"Medical Devices Regulation Update

Ibim Tariah
The EU’s new Medical Device Regulations

- **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 starts
- **mid 2017**: Expected publication of the adopted MDR/IVDR in EUOJ
2016 Actors – What do they do?  

**Blue Guide**

- **Administration**
  - Development comprehensive, coherent and proportionate legislation
  - Support Member States, Ensure co-operation between NBs, Harmonised Standards, NANDO

- **National Law Enforcement**
  - Ensure only safe, compliant products on market
  - Designate Notified Bodies

- **Conformity Assessment**
  - QMS, Product, *Unannounced*
  - Manufacturer, Suppliers, Subcontractor

- ‘... ultimate responsibility for conformity ...’

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**New Legislative Framework**

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Interinstitutional File:  
2012/0266 (COD) 

Brussels, 27 June 2016  
(OR. en)  

10617/16  

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 38 SAN 211 MI 370 COMPET 316 CODEC 722  
No. Cion doc.: 14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1  
Subject: Proposal for a Regulation of the European Parliament and of the Council  
on medical devices, and amending Directive 2001/83/EC,  

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.
Brussels, 22 February 2017

Interinstitutional File:
2012/0266 (COD)

PHARM 43
SAN 284
MI 478
COMPET 402
CODEC 977

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

How to read 566 pages ...
Draft MDR – FEB2017

101 Whereas...

⇒ Why

X Chapters of 123 Articles

⇒ What

XVI Annexes

⇒ How

I. Scope and Definitions
II. Making available on the market and putting into service, obligations of economic operators, reprocessing, CE marking, free movement
III. Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices
IV. Notified Bodies
V. Classification and conformity assessment
VI. Clinical evaluation and clinical investigations
VII. Post-market surveillance, vigilance and market surveillance
VIII. Cooperation between Member states, Medical Device Coordination Group, expert laboratories, expert panels and device registers
IX. Confidentiality, data protection, funding and penalties
X. Final Provisions
Draft MDR – FEB2017

XVII Annexes

1. General Safety and Performance Requirements
2. Technical Documentation
3. Technical Documentation on Post-Market Surveillance
4. EU Declaration of Conformity
5. CE Marking of Conformity
6. Information to be submitted with registration of devices and economic operators and core data elements to be provided to the UDI data-base
7. Requirements to be met by Notified Bodies
8. Classification Rules
9. Conformity Assessment – QMS & Technical Documentation
10. Conformity Assessment – Type Examination
11. Conformity Assessment – Product Conformity Verification
12. Certificates issued by a Notified Body
13. Procedure for Custom-made Devices
14. Clinical Evaluation and Post-market clinical follow-up
15. Clinical Investigations
16. List of groups of products without an intended medical purpose
17. Correlation Table

101 Whereas...

⇒ Why

X Chapters of 123 Articles

⇒ What

XVII Annexes

⇒ How
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

...
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
- Scrutiny for High Risk Devices
- Common Specifications
- Responsible Person for Manufacturers and Authorised Representatives
Key changes

Post-Market Surveillance and Vigilance
- Central Database and Co-ordination
- Trend Reporting
- Enforcement Activities

Transparency and Traceability
- Devices and Economic Operators Registered Centrally
- Unique Device Identification (UDI)
- Implant Cards

Governance and Oversight
- Central Committee: MDCG
- Expert Panel, Expert Laboratories
MDR CE marking on a single slide

