CE Marking for Medical Devices

Amie Smirthwaite, BEng, PhD
Product Technical Specialist, Orthopaedic Implants

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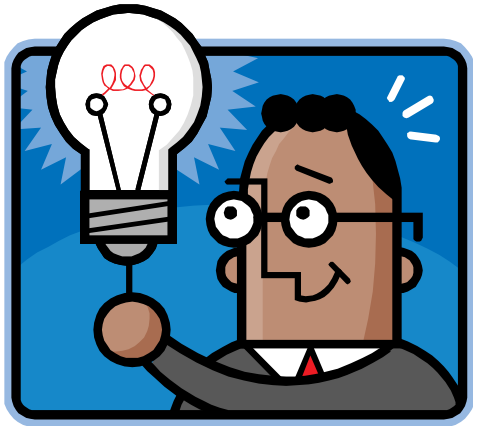
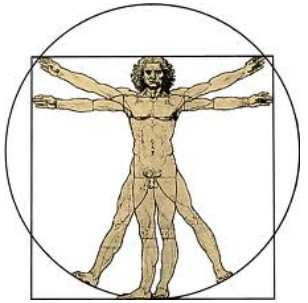
Getting your medical device to market...



Evaluate

Design

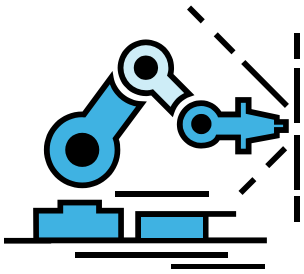


Test

Prototype

Validation

Installation

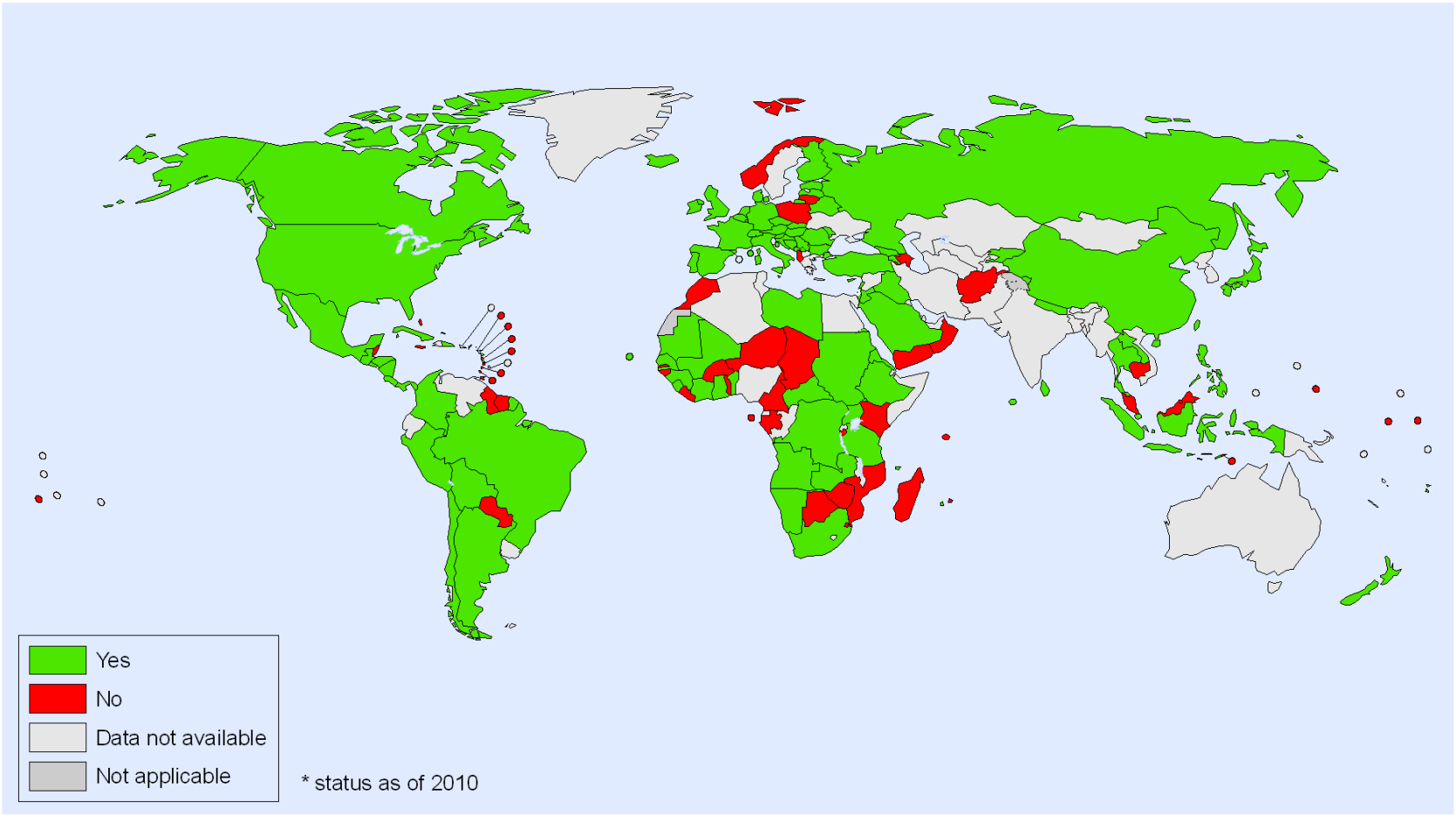


Verification

Procedures

Getting your medical device to market...

