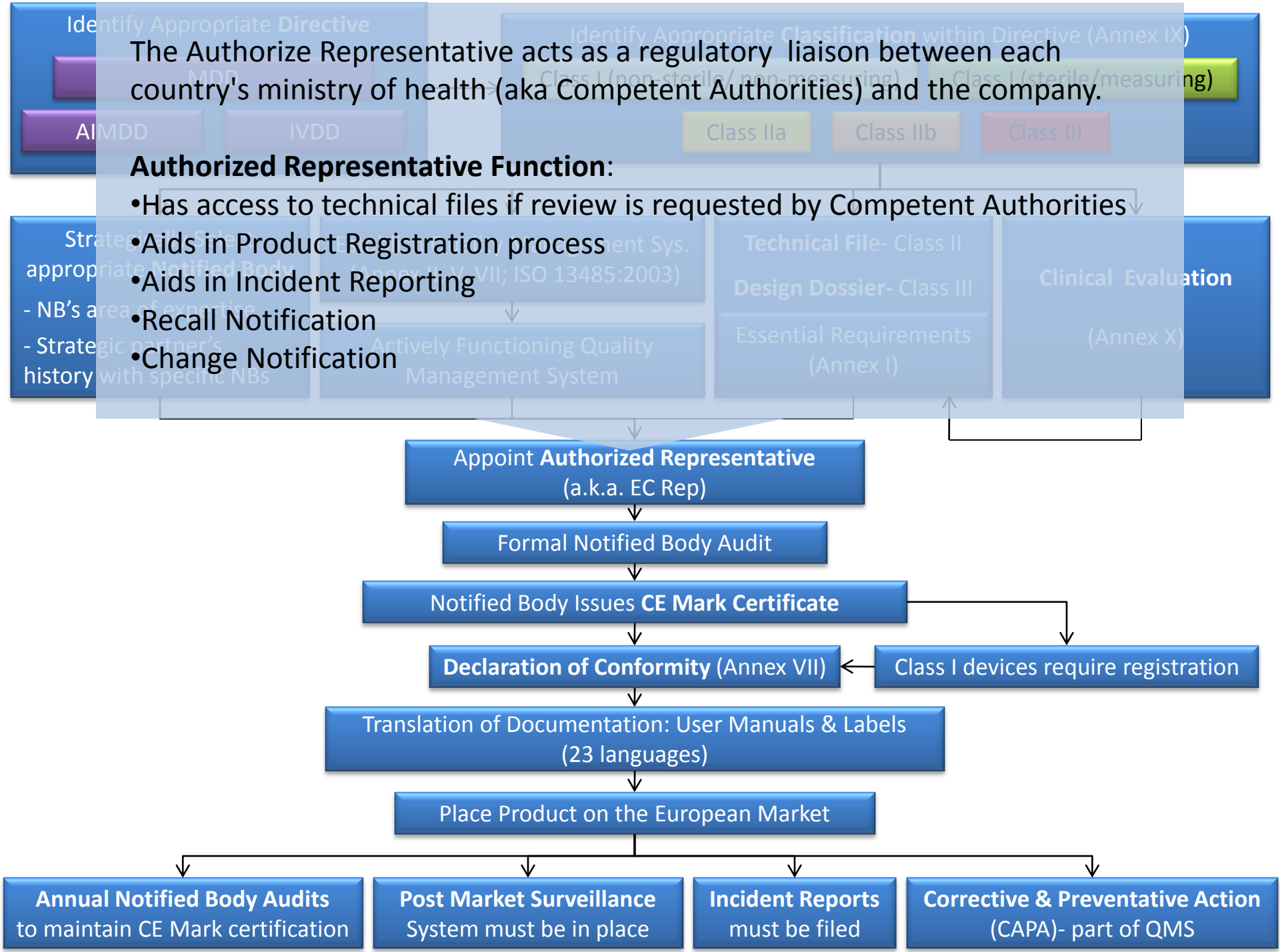
In case of sole product line of implantable heart pacemaker, and being a start-up, or prior strategic partnership with EMKI

