Medical Devices Regulations - 10 Steps to Certification

Ibim Tariah
October 2016
Agenda

• How we got to this point …
• How to read 350 pages …
• Next Steps …
How we got to this point …
Medical Device Regulation (MDR)

2008
EU Commission launches consultation on MD framework

2012
EU Commission publishes proposal for new MD Regulation

2014 Q2
EU Parliament adopts position on MDR

2015 Q3
EU Council adopts position on proposed Regulation

2015 Q4
Trilogues between Commission, Parliament and Council start

End 2016/Early 2017
Expected publication of the adopted MDR in EUOJ
Next steps

- NL Presidency informs the EPSCO ministers of the outcomes (no decision made there)
- The text is translated into all 24 languages
- **COUNCIL approves the political agreement** - (September?)
- COM lawyer linguists to review all translations of the text (likely to take several months)
- **COUNCIL and EP to formally adopt the final text** (late 2016/early 2017?)
- Finalisation (Publication in Official Journal) - current estimate: **end 2016/early 2017**

**Transition period:**
- medical devices ⇒ three years after publication
- in vitro diagnostic medical devices ⇒ five years after publication
Brussels, 27 June 2016

Institutional File:
2012/0206 (COD)

PHARM 41
SAN 278
MI 473
COMPET 394
CODEC 947

NOTE

From: General Secretariat of the Council
To: Delegations

No. prev. doc.: 9364/16 PHARM 30 SAN 211 MI 370 COMPET 316 CODEC 722
No. Conj doc.: 14403/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1


Delegations will find the consolidated text of the proposed Regulation on medical devices in the Annex to this Note. This is a "clean" version without any difference between "new text" and text from the Commission proposal.

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10617/16

DGB 3B

LES + LA /as

EN

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Key Changes …
Key changes

- **Notified Bodies**
  - Strengthened Designation Criteria
  - Joint Audits: Three Member States and Commission (FHAA)
  - Unannounced audits

- **Clinical Evidence**
  - Less Equivalence, More Data for High Risk Devices
  - Publish Safety and Performance Data
  - Post Market Clinical Follow-up

- **Pre-market**
  - Conformity Assessment
  - Scrutiny for High Risk Devices
Key changes

### Post-Market Surveillance and Vigilance
- Central Database and Co-ordination
- PSUR, SSP
- Implementing Acts, Delegated Acts, Common Specifications

### Transparency and Traceability
- Unique Device Identification (UDI)
- Implant Cards

### Governance and Oversight
- Central Committee: MDCG
- Expert Panel, Expert Laboratories
How to read 350 pages …

71 Whereas…

⇒ Why

X Chapters of 97 Articles

⇒ What

XVI Annexes

⇒ How

- Chapter I – Scope and Definitions
- Chapter II – CE Marking, Economic Operators, Reprocessing
- Chapter III – Identification and Traceability of Devices
- Chapter IV – Notified Bodies
- Chapter V – Classification and Conformity Assessment
- Chapter VI – Clinical Evaluation and Investigation
- Chapter VII – Vigilance and Market Surveillance
- Chapter VIII – Cooperation between Member States
- Chapter IX – Confidentiality, Data Protection, Funding, Penalties
- Chapter X – Final Provisions

71 Whereas...

⇒ Why

X Chapters of 97 Articles

⇒ What

XVI Annexes

⇒ How

- Annex I – General safety and performance requirements
- Annex II – Technical Documentation
- Annex III – EU Declaration of Conformity
- Annex IV – CE Marking of Conformity
- Annex V – European UDI System
- Annex VI – Requirements to be met by Notified Bodies
- Annex VII – Classification Criteria
- Annex VIII – Conformity Assessment – QMS and Technical Documentation
- Annex IX – Conformity Assessment – Type Examination
- Annex X – Conformity Assessment – Product Conformity Verification
- Annex XI – Procedure for Custom-made Devices
- Annex XII – Certificates issued by a Notified Body
- Annex XIII – Clinical Evaluation and Post-market clinical follow-up
- Annex XIV – Clinical Investigations
- Annex XV – Products without an intended medical purpose
- Annex XVI – Correlation Table 90/385, 93/42 and Regulation
Implementing and Delegated Acts