National Regulatory Agency for Medical Devices*



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Baseline country survey on medical devices 2010
Map Production: Public Health Information
and Geographic Information Systems (GIS)
World Health Organization

World Health Organization

Medical Device Regulations in Europe

- Medical Devices Directive → CE Marking
- Derogation into law by Member States
- 'Competent Authority'
- Notified Body

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CE marking in a single slide

1.	Check Scope of Medical Device Directive	(Article 1)
2.	Determine "Device Class"	(Article 9, Annex IX)
3.	Select "Conformity Assessment Procedure"	(Article 11)
4.	Identify Applicable "Essential Requirements"	(Article 3, Annex I)
5.	Assemble "Technical Documentation"	(Annex II, III, VII)
6.	Apply Conformity Assessment Procedure	(Annexes II-VII)
7.	Complete "Declaration of Conformity"	(Annexes II-VII)
8.	Affix "CE Mark", Register with CA	(Article 17, Article 14)
9.	Review and update, Post-Market Surveillance	(Annexes II, IV, V, VI, VII, VIII, X)

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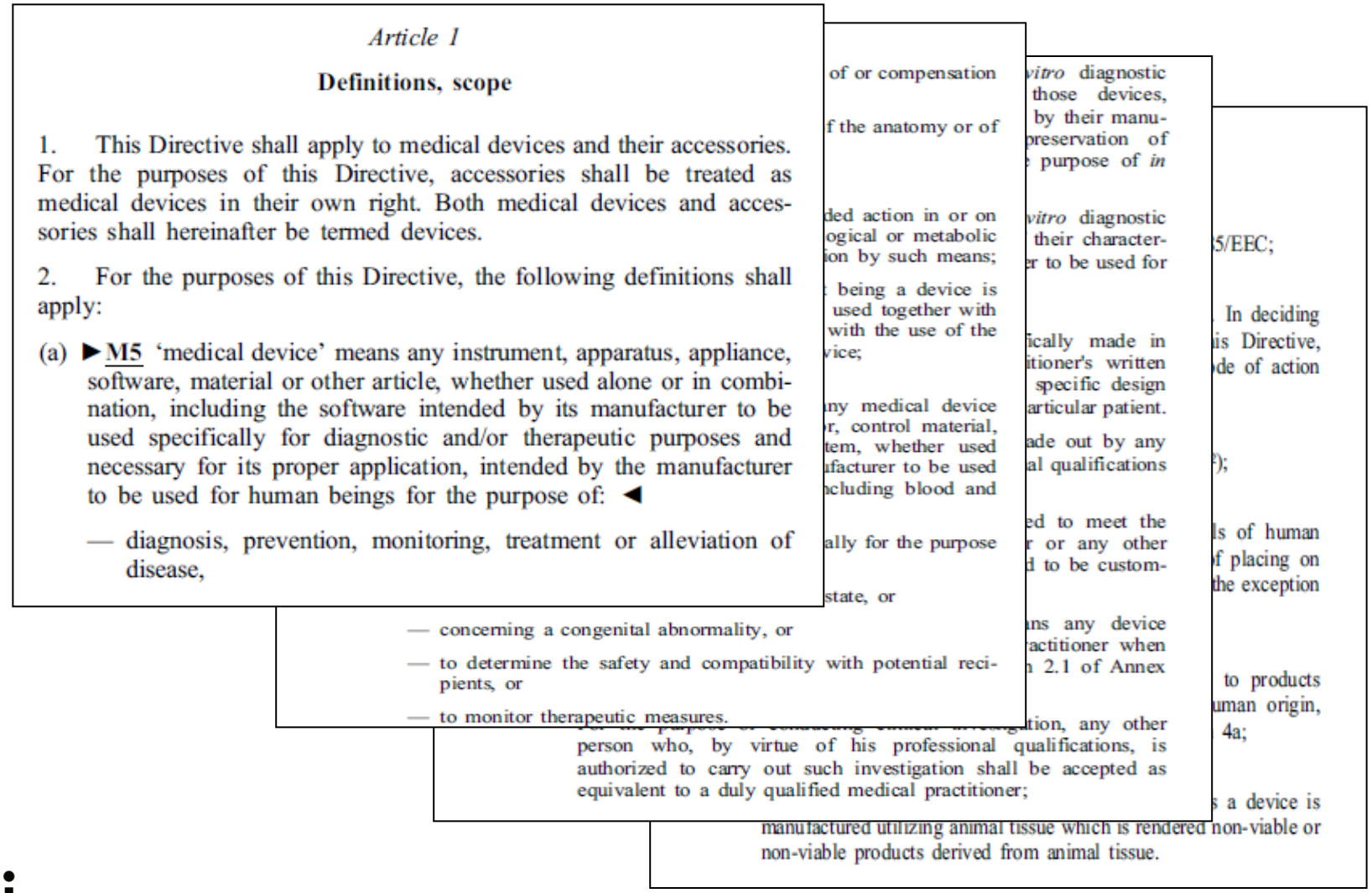
1. Check Scope of Medical Devices Directive

- Is this a medical device?
- Are you the legal manufacturer?

Definition of Medical Device per the Directive...



Article 1

Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) ►M5 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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,

— concerning a congenital abnormality, or

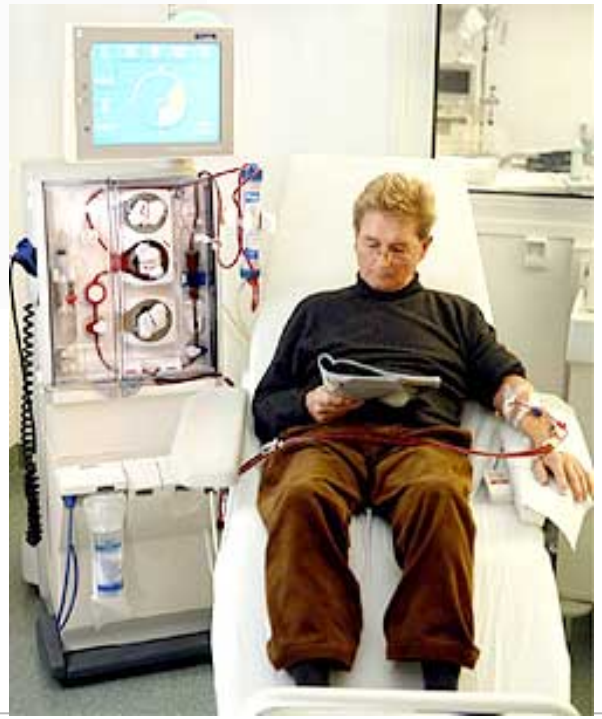
— to determine the safety and compatibility with potential recipients, or

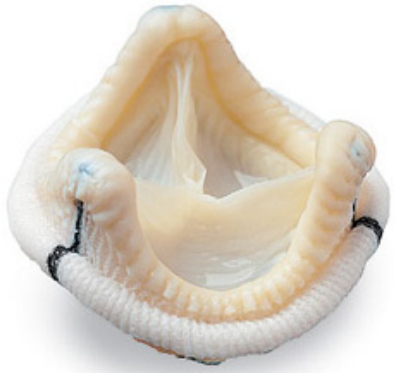
— to monitor therapeutic measures.