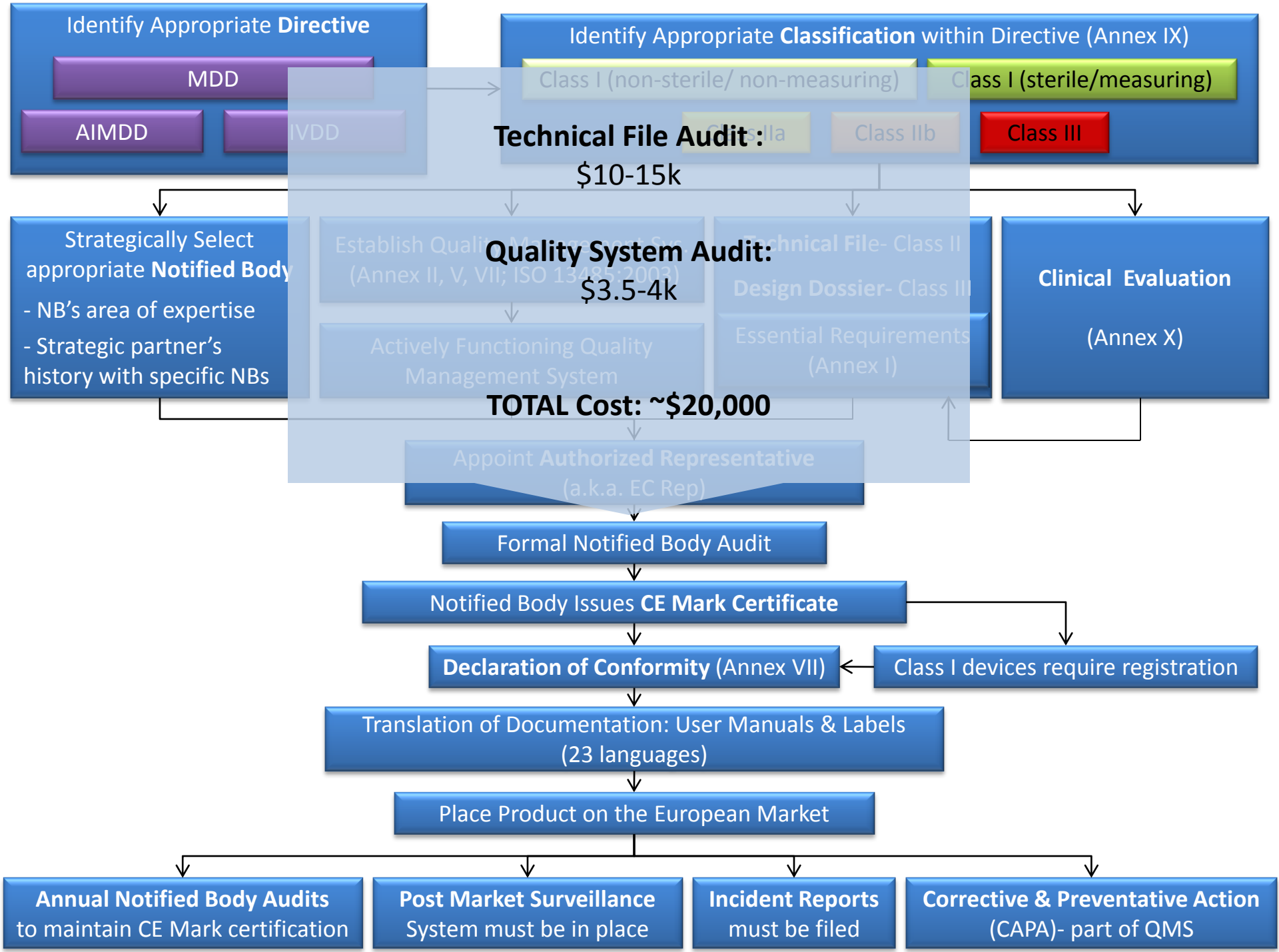
C.A. Conformity Assessment

The Authorize Representative acts as a regulatory liaison between each country's ministry of health (aka Competent Authorities) and the company.

