CE Marking - Changing & Evolving Requirements

September 2013
2013 BSI Healthcare Roadshow
Existing Directives
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)
   Assemble "**Technical Documentation**" (Annexes II, III, VII)
5. Complete "**Declaration of Conformity**" (Annexes II-VII)
6. Affix "**CE Mark**" (Annex XII)

**Directive 93/42/EEC**

**Directive 90/385/EEC ~ similar ~ one class**

**Directive 98/79/EC ~ similar ~ list for classification**
New Regulations - 2015?
New Regulations

Medical Devices

- Draft 26. September 2012
- EU Commission
- Council of Ministers
- European Parliament
- 212+60+907 Proposed amendments 04. April 2013
- Compromise amendments August & September 2013

In vitro Diagnostics

- Draft 26. September 2012
- EU Commission
- Council of Ministers
- European Parliament
- 113+20+399 Proposed amendments 04. April 2013
- Awaiting Compromise amendments
Medical Device Regulation

1. Check Definition of **Device** (Article 2)
2. Determine “**Device Class**” (Article 41, Annex VII)
3. Select “**Conformity Assessment Procedure**” (Article 42, Annexes VIII, IX, X, XI)
4. Identify Applicable “**Safety & Performance Requirements**” (Article 4, Annex I) “**Technical Documentation**” (Annex II)
5. Complete “**Declaration of Conformity**” (Article 17, Annex III)
6. Affix “**CE Mark**” (Article 18, Annex IV)
In vitro Diagnostics Regulation

1. Check Definition of **Device**  (Article 2)

2. Determine “**Device Class**”  (Article 39, Annex VII)

3. Select “**Conformity Assessment Procedure**”  (Article 40, Annexes VIII, IX, X)

4. Identify Applicable “**Safety & Performance Requirements**”  (Article 4, Annex I)
   “**Technical Documentation**”  (Annex II)

5. Complete “**Declaration of Conformity**”  (Article 15, Annex III)

6. Affix “**CE Mark**”  (Article 16, Annex IV)
Device
Medical Device – Article 2

‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for injury or disability,
- investigation, replacement or modification of anatomy or physiological process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,
Medical Device – Article 2

... and which does not achieve its principal intended action ... by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The software intended by the manufacturer of a medical device to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application falls within the definition of a medical device.

The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.
New – Annex XV

- Contact lenses;
- Implants for modification / fixation of body parts;
- Facial or other dermal or mucous fillers;
- Equipment for liposuction and lipolysis;
- Laser equipment to be used on the human body;
- Intense pulsed light equipment;
- Tattoo ink;
- Chemical peels.
Active Medical Device – Article 2

‘Active device’ means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by gravity* and which acts by changing the density of or converting this energy.

Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, are not considered to be active devices.

Stand alone software is considered to be an active device;
In vitro diagnostic medical device - Article 2

‘In vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

• concerning a physiological or pathological state, or
• concerning a congenital abnormality, or
• concerning the predisposition to a medical condition or disease, or
• to determine the safety / compatibility with potential recipients, or
• to predict treatment response or reactions, or
• to define or monitor therapeutic measures.
In vitro diagnostic medical device - Article 2

Specimen receptacles are considered to be in vitro diagnostic medical devices. For the purposes of this Regulation, 'specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

*Article 1 – this Regulation does not apply to:
  a) products for general laboratory use, unless such products, in view of their characteristics, are specifically intended by their manufacturer to-be used for in vitro diagnostic examination;
  b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;
Classification
Classification & Conformity Assessment – Based on Risk

Device Classification:

Medical Device Coordination Group

Scrutiny

Notified Body Conformity Assessment

Self-Certification

Risk

Class III

Class IIb

Class IIa

Class I

Risk

Class D

Class C

Class B

Class A
Annex VII – 21 Classification Rules:

1 - 4  Non invasive devices
5 - 8  Invasive devices
9 - 12  Active devices
13 - 21  Special rules
Changes to Rules - #3:

- All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or infusion into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa.