person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

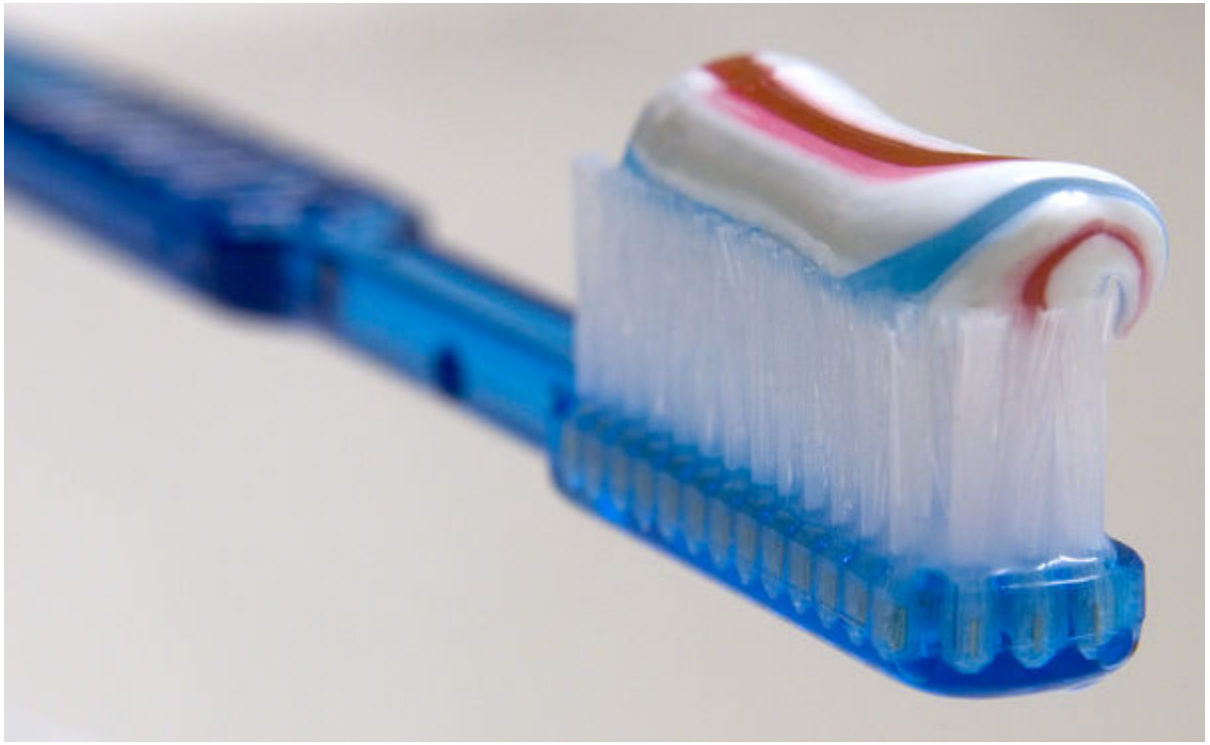
manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

What is a Medical Device?





What is a Medical Device?



What is a Medical Device?

'medical device' means any instrument, apparatus, appliance, software, material or other article... intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- ...(or of) 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 principle intended action ... by pharmacological, immunological or metabolic means..

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What is (or is not) a Medical Device?

Medical Devices Directives do not cover:

- Medicinal products
- Cosmetics
- Human blood derivatives
- Transplants or tissues of human origin
- Transplants or tissues of animal origin (unless non-viable)