**Authorized Representative Function**:

- Has access to technical files if review is requested by Competent Authorities
- Aids in Product Registration process
- Aids in Incident Reporting
- Recall Notification
- Change Notification

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Class I (sterile/measuring)
Class IIa
Class IIb
Class III
**Technical File Audit :**
$10-15k
Strategically Select appropriate **Notified Body**
- NB's area of expertise
- Strategic partner's history with specific NBs
Establish Quality Management System (Annex II, V, VII; ISO 13485:2003)
Actively Functioning Quality Management System
**Quality System Audit:**
$3.5-4k
**Technical File**- Class II
**Design Dossier**- Class III
Essential Requirements (Annex I)
**Clinical Evaluation**
(Annex X)
**TOTAL Cost: ~$20,000**
Appoint **Authorized Representative** (a.k.a. EC Rep)
Formal Notified Body Audit
Notified Body Issues **CE Mark Certificate**
**Declaration of Conformity** (Annex VII)
Class I devices require registration
Translation of Documentation: User Manuals & Labels (23 languages)
Place Product on the European Market
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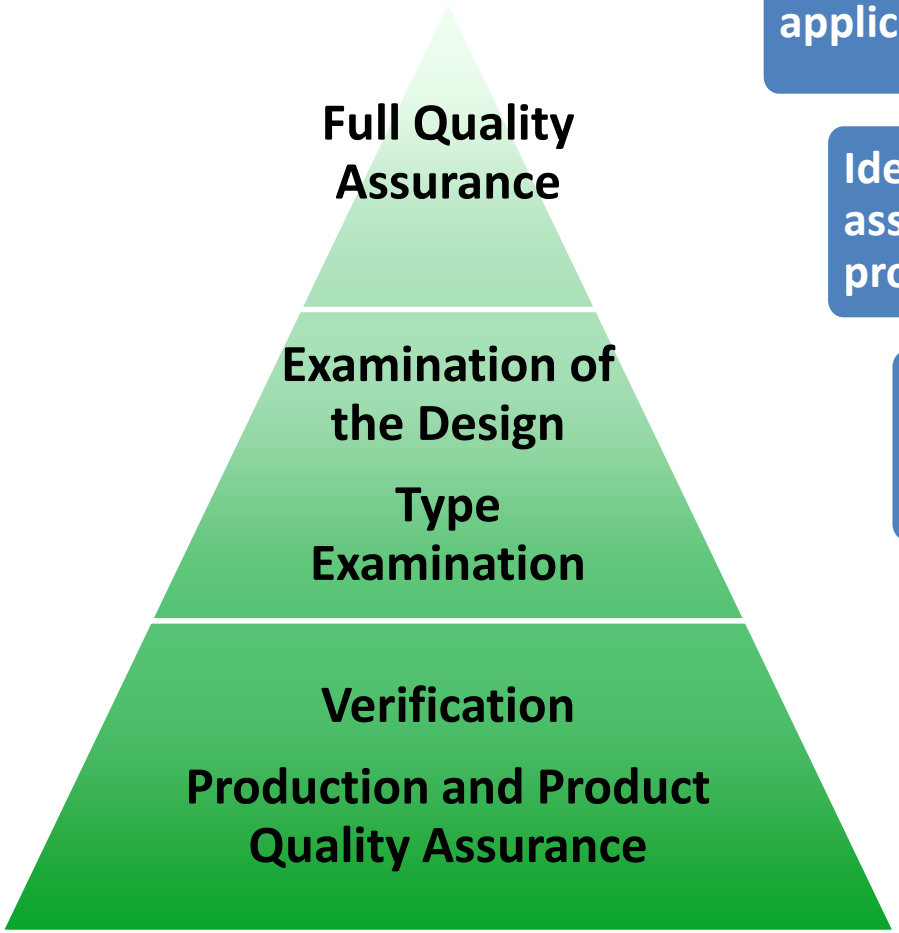
# Conformity Assessment Procedure Options Based on Directive