• Many instances of delegated acts and implementing acts necessary to make MDR “operational”

• Unclear when these will be available…

  e.g:

  • Regulatory status of groups of products
  • Common Specifications
  • Format of Summary of Safety and Performance
  • UDI
  • EUDAMED
  • List of NBOG codes
  • NB designation procedure
  …
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Check <strong>Device</strong> is within Scope of MDR (Chapter I, Articles 1, 2, Annex XV)</td>
</tr>
<tr>
<td>2.</td>
<td>Determine “<strong>Device Class</strong>” (Chapter V, Article 41, Annex VII)</td>
</tr>
<tr>
<td>3.</td>
<td>Select “<strong>Conformity Assessment Procedure</strong>” (Chapter V, Article 42)</td>
</tr>
<tr>
<td>4.</td>
<td>Identify Applicable “<strong>Safety and Performance Requirements</strong>” (Chapter II, Article 4, Annex I)</td>
</tr>
<tr>
<td>5.</td>
<td>Assign UDI (Chapter III, Article 24, Annex V)</td>
</tr>
<tr>
<td>7.</td>
<td>Apply Conformity Assessment Procedure (Annexes VIII, IX, X, or XI)</td>
</tr>
<tr>
<td>8.</td>
<td>Complete “<strong>Declaration of Conformity</strong>” (Chapter II, Article 17, Annex III)</td>
</tr>
<tr>
<td>9.</td>
<td>Affix “<strong>CE Mark</strong>” (Chapter II, Article 18, Annex IV)</td>
</tr>
</tbody>
</table>
Scope of MDR:
Medical and other Devices
Articles 1, 2, Annex XV
Article 2 - Medical Device

‘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 of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ blood and tissue donations.

Article 1 excludes IVD devices from this Regulation.
Article 1 – Scope – Annex XV – No Medical Purpose

• Contact lenses or other articles intended to be introduced into or onto the eye;

• Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings;

• Substances, combinations of substances, or articles intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;

• Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;

• High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;

• Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.
Article 1 – Scope – Annex XV – No Medical Purpose

Within MDR Scope?

- Yes
- No

Scope includes: Contact lenses or other articles intended to be introduced into or onto the eye
Article 1 – Scope – Annex XV – No Medical Purpose

Within MDR Scope?

☐ Yes  ☑ No

Scope includes: surgically invasive devices for modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings
Article 1 – Scope – Annex XV – No Medical Purpose

Within MDR Scope?  yes  no

Scope includes: Substances intended to be used for facial or other dermal or mucous membrane filling
Article 1 – Scope – Annex XV – No Medical Purpose

Within MDR Scope?  ☑ Yes  ❓  ☐ No

Scope includes: High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment...such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment (the device above claims to be IPL, but is it?)
Article 1 – Scope – Annex XV – No Medical Purpose

And also:

• Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;

• Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.
Chapter 1 – Implementing and Delegated Acts

• Add new products to Annex XV
• Amend the definition of nanomaterial
• Decide if specific devices are medical devices or accessories to medical devices
Classification
Annex VII
Classification & Conformity Assessment – Directive

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification

Risk

Class III

Class IIb

Class IIa

Class Im / Is

Class I

Custom Made
Classification & Conformity Assessment - Regulation

Commission Assessment

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification

Class I

Custom Made

Class Im / Is / Ir

Class IIa

Class IIb Implants

Class IIa - more sampling

Class III Implants & Class IIb active - delivering medicines

Animal tissues, human tissues, medicinal substances, absorbable

Risk

Class IIb

Class III Implants & Class IIb active - delivering medicines

Animal tissues, human tissues, medicinal substances, absorbable
21 Classification Rules:

1 - 4 Non invasive devices

5 - 8 Invasive devices

9 - 12 Active devices

13 - 23 Special rules
Changes to Rules:

Rule 2

• All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class IIa:
  • if they may be connected to an active medical device in class IIa or a higher class,
  • if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags, which are in class IIb.
• In all other cases they are in class I.
Changes to Rules:

Rule 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 administration 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 consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body are in class III.
Changes to Rules:

Rule 4

• All non-invasive devices which come into contact with injured skin or mucous membrane:
  • are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
  • are in class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent,
  • are in class IIa in all other cases, including devices principally intended to manage the micro-environment of injured skin or mucous membrane.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.
Changes to Rules:

Rule 5

- All invasive devices with respect to body orifices, other than surgically invasive devices which are not intended for connection to an active medical device or which are intended for connection to a class I active medical device:
  - are in class I if they are intended for transient use,
  - are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are in class I,
  - are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa.
- All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.
Changes to Rules:

Rule 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,
  • are reusable surgical instruments, in which case they are in class I,
  • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are in class III,
  • are intended to supply energy in the form of ionising radiation in which case they are in class IIb,
  • have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,
  • are intended to administer medicinal products 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:

Rule 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 or 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 medicinal products, in which case they are in class III,
  • are active implantable devices or their accessories, in which case they are in class III,
  • are breast implants or surgical meshes, in which case they are in class III,
  • are 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 and implantable devices that come into contact with the spinal column, in which case they are in class III with the exception of components such as screws, wedges, plates and instruments.
Repealed Directives:

- 2003/12/EC
  - Breast implants raised to class III.

- 2005/50/EC
  - Hip, knee and shoulder joint replacements raised to class III.
Changes to Rules:

Rule 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 intended to emit ionizing radiation for therapeutic purposes including devices which control or monitor such devices, or which directly influence their performance are in class IIb.
- All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are in class III.
Changes to Rules:

Rule 10a

• Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:
  • the death or an irreversible deterioration of the state of health, in which case it is in class III;
  • a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.

• Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.

• All other software is in class I.
Changes to Rules:

Rule 13

• All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices, are in class III.
Changes to Rules:

Rule 17

- All devices manufactured utilizing of 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 utilizing 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.
New Rule #19:

• All devices incorporating or consisting of nanomaterial are:
  • in class III if they present a high or medium potential for internal exposure;
  • in class IIb if they present a low potential for internal exposure;
  • in class IIa if they present a negligible potential for internal exposure.

Article 2

• ‘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’ ‘agglomerate’ ‘aggregate’
New Rule #21:

• Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, or applied on skin and that are absorbed by or locally dispersed in the human body are:

• in class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,

• in class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body,

• in class IIb in all other cases, except if they are applied on skin, in which case they are in class IIa, or

• if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities, in which case they are in class IIa.
New Rule #22:

• All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are in class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product and those that are intended to treat life threatening conditions, in which case they are in class IIb.
New Rule #23:

• Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determines the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.
Conformity Assessment Procedures
Annex VIII, IX, X, XI
Custom Made Devices (Article 42.7)

Annex XI
PROCEDURE FOR CUSTOM-MADE DEVICES

Annex XIII
PMS / PMCF / Incidents

Name of Person Authorised to make out prescription, Name of Healthcare Institution & Name of Particular Patient + Meets Requirements of Annex I
Class III Implantable – Custom Made Devices (Article 42.7a)

Annex XI
PROCEDURE FOR CUSTOM-MADE DEVICES

Annex VIII
QMS

Annex X – Part A
Production
Quality Assurance

Name of Person Authorised to make out prescription, Name of Healthcare Institution & Name of Particular Patient + Meets Requirements of Annex I

Ce 0086 Ce 0086
Class I Device (Article 42.5)
(non-sterile / no measuring function / not reusable surgical instrument)

Annex II
Technical Documentation

Declaration of Conformity (Annex III) & CE Marking (Annex IV)
Class I Device (Article 42.5) (sterile / measuring function / reusable surgical instruments)

**Annex II**
Technical Documentation

* Only aspects related to sterility / metrology / risks of reuse

**Annex VIII***
QMS

**Annex X – Part A***
Production Quality Assurance

Declaration of Conformity (Annex III) & CE Marking (Annex IV)
Class IIa Device (Article 42.4)

Annex II
Technical Documentation

Minimum sample: one representative device for each category of device

Annex VIII
QMS

Declaration of Conformity (Annex III) & CE Marking (Annex IV)

Annex X – Part A
Production Quality Assurance

Annex X – Part B
Product Verification

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Class IIb Device (Article 42.3)