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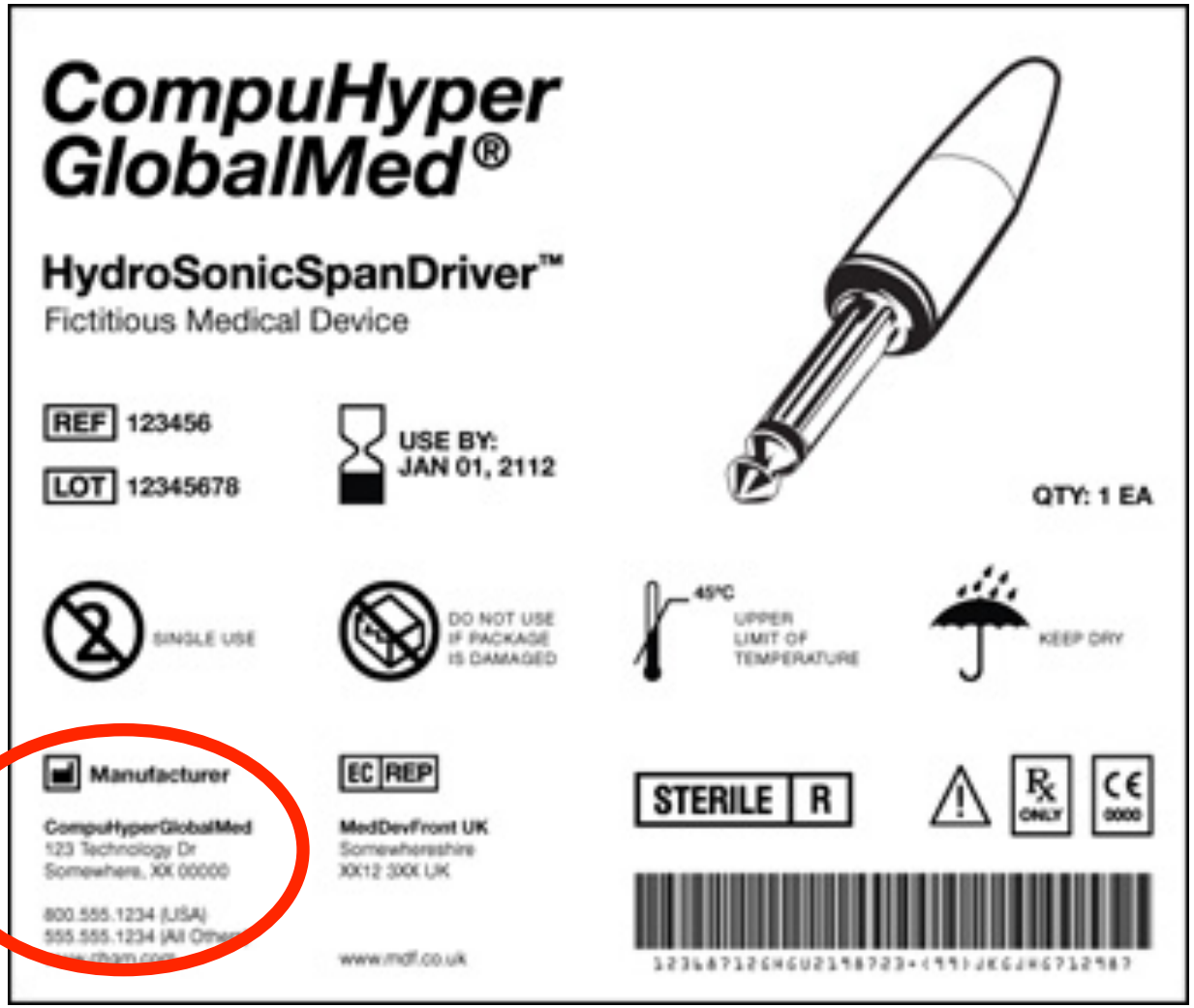
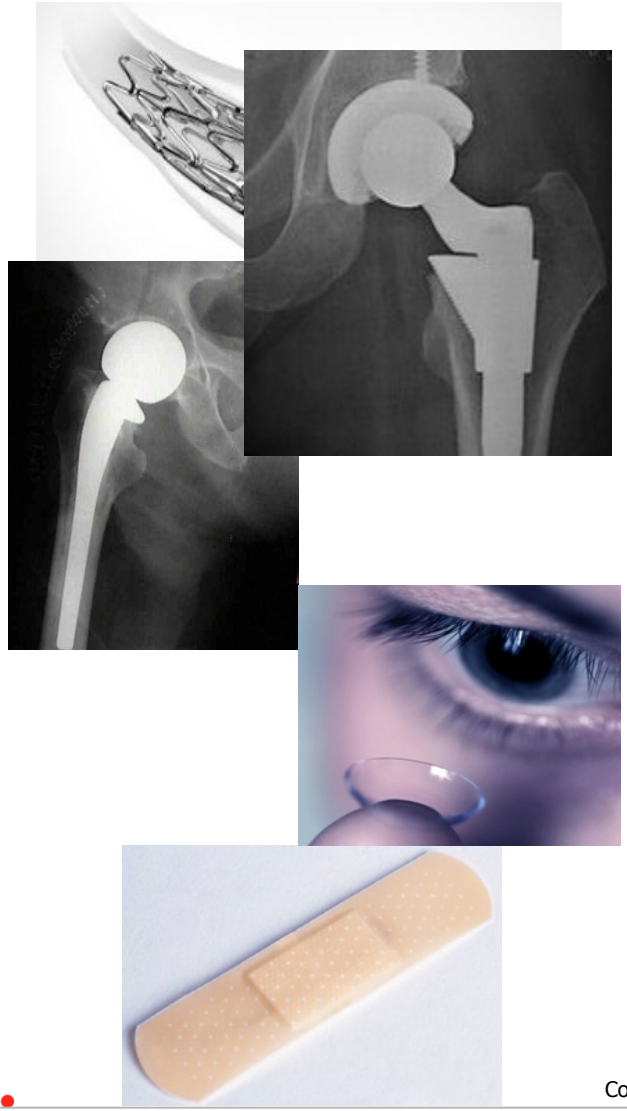
Who is the legal manufacturer?