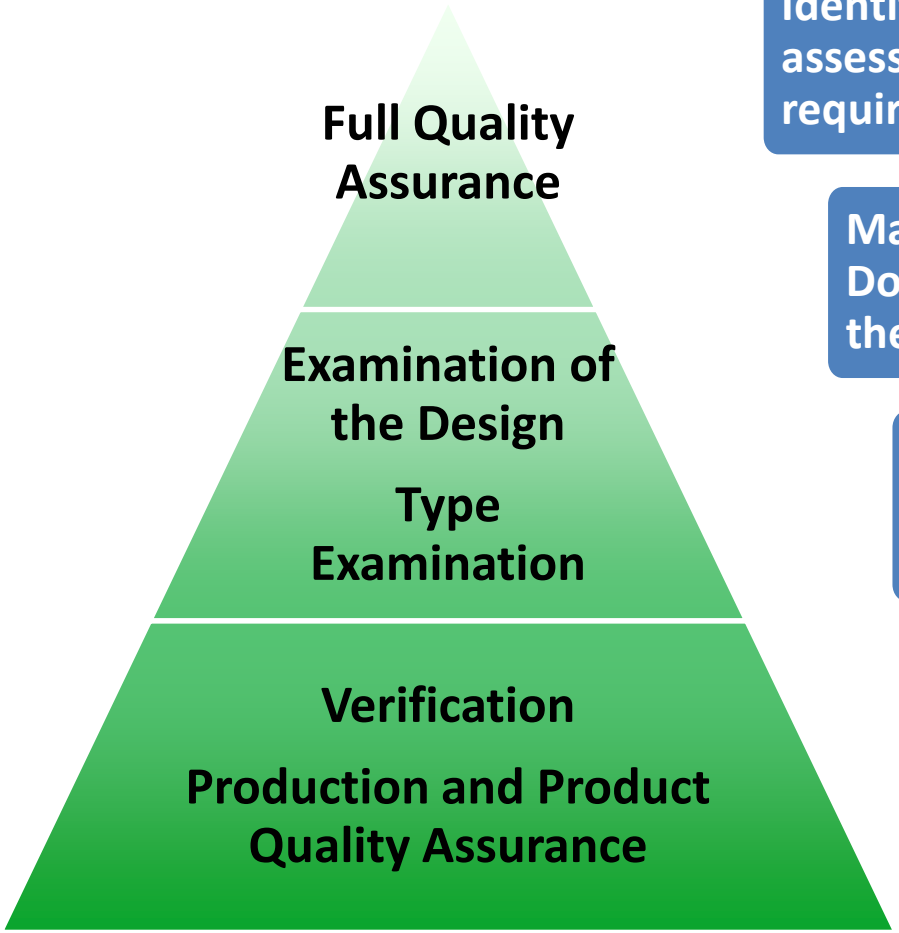
- A • Internal production control
- Aa • Intervention of a Notified Body
- B • EC type-examination
- C • Conformity to type
- D • Production quality assurance
- E • Product quality assurance
- F • Product verification
- G • Unit verification
- H • Full quality assurance

# Notified Body's Roles within CEM Certification




- Identify the Directive (s) applicable to product
- Identify the conformity assessment procedure based on product & Directive
- Determine key milestones and actionable schedule
- Identify if there are any Harmonized European Standards
- Ensure product compliance with all the essential requirements of the Directive(s)

# Notified Body's Roles within CEM Certification




- Identify whether independent assessment of conformity is required by NBs
- Maintain Technical Documentation required by the Directive(s)
- Prepare the Declaration of Conformity and the required supporting evidence
- Check that no other purely national requirements exist in the market country
- Affix CE marking on the product and/or packaging

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Class IIb

Class III

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Establish Quality (Annex II, V, VI