Annex II
- Technical Documentation *each Generic Device Group

Annex VIII
- QMS

Annex IX
- Type Examination

Annex X – Part A
- Production Quality Assurance

Annex X – Part B
- Product Verification

Declaration of Conformity (Annex III) & CE Marking (Annex IV)

Minimum sample: one representative device for each Device Group

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Class IIb Implantable Device (Article 42.3)

Declaration of Conformity (Annex III) & CE Marking (Annex IV)

Annex VIII
Technical Documentation *each Generic Device Group

Exceptions: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

Annex VIII
QMS

Article 42.3a: list above can be amended by delegated acts

Declaration of Conformity (Annex III) & CE Marking (Annex IV)
Class III Device (Article 42.2)  
(including those with medicinal substances, human tissues or animal tissues)

Annex VIII  
Technical Documentation

Annex VIII  
QMS

Annex IX  
Type Examination

Annex X – Part A  
Production Quality Assurance

Annex X – Part B  
Product Verification

Consultation – 2001/83/EC, 2004/23/EC, 722/2012/EU (Section 6, Annex VIII)

Declaration of Conformity (Annex III) & CE Marking (Annex IV)
Class III Device* (Implants)
(including those with medicinal substances, human tissues or animal tissues)

Annex VIII
Technical Documentation

Annex VIII
QMS

Annex IX
Type Examination

Annex X - Part A
Production Quality Assurance

Annex X - Part B
Product Verification


Consultation Procedure – Annex VIII or Annex IX Section 6.0

Declaration of Conformity (Annex III) & CE Marking (Annex IV)
Annex VIII – Clause 6 / Annex IX – Clause 6

Notified Body Review

21 days

Notified Body Review

39 days

Notified Body Review

Complete Conformity Assessment

Implantable Class III

- Manufacturer’s Clinical Evaluation
- NB Clinical Evaluation Assessment Report
- PMCF Plan
- IFU
- Summary of Safety and Performance

EU Commission

- Benefit: Risk Determination
- Consistency with indications
- PMCF Plan

Notified Body Certificate

- No ‘scientific opinion’

NB Further Review

- Restrict indications
- Limit duration of certificate
- Undertake specific PMCF studies
- Adapt IFU or Summary of Safety and Clinical Performance
- Impose other restrictions

- Duly justify if advice not followed

Notified Body Certificate

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Annex I: Safety & Performance Requirements
Annex I – Safety & Performance Requirements

1. Safe, Perform as Intended, State of the Art

Much more emphasis on risk management (summarises risk management process from EN ISO 14971)
Annex I – Safety & Performance Requirements

1. Safe, Perform as Intended, State of the Art
2. Risk Reduction, Risk Management, Risk Control
3. Lifetime
4. Packaging
Annex I – Safety & Performance Requirements

1. Safe, Perform as Intended, State of the Art

2. Risk Reduction, Risk Management, Risk Control

3. Lifetime

4. Packaging

5. Evaluated Benefits of achieved performance > Known and Foreseeable Undesirable Side Effects

6. Devices with no medical purpose – “shall not present any risk or only the maximum acceptable risks”

Annex I – Safety & Performance Requirements

7. Chemical, Physical & Biological Properties

• Not just biocompatibility – also addresses mechanical properties such as strength, ductility, fracture resistance, surface properties, etc.

• Includes more detail on risks of leachables (e.g. endocrine disruptors) and labelling.
Annex I – Safety & Performance Requirements

7. Chemical, Physical & Biological Properties

8. Infection & Microbial Contamination

9. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body

10. Devices incorporating materials of biological origin
Annex I – Safety & Performance Requirements

7. Chemical, Physical & Biological Properties

8. Infection & Microbial Contamination

9. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body

10. Devices incorporating materials of biological origin

11. Construction and environmental properties

- Similar to ER9, but with more clarifying detail
Annex I – Safety & Performance Requirements

7. Chemical, Physical & Biological Properties

8. Infection & Microbial Contamination

9. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body

10. Devices incorporating materials of biological origin

11. Construction and environmental properties

12. Devices with a diagnostic or measuring function

13. Protection against radiation
Annex I – Safety & Performance Requirements

14. Electronic programmable systems

15. Active devices and devices connected to them

16. Protection against mechanical and thermal risks

• Detailed requirements for protection of patients and users against mechanical risks (e.g., resistance to movement, moving parts, instability)
Annex I – Safety & Performance Requirements

