The New Medical Device Regulation (MDR)
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TÜV SÜD Product Service
About this Webinar

- 60 min in length, unfortunately no live questions
- Due to confidentiality you can only see yourself online
- This is only an introduction to the new MDR
- The new IVDR is not part of this webinar
- Slides and webinar will be available at our website
- Q&A will be available at our website
The new MDR is not published yet

This presentation is based on information available as of today and prepared to best of our knowledge

The text of the MDR may change in the future
1. Latest News on MDR
2. General Changes
3. Definitions
4. Classification
5. Annexes and Routes to Conformity
6. Summary
Where did it all started...

2012:
• Commission adopted a package of measures on innovation in health → The Regulation Proposal was born

Objectives of the revision:
• Consistent high level of health and safety for EU Citizens
• Free and fair trade of the products throughout the EU
• Adaptation to the significant technological and scientific progress
• Better supervision of independent assessment bodies
• Clear rights for manufacturers/distributors
• Stronger requirements for medical evidence
• Adaptation of legislation to reflect a globalised market
Implications

Positive

• Enhanced patient safety and product performance
• New strategic decisions are possible
• Fast movers = marketing edge
• Better product performance monitoring
• Early scientific advice
• One Regulation for all

Challenges

• Increased Scrutiny / verification
• Clinical Requirements
• UDI & Label updates
• Reclassification
• New Reprocessing rules
• Resource issues
• Registration database
• Fees
1. This Regulation shall **enter into force** on the twentieth day after its publication in the *Official Journal of the European Union* (2016?)

2. It shall **apply from** [three years after entry into force] = **date of application** (2019?)

Paragraph 3 describes several specific rules that postpones the application of some requirements, e.g. registration requirements for specific products.
The Big Question – WHEN?

- Earliest application date for rules dependent on full functionality of EN database and UDI system
- Start date of importer/distributor notification obligations
- Deadline for importer labelling
- Deadline for Mfr MDR designation of AR
- Deadline for AR to appoint QP

MDR rules apply for NBs newly designated under Art.31 MDR

Date of Application = EIF + 3 years

Last date for placing MDD products on the market

Entry into Force = OJ + 20 days

3 Years

1 Year

18 months

3 Years

4 Years

1 Year

UDI Carrier mandatory (Class IIa/IIb) (2 years later for reusables in these classes where UDI is on device)

Latest validity date for MDD NB certs issued after EIF

Final making available and putting into service date for MDD products

UDI Carrier mandatory (Class Is) (2 years later for reusables in these classes where UDI is on device)
Structure of the MDR

MDD

- 60 Pages
- 12 Annexes
- 23 Articles

MDR

- 352 Pages
- 16 Annexes
- 97 Articles between 10 Chapters and 5 Sections
- 71 Legislative Procedures
1. Latest News on MDR
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It might lead to reclassification of certain medical devices

For Manufacturer:

check if the respective classification rule is still applicable.

In case of disputes regarding the classification of medical devices, different scenarios may occur
Classification dispute – scenarios – Article 41

Manufacturer (registered place of business) and notified body in the **same** member state

Manufacturer

Classification

Notified Body

Dispute

Accepted

Manufacturer (registered place of business) and notified body in the **different** member state

Consultation with competent authority of the member state which designated the notified body

Notification to MDCG

Competent authority of the member states of the manufacturer (address of business)

Dispute

Accepted

Consultation with competent authority of the member state which designated the notified body

Competent authority of the member states of the manufacturer (address of business)
Periodic Safety Update Reports as part of systematic PMS process
At least annually (class IIb and III) or every two years (class IIa)
Applicable also for custom made devices
Summarized information throughout product lifetime
Reports for class III and implantable devices submitted via electronic system
→ reviewed + evaluated by Notified Body

Now Include statements from:
MEDDEV 2.7.1
MEDDEV 2.12
EN ISO 14155

General changes under MDR

For Clinical Investigation:
More extensive and rigid requirements
Summary report available to the intended user
Damage compensation
Adequate monitoring
Data protection

Clarification of definitions such as Clinical Evidence, Evaluation and Data
Greater Control over determination of Clinical Evidence
Requirements for ‘Clinical Equivalence’ tightened
Clinical Investigation shall not apply to implantable devices and class III:

If lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC AND for which the clinical evaluation is based on sufficient data AND is in compliance with the relevant common specification (if available)

Mandatory For class III and implantable devices PCMF to be updated at least annually for class III

Alternatively, not applicable if they are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient data and is in compliance with the relevant common specification (if available)

Exemptions for investigation if:

a 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 the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

Admission for approved Clinical Investigations can be withdrawn / suspended by the Member States (Article 56)
Clinical Evaluation

Prior consultation by expert panel possible for class III (not exempted)
Sufficient clinical evidence based on data in specific target groups
Consideration must be given to benefit-risk ratio, alternative treatment options

Clinical evaluation based on clinical data only if:
1) Devices equivalency can be demonstrated
2) Equivalence must always be based on proper scientific justification.
3) Manufacturers must be able to clearly demonstrate that they have sufficient levels of access to the data on devices to which they are claiming equivalence in order to justify that claimed equivalence.