- All non-invasive devices intended to be used for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions, are in class IIb.
Changes to Rules – #6:

- All surgically invasive devices intended for transient use are in Class Iia unless they are:
  - intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,
  - reusable surgical instruments, in which case they are in Class I,
  - intended specifically for use in direct contact with the central nervous system, in which case they are in Class III,
  - intended to supply energy in the form of ionising radiation in which case they are in Class IIb,
  - intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,
  - intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.
Changes to Rules – #8:

• All implantable devices and long-term surgically invasive devices are in class IIb unless they:
  • – are intended to be placed in the teeth, in which case they are in class IIa,
  • – are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,
  • – have a biological effect or are wholly or mainly absorbed, in which case they are in class III,
  • – are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class III,
  • – are active implantable medical devices or implantable accessories to active implantable medical devices, in which case they are in class III,
  • – are breast implants, in which case they are in class III,
  • – are hip, knee, shoulder, hand, wrist and ankle total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
  • – are spinal disc replacement implants, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments.
Changes to Rules – #9:

- All active therapeutic devices intended to administer or exchange energy are in class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in class IIb.
- All active devices intended to control or monitor the performance of active therapeutic devices in class IIb, or intended directly to influence the performance of such devices are in class IIb.
- All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable medical devices are in class III.
Changes to Rules – #11:

• All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in class IIb.

• Active therapeutic device intended to define therapeutic measures are in class IIa, unless there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring in which case they are in class IIb.
Changes to Rules – #17:

• All devices manufactured utilising* tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising* tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only.

Directive 2003/32/EC Obsolete

Regulation No 722/2012 Repealed
New Rule – #19:

• ‘nanomaterial’ means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

• Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

• – ‘particle’ means a minute piece of matter with defined physical boundaries;

• – ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

• – ‘aggregate’ means a particle comprising of strongly bound or fused particles;
New Rule – #20:

Aphaeresis

Class III?
New Rule - #21:

- Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.
New Rule – #?:

• All invasive devices with respect to body orifices, other than surgically invasive devices which are intended to administer medicinal products by means of a delivery system via the pulmonary route are in class IIa, unless their mode of operation has an essential impact on the efficacy and safety of the administered medicines and those are intended to treat severe diseases. In this case they are in class IIb.
New Rule – #?:

- Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.

Class III
Annex VII – 8 New Classification Rules

Class D (Blood screening)

- Transmissible agents; life threatening or high risk of propagation
- Blood grouping, tissue typing (ABO, Rhesus, Kell, Kidd and Duffy systems)
Annex VII – 8 New Classification Rules

Class C

• Blood grouping, tissue typing - immunological compatibility
• Screening to detect infectious agents with limited risk of propagation
• STD’s; pre-natal screening; infectious agents where risk could cause death/damage to individual/offspring
• Determining infectious diseases or immune status, if risk that error would lead to death
• Management of patient suffering from life-threatening disease
• Screening for congenital disorders in foetus
• Screening, diagnosis, or staging of cancer
• Monitoring medicinal products, substances or biological components given to patient
Annex VII – 8 New Classification Rules

Class B
• Any IVD not listed under Classes D, C or A.
• Controls without a qualitative or quantitative assigned value

Class A
• Reagents, other articles with specific characteristics
• Instruments intended specifically for use in IVD procedures
• Specimen receptacles
Classification:

**IVD Directive**
- Require a Notified Body
- Do not require a Notified Body

**IVD Regulation**
- Require a Notified Body
- Do not require a Notified Body
Conformity Assessment
Class I Device
(non-sterile / no measuring function)

Annex II
Technical Documentation

Declaration of Conformity & CE Marking
Class I Device
(sterile / measuring function)

Annex II
Technical Documentation

* Only aspects related to sterility / measuring function

Annex VIII*
Full Quality Assurance

Annex X*
Batch Verification

Declaration of Conformity & CE Marking

bsi. Medical Devices

0086

0086

Article 42 Point 5
Class II b Device

Annex IX
Type Examination

Annex VIII
Full Quality Assurance

Annex X
Batch Verification

Declaration of Conformity & CE Marking

BSI
Class III Device

Annex VIII
Design Examination

Annex VIII
Full Quality Assurance

Annex IX
Type Examination

Annex X
Batch Verification

Article 44 MDCG Scrutiny

Declaration of Conformity & CE Marking
EU Commission

- Medical Device Coordination Group (MDCG) – Article 78
  - n=1 from each Member State MD / n=1 from each Member State IVD

Tasks of the MDCG – Article 80

- Article 32 – Assessment of Applications of Notified Bodies
- Article 35 – Monitoring of Notified Bodies
- Article 41 – Classification Disputes
- Article 44 – Conformity Assessment of Class III Devices
Annex XIII – Part B – Clause 3

• 3. For class III medical devices, the manufacturer's PMCF evaluation report shall be reviewed by an independent body under the principles of highest scientific competence and impartiality.