14. Electronic programmable systems

15. Active devices and devices connected to them

16. Protection against mechanical and thermal risks

17. Protection against the risks posed to the patient or user by supplied energy or substances

18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

19. Information Supplied by the Manufacturer + Implant Card (Article 16) + Promotional Material CE Marked (Article 18) + UDI (Article 24)
Chapter II, Article 4

The Commission may adopt implementing acts to ensure the uniform application of Annex I, to the extent necessary to resolve issues of divergent interpretation and practical application.
Where:

• no harmonized standards exist or
• where relevant harmonized standards are not sufficient, or
• where there is a need to address public health concerns,
the Commission ... **may** adopt common specifications (CS)

⇒ adopted by means of implementing acts

Where can these apply?

• the general safety and performance requirements set out in Annex I,
• the technical documentation set out in Annex II
• the clinical evaluation and post-market clinical follow-up set out in Annex XIII
• the requirements regarding clinical investigation set out in Annex XIV.
Identification and Traceability of Devices - Article 27 – European Databank
Identification and Traceability of Devices – Article 27 – European Databank

EUDAMED

- Electronic System on Registration / Conformity Assessment
  - Applications + Summary of Safety and Clinical Performance
- Electronic System on Certificates
  - (issued, reissued, refused, suspended, withdrawn)
- Electronic System on Vigilance
  - (incidents, FSCA, FSN) + Periodic Safety Update Report
- Electronic System on Market Surveillance
  - (measures taken by Member States)
- Electronic System on Clinical Investigations
  - (sponsors, description of investigational device, comparators, purpose, status)

Electronic System on UDI

Electronic System on Registration – Manufacturers & Authorised Representatives – SRN
Unique Device Identifiers: Chapter III, Annex V
Article 24

4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.
Article 24

4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.

• The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61.

• The Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 17.

• The manufacturer shall keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.
Article 24

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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 be established]
EU Authorised Representative: [Name and Address]

Devices:
- Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered (it may include a photograph, where appropriate)
- UDI device identifier

Risk class of the device in accordance with Annex VI

References to the relevant harmonised standards / common technical specifications
Where applicable, additional information

Notified Body: [Where applicable, name and 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 Regulation 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: [Signature]
Indication for and on behalf of whom he/she signs
Date: [Date]
Place and date of issue: [Place and date of issue]
Article 24

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- The manufacturer shall keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unequivocal way and shall include:

1. **DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES**
   - Device description and specification + **UDI**
   - Reference to previous / similar generations of the device

2. **INFORMATION SUPPLIED BY THE MANUFACTURER**

3. **DESIGN AND MANUFACTURING INFORMATION**

4. **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**

5. **RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**

6. **PRODUCT VERIFICATION AND VALIDATION**
   - Pre-clinical and clinical data
   - Additional information in specific cases
Technical Documentation – Annex II

The technical documentation and, if applicable, the (STED) to be drawn up by the manufacturer shall include:

1. DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES
   • Device description and specification
   • Reference to previous / similar generations of the device

2. INFORMATION SUPPLIED BY THE MANUFACTURER

3. DESIGN AND MANUFACTURING INFORMATION

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT

6. PRODUCT VERIFICATION AND VALIDATION
   • Pre-clinical and clinical data
   • Additional information in specific cases
Declaration of Conformity
Annex III
Declaration of Conformity – Annex III

- Name, Single Registration Number and address of the manufacturer;
- If applicable, name and address of the authorised representative;
- A statement that the declaration of conformity is issued under the responsibility of the manufacturer;
- UDI – Article 24;
- Product and trade name, product code, catalogue number or other unambiguous reference, including intended purpose;
- Risk class of the device in accordance with Annex VII;
- A statement that the device is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
- References to the relevant harmonised standards / common specifications used in relation to which conformity is declared;
- Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;
- Where applicable, additional information;
- Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.
Certificates & CE Mark
Annex XII & Annex IV
Certificates Issued by a Notified Body – Annex XII:

- name, address and identification number of the notified body;
- name and address of ONE manufacturer and, if applicable, of the authorised representative;
- unique number identifying the certificate;
- single registration number of the manufacturer;
- date of issue;
- date of expiry;
- data needed for the unambiguous identification of the device(s);
- Product Specific: clear identification (name, model, type) of device, intended purpose (same as in IFU), risk classification and UDI;
- Quality System: identification of device or groups of devices, risk classification and for Class IIb the intended purpose;
- if applicable, reference to a replaced previous certificate;
- reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
- examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);
- if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
- if applicable, information about the surveillance by the notified body;
- conclusions of the notified body’s conformity assessment with regard to the relevant Annex;
- conditions for or limitations to the validity of the certificate;
- legally binding signature of the notified body according to the applicable national law.
Post Market
True or False?

Existing devices will be automatically grandfathered into the new Regulation without need for clinical investigation or further documentation.

☑️ True ☐️ False
QMS

PMS
Article 60a

Vigilance
Article 61-66

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up
Annex XIII

Applies to every class of device under every route of conformity.
Post-market surveillance, vigilance and market surveillance - Article 60 C - Periodic Safety Update Report

- Per device and where relevant per category or group of devices, manufacturers of devices in class IIa, IIb and III shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.

- Manufacturers of class IIb and III devices shall update the report at least annually.
- Manufacturers of class IIa devices shall update the report when necessary and at least every two years.
- Manufacturers of devices in class III or implantable devices shall submit reports by means of the electronic system to the notified body. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.

Throughout lifetime:

- Conclusions of the benefit risk determination
- Main findings of PMCF
- Volume of Sales
- Estimate of the Population that use the device
- Where practicable usage frequency of the device
Identification and Traceability of Devices  
- Article 26 - Summary of Safety and Clinical Performance

- In the case of devices classified as class III and implantable devices, the manufacturer shall draw up a summary of safety and clinical performance.
- It shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be available to the public via EUDAMED.
- The draft of this summary shall be submitted to the notified body and shall be validated by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.

Article 49 – Clinical Evaluation

For devices classified as class III and implantable devices, the PMCF report and, if indicated, the summary of safety and clinical performance shall be updated at least annually with these data.
Next Steps …
Notified Body Designation – Key Steps

STEP 1
- **NB** prepares Dossier and Applies for Designation under MDR
- **CA** checks & reviews application dossier, if satisfactory prepares preliminary assessment report and submits to EU Commission
- **EU Commission** upon receipt of Application transmits to JAT & MDCG

STEP 2
- **JAT** (minimum 3 experts) reviews application dossier -> Plans and conducts NB on site assessment
- **NB** prepares any CAPA plan & submits to CA
- **CA** assesses NB CAPA plan and prepares final assessment report -> JAT, EU and MDCG
- **JAT** receives and reviews CAPA Plan & provides final opinion to EU Commission, immediately

STEP 3
- **EU Commission** submits opinion to MDCG
- **MDCG** receives NB application and subsequently CA preliminary assessment report
- **MDCG** receives & reviews final opinion and if satisfactory makes recommendation to CA on draft Designation
- **CA** gives consideration to MDCG recommendation
Notified Body Designation – Key Steps (2)

**STEP 4**
- **CA** designates NB under MDR
- **CA** posts notification decision on EUDAMED
- **EU Commission** publishes notification on NANDO

**TOTAL DURATION**
- From Start to Finish Approx. 18 Months!
Transition timeline for MDR – Article 94

- **Entry into Force (EUOJ)** (Q1 2017)
- **Q4 2016 Adoption of MDR**
- **Transition period** 3 years
- **Date of Application** (Q1 2020)
- **MDD/ AIMD 4 years « grace » period**
- **Last MDD/ AIMD certificates expire** (Q1 2024)
- **MDR certificates**
- **Batch Release certificates shall become void at the latest 2 years after date of Application**

**NBs designation** under MDR

**MDD/ AIMD certificates**
Conclusions

• Become familiar with the draft MDR
• Conduct MDR impact assessment on your business
• Plan....
  • Maintenance of MDD system in your organization
  • Implementation of MDR in your organization
  • Continuously check for changes as Common Specifications, Implementing Acts and Delegated Acts are published
• Hire competent people
Thank You!
bsi.

...making excellence a habit™