1. Check **Device** is within Scope of MDR  
   (Chapter I, Articles 1, 2, Annex XVI)
2. Determine “**Device Class**”  
   (Chapter V, Article 51, Annex VIII)
3. Select “**Conformity Assessment Procedure**”  
   (Chapter V, Article 52)
4. Identify Applicable “**Safety and Performance Requirements**”  
   (Chapter II, Article 5, Annex I)
5. Assign UDI  
   (Chapter III, Article 27, Annex VI)
6. Assemble “**Technical Documentation**”  
   (Annex I => Annex II, Annex XV)
7. Apply Conformity Assessment Procedure  
   (Annexes IX, X, XIA or XIB)
8. Complete “**Declaration of Conformity**”  
   (Chapter II, Article 19, Annex IV)
9. Affix “**CE Mark**”  
   (Chapter II, Article 20, Annex V)
10. Post Market Surveillance & Updates  
    Technical Documentation  
    (Chapter VII, Articles 83 to 86, Annex XIV => Annex III)
Scope of MDR: Medical and other Devices Articles 1, 2, Annex XVI
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 – 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 2 - Economic Operators

• **Manufacturer** means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

• **Authorized Representative** means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

• **Importer** means any natural or legal person established within the Union that places a device from a third country on the Union market.

• **Distributor** means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.
Article 25 - Identification Within The Supply Chain

- Economic operators shall be able to identify the following to the competent authority, for 10 years in general and 15 years for implantable devices:
  
  (a) any economic operator to whom they have directly supplied a device;

  (b) any economic operator who has directly supplied them with a device;

  (c) any health institution or healthcare professional to which they have directly supplied a device.
## Certification Process with the new Regulations

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Additional Essential Requirements clauses</strong></td>
<td>• General Safety and Performance Requirements</td>
</tr>
<tr>
<td><strong>Additional requirements per common specifications</strong></td>
<td>• Product Specific</td>
</tr>
<tr>
<td><strong>Pre- and Post-Approval Scrutiny Process</strong></td>
<td>• Focus on clinical and post-market surveillance plans</td>
</tr>
<tr>
<td><strong>Medical Device Coordination Group</strong></td>
<td>• Coordination and establishment of new guidance</td>
</tr>
<tr>
<td><strong>Expert Panel</strong></td>
<td>• Opinion but legally not binding</td>
</tr>
<tr>
<td><strong>Sample Check and Product Testing. Reference Labs for IVD.</strong></td>
<td>• Unannounced Audit</td>
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</tbody>
</table>
Article 15 - Person Responsible for Regulatory Compliance

• Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

• Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

• Staff headcount and financial ceilings determining enterprise categories –
  • Microenterprise - employs fewer than 10 persons and whose annual turnover does not exceed €2 million.
  • Small enterprise - employs fewer than 50 persons and whose annual turnover does not exceed €10 million.

• Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.
### Article 15 - Person Responsible for Regulatory Compliance

The person responsible for regulatory compliance activities shall at least be responsible for ensuring that:

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a)</td>
<td>the conformity of the devices is appropriately checked in accordance with the quality management system under which these devices are manufactured before a device is released;</td>
</tr>
<tr>
<td>b)</td>
<td>the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;</td>
</tr>
<tr>
<td>c)</td>
<td>the post-market surveillance obligations in accordance with Article 10(10) are complied with;</td>
</tr>
<tr>
<td>d)</td>
<td>the reporting obligations referred to in Articles 87 to 91 are fulfilled;</td>
</tr>
<tr>
<td>e)</td>
<td>in the case of investigational devices the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.</td>
</tr>
</tbody>
</table>
Classification
Annex VIII
Changes in Medical Device Classification Rules

- New Process in case of dispute between NB and Manufacturer
- Addition of the active implantable medical devices to the classification rules
- Addition of tissue engineered products
- Up-classification of devices in direct contact with the heart or the central circulatory system
- Up-classification of orthopedic devices and devices in contact with the spinal column
- Addition of Nanomaterials
- Update of the wording regarding human origin material
Classification & Conformity Assessment – Regulation

Commission Assessment

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification

Risk

Class III

Class IIb

Class IIa

Class Im / Is / Ir

Class I

Custom Made

Custom Made Class III Implants

Class IIb Implants

Class IIa – more sampling

Animal tissues, human tissues, medicinal substances, absorbable

Class III Implants & Class IIb active – delivering medicines
21 Classification Rules:

1 - 4 Non invasive devices

5 - 8 Invasive devices

9 - 12 Active devices

13 - 23 Special rules
Conformity Assessment Procedures
Annexes IX, X, XIA or XIB
Custom Made Devices (Article 52.8)

Annex XIII
PROCEDURE FOR CUSTOM-MADE DEVICES

Annex XIV
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 52.8)

Annex XIII
PROCEDURE FOR CUSTOM-MADE DEVICES

Annex IX
QMS

Annex XI – 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

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Class I Device (Article 52.7)
(non-sterile / no measuring function / not reusable surgical instrument)

Annex II & III
Technical Documentations

Declaration of Conformity (Annex IV) & CE Marking (Annex V)
Class I Device (Article 52.7 a,b,c) (sterile / measuring function / reusable surgical instruments)

Annex II & III
Technical Documentations

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

Annex IX*
QMS

Annex XI – Part A*
Production Quality Assurance

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

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Class IIa Device (Article 52.6)

Annex II
Technical Documentation

Annex III
Technical Documentation

Minimum sample: one representative device for each category of device

Annex IX
QMS

Annex XI – Part A
Production Quality Assurance

Annex XI – Part B
Product Verification

Declaration of Conformity (Annex IV) & CE Marking (Annex V)
Class IIb Device (Article 52)

- **Annex II & III**
  - Technical Documentations *each Generic Device Group

- **Annex IX**
  - QMS

- **Annex X**
  - Type Examination

- **Annex XI – Part A**
  - Production Quality Assurance

- **Annex XI – Part B**
  - Product Verification

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

Minimum sample: one representative device for each Device Group.
Class IIb Implantable Device (Article 52.4)

Annex II & III
Technical Documentations ≠ each Generic-Device-Group

Annex IX
QMS

Annex X
Type Examination

Annex XI – Part A
Production Quality Assurance

Annex XI – Part B
Product Verification

Declaration of Conformity (Annex IV) & CE Marking (Annex V)
Class IIb Implantable Device (Article 52.4)

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

Annex II & III
Technical Documentations *each Generic Device Group

Annex IX
QMS

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

Article 52.5: list above can be amended by delegated acts
Class III Device (Article 52.3) (including those with medicinal substances, human tissues or animal tissues)

Annex II & III
Technical Documentations

Annex IX
QMS

Annex X
Type Examination

Annex XI – Part A
Production Quality Assurance

Annex XI – Part B
Product Verification


Declaration of Conformity (Annex IV) & CE Marking (Annex V)
Annex IX, Clause 5.1 / Annex X, Clause 6 – Article 55

Notified Body Review

21 days

39 days

Notified Body Review

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

No ‘scientific opinion’

Notified Body Certificate

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

Complete Conformity Assessment

Notified Body Certificate

• Duly justify if advice not followed
Annex I: Safety & Performance Requirements
Annex I

• The General Safety And Performance Requirements serve an analogous function to the Annex I Essential Requirements in the MDD.

• The are 3 major chapters:
  • Chapter I. General requirements (GSPR 1 to 9)
  • Chapter II. Requirements regarding design and manufacture (GSPR 10 to 22)......large number of subsections
  • Chapter III. Requirements regarding the information supplied with the device (GSPR 23)
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.
Common Specifications – Chapter II, Article 9

...where:
• no harmonized standards exist or
• where relevant harmonised 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 XIV
• the requirements regarding clinical investigation set out in Annex XV.
Clinical data
Clinical Data

Chapter VI – Clinical evaluation and clinical investigations:

“Confirmation of conformity with the general safety and performance requirements referred to in Annex I ..., shall be based on clinical data providing sufficient clinical evidence.”
Clinical Evaluation
### Clinical Evidence

- the **clinical data** and **clinical evaluation report** pertaining to a device
- **sufficient amount** and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer

### Clinical Evaluation

- a methodologically sound / **systematic and planned process** to continuously generate, collect, analyse and assess the **clinical data** pertaining to a device
- to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

### Clinical Data

- **clinical investigation** on the device concerned
- **clinical investigation** reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated
- **peer reviewed** scientific literature on other clinical experience of either the device in question or a similar device for which equivalence can be demonstrated
- **data from the manufacturer’s post-market surveillance system**, in particular post-market clinical follow-up

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Clinical Evaluation – Article 61

**Exemption** for some class III and IIb implants* already on the market: manufacturers may use existing clinical data collected and systematically reviewed under MDD/AIMD.