1. Check Scope of Medical Device Directive

2. Determine Device Class

Annex IX Classification Rules



RISK

Class III

Class IIb

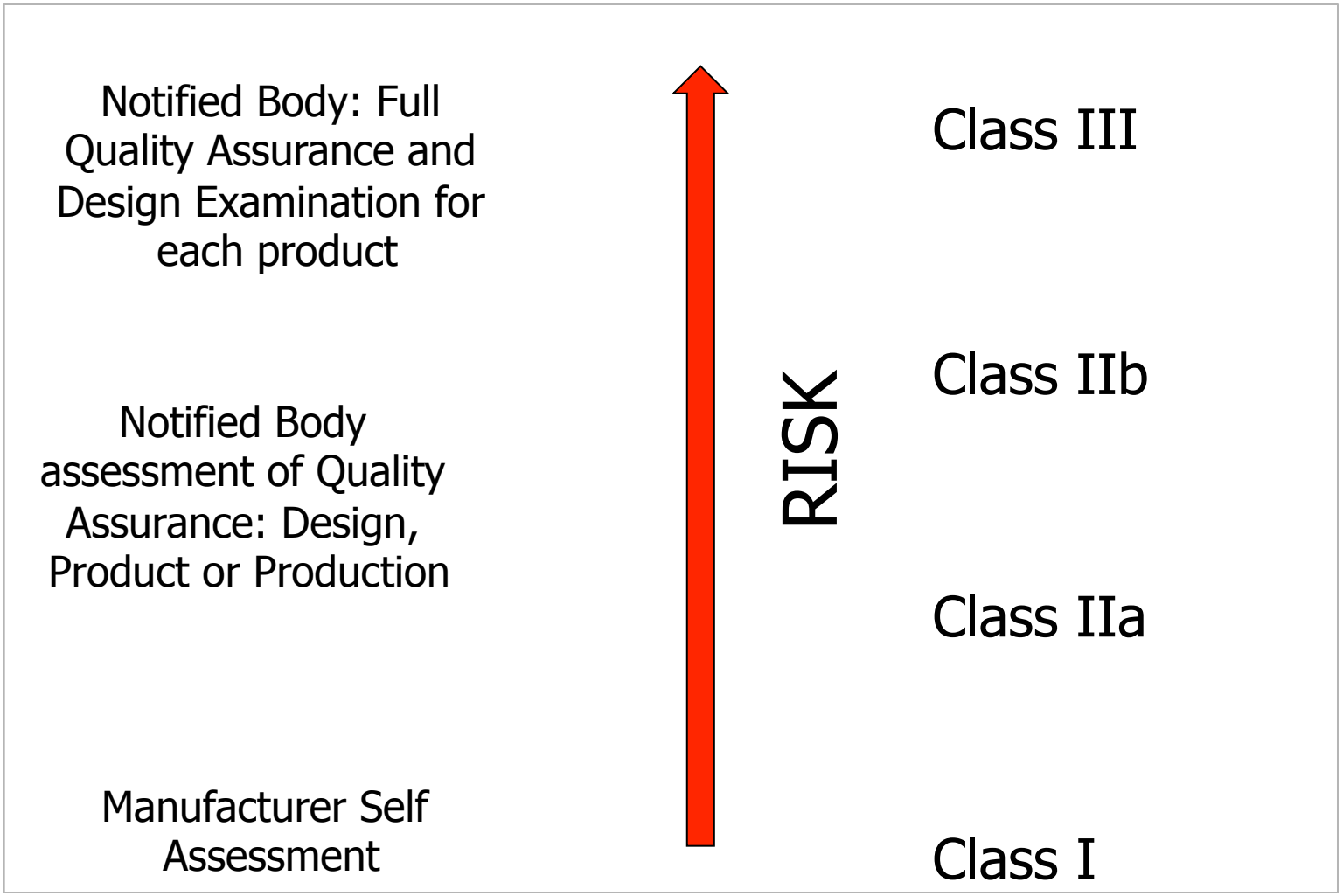
Class IIa

Class I

1. Check Scope of Medical Device Directive
2. Determine Device Class

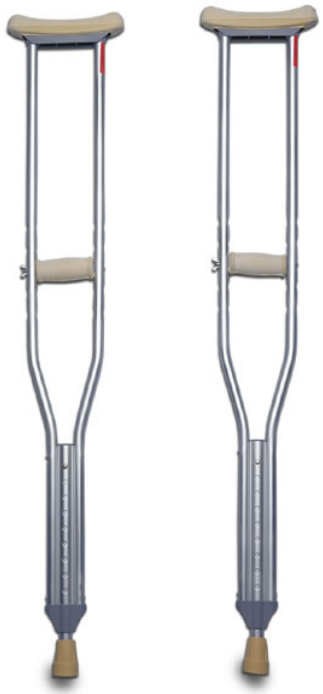
3. Select "Conformity Assessment Procedure"

“Conformity Assessment Procedure” according to Risk



“Conformity Assessment Procedure” – Class I

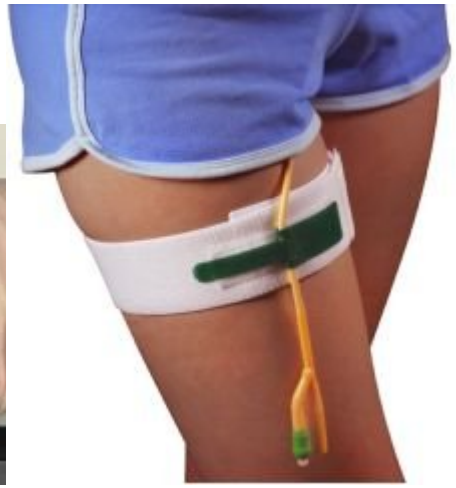
- Self-certification – no Notified Body involvement
- Assemble technical documentation + register with Competent Authority



“Conformity Assessment Procedure” – Class IIa

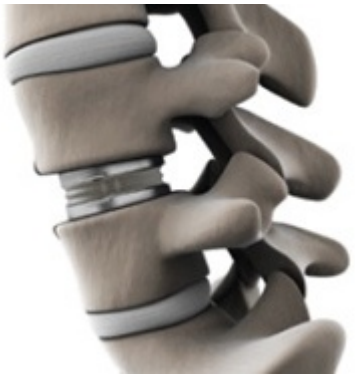
- Batch testing OR
- Production Quality Assurance OR
- Product Quality Assurance (final inspection and test) OR

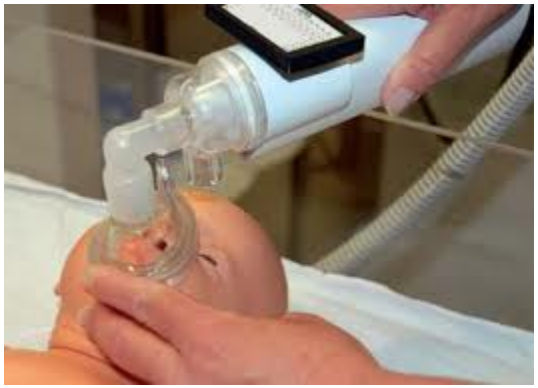
- Full Quality Assurance (includes sample of technical documentation)



“Conformity Assessment Procedure” – Class IIb

- Routes as for Class IIa devices + “Type Examination” OR
- Full Quality Assurance (includes sample of technical documentation)



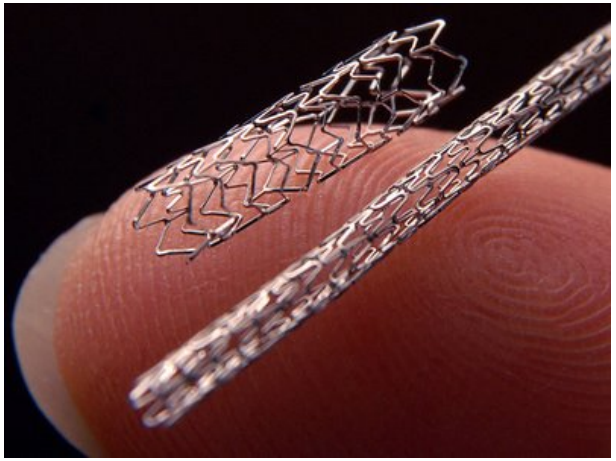


“Conformity Assessment Procedure” – Class III

- ‘Type’ Examination + Batch or Production QA OR
- Full Quality Assurance + Design Examination