**Clinical File**- Class II

**Technical Dossier**- Class III

Actively Func Managem

Essential Requirements (Annex I)

**Clinical Evaluation**

(Annex X)


EC Attestation of Conformity

No.: EB 03 10 51149 002

TÜV

CE

Formal Notified Body Audit

Notified Body Issues **CE Mark Certificate**

**Declaration of Conformity** (Annex VII)

Class I devices require registration

Translation of Documentation: User Manuals & Labels (23 languages)

Place Product on the European Market

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Class IIa

**Components:**

- Product identification
- Product classification
- EU directives with which the product complies
- Standards used
- Name of the Notified Body used
- The manufacturer's name and address
- CE Mark certificate number
- Signature on behalf of the manufacturer or EC Rep.


CE

DECLARATION OF CONFORMITY

TG7872-4011TO

Oberon - model: 4011 sn.: 92315252

Establish Quality Management Sys.

Actively Functioning Quality Management System

Technical

Design Doss

Essential Re

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Essential Requir… (Annex …

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…ex X)

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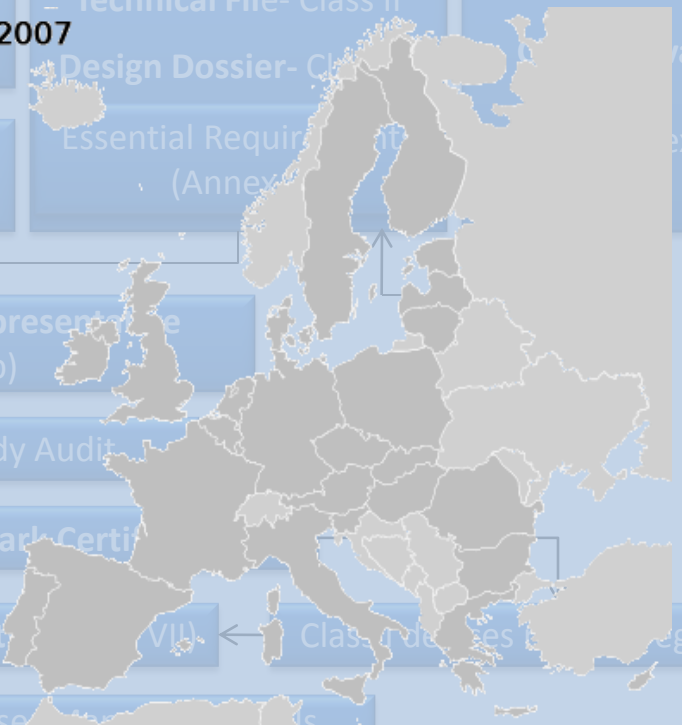

CE Mark is recognized by all 27 countries within the European Union (EU) as well as others in the region that are not necessarily part of the EU plus Canada, Australia, etc. around the globe

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# EU Medical Device Classification & CE Mark Requirements Summary

| EU Class | Device Risk | Type of devices | Technical File Required | Requires Full Quality System | Requires NB Auditing | Requires Authorized Representative | Form of Clinical Evaluation | Requires device to be Registered |
|---|---|---|---|---|---|---|---|---|
| **Class I (non-sterile/ non-measuring)** | Low | examination gloves | Yes | No | No; Self declaration of conformity by manufacturer is acceptable | Yes | Possible Scientific Literature Review | Yes |
| **Class I (sterile/ measuring)** | Low | surgical gloves, patient scales | | Yes | Yes | | | |
| **Class IIa** | Medium | Natural Orifice Access; wound management; hearing devices, EKG, etc. | | | | | Scientific Literature Review; Preclinical Work; Possible clinical trial | No ; Notified Body conducts annual audits |
| **Class IIb** | Medium | Partial/Total Implantable; surgical lasers, ventilators | | | | | | |
| **Class III** | High | Devices that affect vital organs; Life Support; heart valves | Yes, in the form of a Design Dossier | | | | Highly Likely that clinical trial is required | |