IF:
- sufficient clinical data are available in the Clinical Evaluation

AND:
- compliance with product-specific CS for clinical evaluation (where such CS is available)

* sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, and wires, pins, clips and connectors. List subject to revision (addition, deletion) by delegated act.
In the case of **implantable devices and devices falling within class III**, clinical investigations shall be performed except if:

1. The device has been designed by modifications of a device already marketed **by the same manufacturer**.
2. The modified device has been demonstrated by the manufacturer to be equivalent to the marketed device....and this demonstration has been endorsed by the notified body, and
3. The clinical investigation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.
A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

- the original clinical evaluation has been performed in compliance with the requirements of this Regulation, and the manufacturer of the second device provides clear evidence thereof to the notified body.
Chapter VI – Clinical Evaluation and Investigations – Article 61

• Clinical Evaluation and its documentation shall be updated throughout the life cycle of the device...with clinical data obtained from implementation of PMCF.

• PMCF and if indicated summary of safety and clinical performance shall be updated at least annually with these data.

• The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report....shall be part of the technical documentation relating to the device concerned
Technical
- be of similar design
- used under similar conditions of use
- have similar specifications and properties (e.g. physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, software algorithms, porosity, particle size, nanotechnology, specific mass, atomic inclusions – nitrocarburising, oxidability)
- use similar deployment methods (if relevant)
- have similar principles of operation and critical performance requirements

Biological
- use same materials or substances in contact with the same human tissues or body fluids
- for a similar kind and duration of contact and similar release characteristics of substances
- including degradation products and leachables
- Exceptions can be foreseen for devices in contact with intact skin and minor components; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material. Evaluators should consider biological safety (e.g. ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any difference.

Clinical
- used for the same clinical condition or intended purpose (including similar severity and stage of disease, medical indication)
- at the same site in the body
- in a similar population (including age, gender, anatomy, physiology)
- have same kind of user
- not foreseen to deliver significantly different performances
- have similar relevant critical performance according to the expected clinical effect for a specific intended purpose
Identification and Traceability of Devices – Article 33 – European Database on Medical Devices
Identification and Traceability of Devices
– Article 32 – 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 61 – 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.

• Manufacturer + SRN
• Device + UDI
• Intended Purpose, Indications, Contraindications
• Description, previous variant(s), differences, accessories, other products intended to be used in combination
• Possible diagnostic or therapeutic alternatives
• Harmonised Standards / Common Specifications
• Summary of the Clinical Evaluation Report + PMCF
• Suggested profile and training for users
• Information on residual risks, undesirable effects, warnings & precautions
Identification and Traceability of Devices – Article 33 – 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 VI
Unique Device Identification – Article 27

- COMMISSION RECOMMENDATION – 2013/172/EU on a common framework for a unique device identification system of medical devices in the Union.

- Work toward GHTF / IMDRF UDI

- FDA have completed specifications

- EN ISO 15223 – date format – YYYY/MM/DD

*EU will probably allow GS1 & HIBCC

*GS1 & HIBCC accepted by Turkey, Japan, India, USA

+ Argentina, China, Canada, Brazil, Korea, Saudi Arabia
UDI Update

• Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.
The manufacturer of an implantable device shall provide together with the device the following:

- device name
- serial number
- batch code or lot number
- **Unique Device Identification**
- device model
- manufacturer name, address and URL of the website
- any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- any information about the expected lifetime of the device and any necessary follow-up;
- any other information to assure a safe use of the device by the patient
- including the information in Annex I, Section 19.3 – Instructions for Use
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 IV
Declaration of Conformity – Annex IV

- 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 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 V
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 Surveillance
Article 2 Definitions – ‘post market surveillance’

- all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
Post Market Surveillance – Article 83

• If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body.