Aortic Model

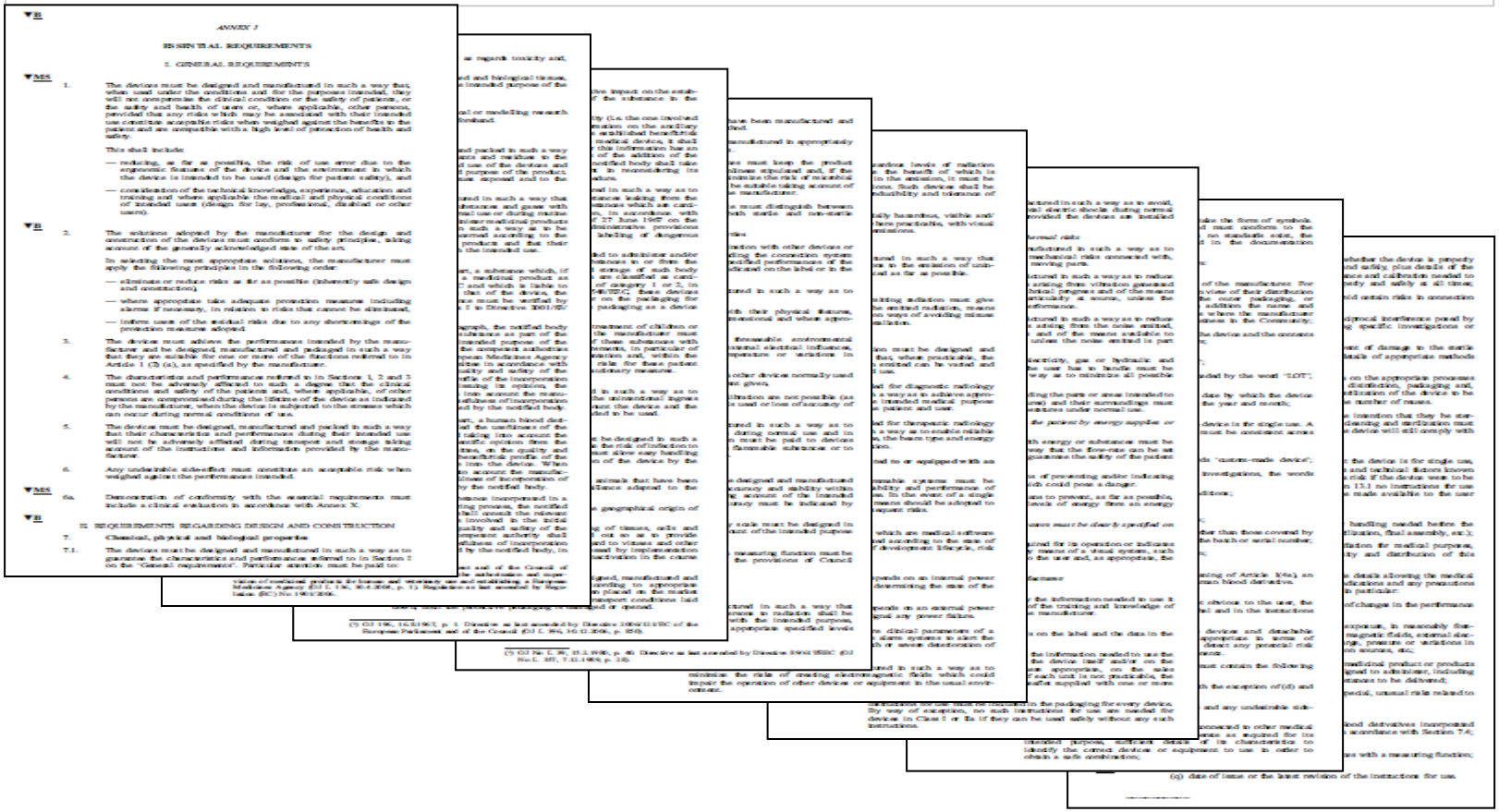
Mitral Model



1. Check Scope of Medical Device Directive
2. Determine Device Class
3. Select "Conformity Assessment Procedure"

4. Identify Applicable "Essential Requirements"

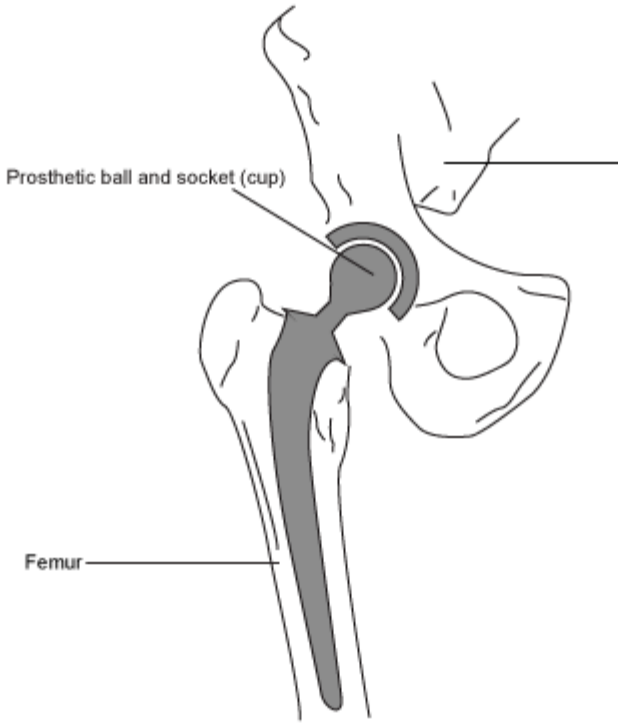
Essential Requirements (ER) What are they?



Essential Requirements (ER) What are they?

- Devices must be safe, effective, and fit for purpose
  - General: performance as intended, safe, state of the art, risks must outweigh benefits, durable over lifetime, packaging, shelf life
  - Clinical evaluation
  - Specific: biocompatibility testing, sterilisation validation, mechanical testing, software validation, electrical safety, compatibility with other devices, etc...
  - Reference to harmonised and other key standards
  - Warnings, labels, instructions

Applicable Essential Requirements - examples



- Mechanical test data (fatigue, wear, surface finish, sphericity, etc)

  (ISO 21534, ISO 7206, ISO 14242, etc...)
- Biocompatibility (ISO 10993 series)
- Useability / ergonomics of instruments (EN 62366)
- Sterilisation (EN 556, etc)
- Packaging (ISO 11607 and related standards)
- Clinical Evaluation (ISO 14155)
- Labelling (EN 1041, EN 980)