• In order to conduct its review, the manufacturer shall provide the relevant data to the independent body. Both the manufacturer's PMCF evaluation report and its review by an independent body shall be part of the technical documentation for class III medical devices.
Class A Device

Annex II
Technical Doc.

Declaration of Conformity & CE Marking
Class A Device
(sterile / measuring function)

Annex II
Technical Doc.

Annex VIII*
Full Quality Assurance

Annex X*
Batch Verification

Declaration of Conformity & CE Marking

* Only aspects related sterility / measuring function
Class B Device

Annex VIII
- Full Quality Assurance

Declaration of Conformity & CE Marking

CE 0086  CE 0086
Class C Device

Annex IX
Type Examination

Annex VIII
Full Quality Assurance

Annex X
Production Quality Assurance

Declaration of Conformity & CE Marking
Safety & Performance Requirements
General Requirements #1-6

Moving to GHTA Wording
Requirements MD #7-19 / IVD #7-18

7. Chemical, Physical & Biological Properties
8. Infection & Microbial Contamination
9. Incorporating Medicinal Substance
10. Incorporating Biological Materials
11. Interaction with their environment
12. Diagnostic or measuring function
13. Protection against radiation
14. Software
15. Active devices and devices connected to them
16. Protection against mechanical and thermal risks
17. Protection against energy / Self Test & Near Patient Testing
18. Protection against risks posed devices for use by lay persons
19. Information Supplied by the Manufacturer
Clinical Evidence - NO Safety & Performance Requirement

Critical Evaluation of Scientific Literature
- clinical safety & performance
- equivalent devices
Annex XIII

Critical Evaluation of combination of
- Evaluation of Literature
- Investigations

Critical Evaluation of Clinical Investigations
Annex XIV

Every class of device under every route of conformity has Technical Documentation (Annex II).
Article 61 applies to every class of device under every route of conformity.
Technical Documentation
Annex II

• The technical documentation and, if applicable, the (STED) to be drawn up by the manufacturer shall include:
  
• **Device description and specification**
• **Reference to previous and similar generations of the device**
• **INFORMATION SUPPLIED BY THE MANUFACTURER**
• **DESIGN AND MANUFACTURING INFORMATION**
• **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**
• **RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**
• **PRODUCT VERIFICATION AND VALIDATION**
• **Pre-clinical and Clinical data / Clinical Performance data**
• **Additional information in specific cases**
Declaration of Conformity
EU Declaration of Conformity – Annex III:

Declaration of Conformity

Manufacturer: Name, registered trade name or registered trade mark

Address: Address of their registered place of business
Where they can be contacted and their location is established

EU Authorised Representative: Name and address

Devices:

• Product or model name, product number, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered (it may include a photograph, where appropriate)
• EU device identifier

Risk class of the device in accordance with Annex V

References to the relevant harmonised standards / common technical specifications

Where applicable, additional requirements

Official Body: The name, registered identification number

Description of the conformity assessment procedure performed

Identification of the certificate(s) issued

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

A statement that the device is in conformity with this legislation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity.

Name and function of the person who signs

Signature _______ Indication for and on behalf of whom he/she signs _______

Date ______ Place and date of issue ________
CE Mark
Questions?
### Timelines:

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1. **1ST Reading** – 19 November 2013
2. **2nd Reading** – either Q1 2014 or Q3/Q4 2015
3. **Designation of Notified Bodies**
4. **3 Year Transition**
5. **5 Year Transition**

**Regulation covering MD & AI MD**

**Regulation covering IVD**

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BSI. Medical Devices | In Vitro Diagnostics