‘serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person,
b) the temporary or permanent serious impairment of the patient's, user's or other person's state of health,
c) a serious public health threat;

‘field safety corrective action’ means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

• Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.
Periodic Safety Update Report – Article 86

**Article 86 – PSUR:**
- 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

- 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.
Summary of Safety and Clinical Performance – Article 32

**Article 32 – SSCP:**
- Manufacturer + SRN
- Device + UDI
- Intended Purpose, Indications, Contraindications
- Description, previous variant(s), differences, accessories, other products intended to be used in combination
- Possible diagnostic or therapeutic alternatives
- Harmonised Standards / Common Specifications
- Summary of the Clinical Evaluation Report + PMCF
- Suggested profile and training for users
- Information on residual risks, undesirable effects, warnings & precautions

**Article 61 – 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.
Technical Documentation on PMS – Annex III

Information

FSCA
PSUR
Information on similar devices
Trend reporting
Literature, Databases, Registries
Complaints, User & Economic Operator Feedback
Incidents

Plan

Proactive, systematic process to collect information to characterize, compare and assess the device
Clear, organized, readily searchable and unequivocal
Defines indicators & threshold values for risk benefit analysis
Defines complaint analysis methods including statistical analysis
Methods & protocols for trend reports
Procedures to identify, initiate & trace CAPA

Report

Class IIa, IIb & III Periodic safety Update Report article 86
Class I Post Market Surveillance Report article 85
Technical Documentation Annex XIV Part B PMCF evaluation report

Complaints, User & Economic Operator Feedback
Incidents

Methods & protocols for CA, NB Economic Operator communication
Includes PMCF plan per Part B Annex XIV or justification if N/A
NB Designation and Transitional Provisions
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

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 Timelines MDR (Article 120 of the Draft text Nov. 2016)

Entry into Force (EUOJ + 20days) (June 2017*)
May 2017* Adoption of MDR

Transition period 3 years

Date of Application (June 2020*)

MDD/AIMD certificate validity (4 years )

Annex IV certificates expire (June 2022*)
MDR certificates

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

No more « placing on the market » of devices covered by MDD/AIMD certificates

Last MDD/AIMD certificates expire (June 2024*)

NBs designation under MDR

* Dates are « best guess » based on our current understanding on the process/steps to be completed
Transitional Provisions MDR (Article 120 of draft text Feb 2017)

No significant changes in design or intended purpose.

Date of Application (June 2020*)

Post Market Surveillance, Vigilance, Registration
- Incident reporting – maximum 15 days
- Person responsible for regulatory compliance
- EUDAMED

Transition period 3 years

MDD/AIMD certificate validity (4 years)

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

MDR certificates

NBs designation under MDR
What is the plan for implementation of the MDR?

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<th>Year</th>
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- Certificates issued under MDD and AIMD before MDR adoption have full five year validity.
- Batch verification certificates issued before MDR adoption are valid until two years after application.
- Certificates to the MDD or AIMD issued after MDR adoption have full five year validity, unless that exceeds four years after the date of application.
- Certificates to the MDR can be issued from a designated Notified Body from MDR adoption, and have certificate validity of five years.

**Note:** The blocks display the time period within which a certificate type can be valid, not the period of validity for a single certificate.
Conclusions

• Become familiar with latest draft MDR.
• Conduct MDR impact assessment on your business.
• Plan how to:
  ➢ Maintain MDD in your organization till end of grace period.
  ➢ Implement MDR in your organization.
  ➢ Handle Significant changes & Intended Use changes from Date of Application
  ➢ Implementation of PMS, Vigilance, Registration, Incident Reporting and Responsible Person from Date of Application
  ➢ Continuously check for changes to: Common Specifications, Implementing Acts and Delegated Acts as and when published.
• Hire competent people.
Thank You!