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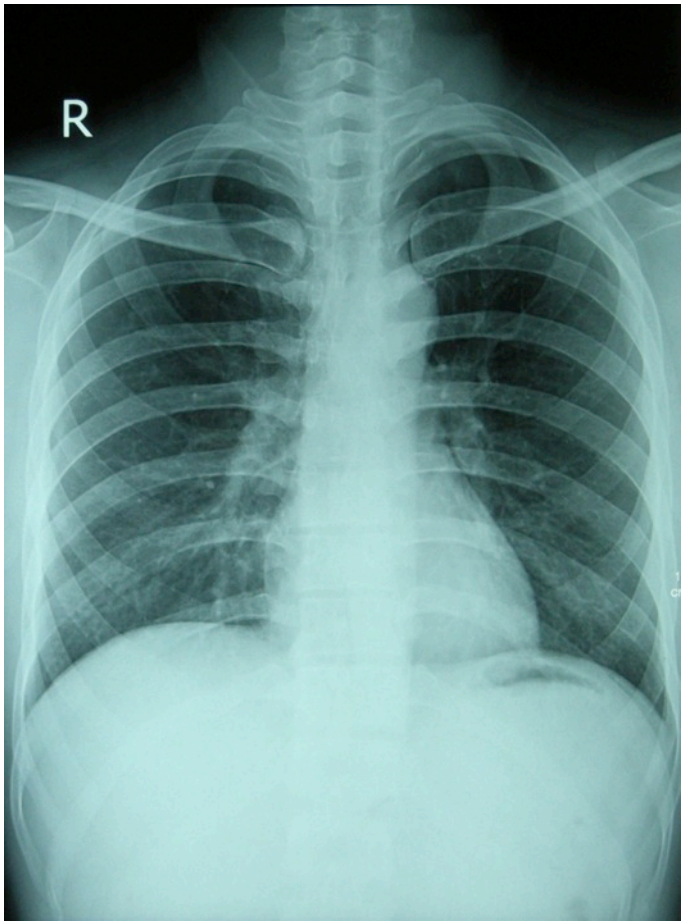
Applicable Essential Requirements - examples



- Electrical safety (EN 60601-2-44)
- Ionising radiation (EN 60601-1-3, EN 60601-2-8, EN 60601-2-38)
- Imaging resolution and accuracy (EN 62220-1)
- Usability / ergonomics (EN 62366)
- Clinical Evaluation (ISO 14155)
- Labelling (EN 1041, EN 980)

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1. Check Scope of Medical Device Directive
2. Determine Device Class
3. Select "Conformity Assessment Procedure"
4. Identify Applicable "Essential Requirements"

5. Assemble "Technical Documentation"

What is “Technical Documentation”?

- Device description and manufacturing process
- Risk evaluation
- Results of testing to demonstrate compliance to ERs (biological safety, sterilisation validation, packaging validation, mechanical testing, etc)
- Clinical evaluation
- Labelling and instructions
- Post-market surveillance plan

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Post Market Surveillance

- Application for assessments of quality systems (ie conformity routes) must include: "an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase,"
- Requirement for all medical devices, to ensure safety and performance are still comparable with state of the art
- Impact of clinical evaluation by design equivalence

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Post Market Experience - example

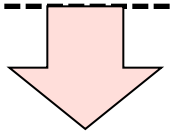
1. Check Scope of Medical Device Directive
2. Determine Device Class
3. Select "Conformity Assessment Procedure"
4. Identify Applicable "Essential Requirements"
5. Assemble "Technical Documentation"

6. Apply Conformity Assessment Procedure

Conformity Assessment Procedure

- Class I: Assemble technical documentation + register with Competent Authority

- Class IIa or IIb: Send product samples to NB for testing, or arrange appropriate quality system audits and technical documentation samples
- Class III: NB to audit Full Quality System and Design Examination of device



Certificate(s)

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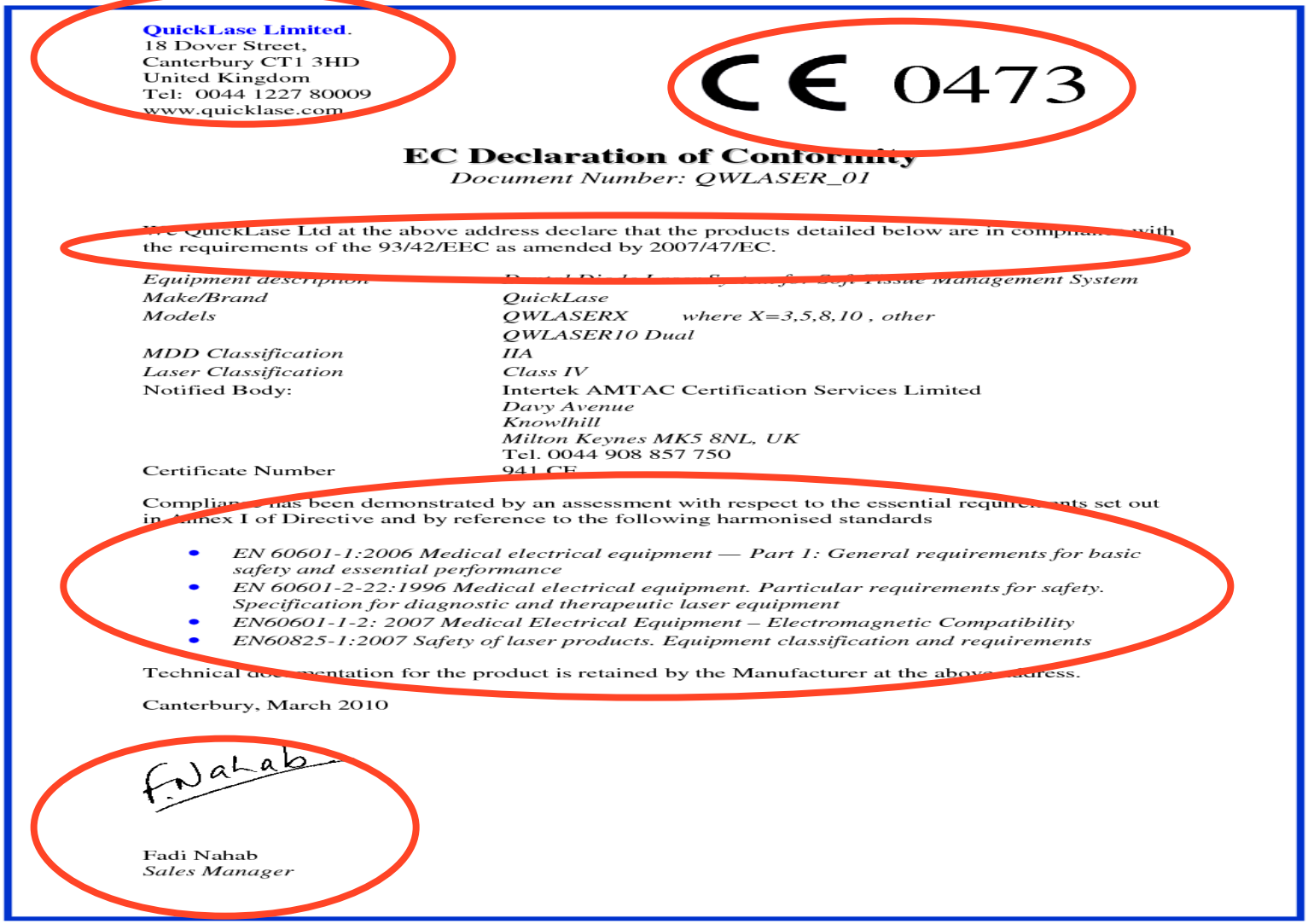
2. Determine Device Class
3. Select "Conformity Assessment Procedure"
4. Identify Applicable "Essential Requirements"
5. Assemble "Technical Documentation"
6. Apply Conformity Assessment Procedure

7. Complete "Declaration of Conformity"

Example "Declaration of Conformity"



QuickLase Limited.
18 Dover Street,
Canterbury CT1 3HD
United Kingdom
Tel: 0044 1227 80009
www.quicklase.com

CE 0473

EC Declaration of Conformity

Document Number: QWLASER_01

We QuickLase Ltd at the above address declare that the products detailed below are in compliance with the requirements of the 93/42/EEC as amended by 2007/47/EC.

Equipment description	*Dental Diode Laser System for Soft Tissue Management System*
Make/Brand	*QuickLase*
Models	*QWLASERX where X=3,5,8,10 , other* *QWLASER10 Dual*
MDD Classification	*IIA*
Laser Classification	*Class IV*
Notified Body:	Intertek AMTAC Certification Services Limited *Davy Avenue* *Knowlhill* *Milton Keynes MK5 8NL, UK* Tel. 0044 908 857 750
Certificate Number	941 CE

Compliance has been demonstrated by an assessment with respect to the essential requirements set out in Annex I of Directive and by reference to the following harmonised standards

- *EN 60601-1:2006 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
- *EN 60601-2-22:1996 Medical electrical equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment*
- *EN60601-1-2: 2007 Medical Electrical Equipment – Electromagnetic Compatibility*
- *EN60825-1:2007 Safety of laser products. Equipment classification and requirements*

Technical documentation for the product is retained by the Manufacturer at the above address.

Canterbury, March 2010

F.Nahab

Fadi Nahab
Sales Manager

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8. Affix "CE Mark", Register with CA

Article 14:
"Any manufacturer who, under his own name, places devices on the market .... shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned."

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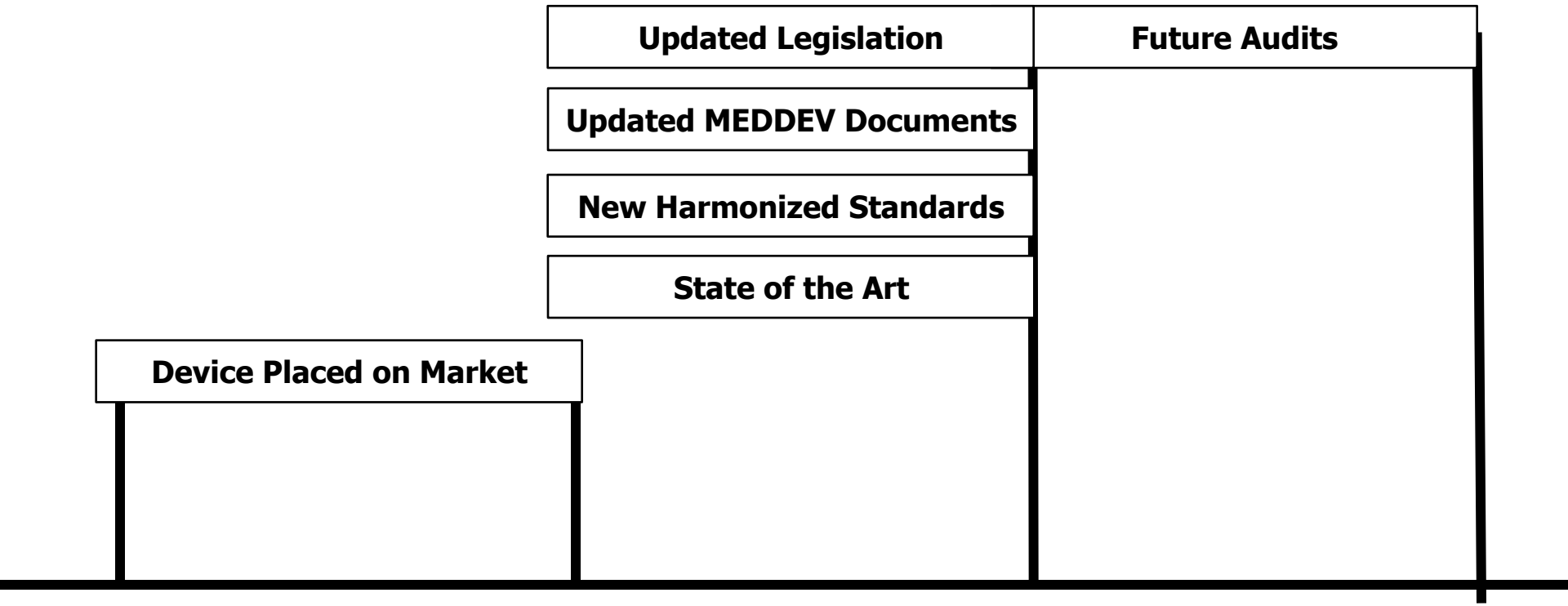
9. Review and update, Post-Market Surveillance

Updating the Information:



Feedback from manufacturers...

Dear Ms Smirthwaite,

We were extremely dismayed to hear your opinion that the [redacted] *requires a clinical trial.*

The cost of clinical trials is prohibitive, and we are a small company and cannot possibly afford this.

Moreover, we secured venture capital on the basis that we would be able to market the device in Europe by Q3 2013. Without the revenue and clinical data generated by the European launch, we will be unable to gain market approval for these devices in the US...

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CE marking in a single slide

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Any Questions?