Equivalency: Technical, biological and clinical characteristics shall be taken into consideration resulting in insignificant difference in the safety and performance of the devices.

Points of consideration for Clinical Evaluation
Reference to clinical development plan
gaps in clinical data
Consideration of favourable and unfavourable data
Class III and implantable devices at least annually update
Scrutiny by expert panel on class IIb active medical devices intended to administer or remove a medicinal product and implantable class III devices

Equivalency demonstrated with marketed devices of other manufacturer if:
1) A contract is in place between the two manufacturer for full TD access on an ongoing basis
2) The original clinical evaluation has been performed in compliance with the MDR
3) The manufacturer of the second device provides clear evidence thereof to the notified body.
Vigilance – Article 61

What

• Vigilance cases to be reported through Eudamed, including risk assessment
• Not to report: expected side-effects, clearly documented in the product information, quantified in the technical documentation
• FSCA for devices in the EU market including actions in a 3rd country

When

• General rule: time period for reporting in relation of the severity of the serious incident, however
  • Serious incident: Immediately and not later than 15 days after awareness
  • Serious public health threat: immediately, and not later than 2 days after awareness
  • Death or unanticipated serious deterioration in state of health: immediately, but not later than 10 days after awareness

Note:
In case of multiple member states involved, the competent authorities shall nominate one single competent authority to coordinate the process
Post Market Surveillance - Art 60a / 60b /60ba / 60c

**What**
- PMS must be part of the QMS and proportionate to the risk of the device
- Data obtained throughout product lifetime
- Feedback provided to CAPA process

**How**
- Focus on quality, performance and safety of the device
- Report back to CA and NB as necessary (Vigilance)
- For Class I devices → PMS report according to Annex IIa (TD on PMS)
- For other classes → Periodic Safety Update Report (PSUR) according to Annex IIa

*Note:* for class IIb and III, PSUR must be updated at least annually for class IIa, at least every two years
Common specifications – Article 7

What

• CS are defined by the commission after consultation with the MDCG in respect of
  • Essential Requirements
  • Technical Documentation
  • Clinical Evaluation / PMCF
  • Clinical Investigation

When

• If no harmonized standards exist or if not sufficient, or there is a need to address public health concerns, common specifications must be adopted
• Specific list in Annex XV (no medical purpose) shall comply with the relevant CS
• Manufacturers shall comply with the CS unless they can duly justify

Note:
If device is in conformity with CS, it is “presumed” to be in conformity with the regulations
Eudamed Databank

It’s all about sharing non-confidential information (certificates, devices, economic operators…)

- Eudamed and its Electronic System are controlled by the Commission
- Overall transparency; better access to information for public
- Unique identification of device → Better traceability
- Allows the public to be adequately informed about clinical investigations, PMS, Vigilance

Corrections and deletions to Eudamed must be carried out immediately, but not later than 60 days
UDI (Unique Device Identifier)

- **PI (Production Identifier)**: Identifies the device's unit.
- **DI (Device Identifier)**: Specific to a manufacturer and a device.

- UDI placed on the label and on all higher level of packaging – excluding shipping containers
- Storage of UDI by economic operators, health institutions and healthcare professionals (class III implantable, for other classes it is encouraged)
- UDI on EU Declaration of Conformity
- UDI referenced on the EC Certificate

**numeric/alphanumeric code**
New Devices

Scope addition: Non-medical (aesthetic) products

- Contact lenses and eye products
- Implants with the exception of tattooing products and piercings
- Fillers
- Liposuction, lipolysis or lipoplasty equipment
- Laser treatment
- Brain stimulation
Person Responsible for Regulatory Compliance – Article 13

**What**

- At least one person available within the organization
- Responsible for regulatory compliance
- Possesses expert knowledge in the field of medical devices
- Expertise must be demonstrated

**Who**

- A recognized diploma, certificate or other evidence in relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices OR
- four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

**Note:**
Manufacturer of custom-made devices need at least 2 years of experience in the sector
Not required for Micro and Small Enterprises but shall have such person permanently and continuously at their disposal.

<table>
<thead>
<tr>
<th>Category</th>
<th>Headcount</th>
<th>Turnover</th>
<th>OR</th>
<th>Balance sheet total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>&lt; 10</td>
<td>&lt;= 2.000.000€</td>
<td>&lt;= 2.000.000€</td>
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<tr>
<td>Small</td>
<td>&lt; 50</td>
<td>&lt;= 10.000.000€</td>
<td>&lt;= 10.000.000€</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>&lt; 250</td>
<td>&lt;= 50.000.000€</td>
<td>&lt;= 43.000.000€</td>
<td></td>
</tr>
</tbody>
</table>
All the usual information, plus **It shall also:**

- be continuously updated
- translated into an official Union language(s) required by the Member State(s)
- claim conformity also to other directives, where applicable, under a single EU DoF
- mention the UDI-DI and the Single Registration Number
- References to CS used
- All possible information for easy traceability and identification (may include a photograph, intended purpose etc…) if not provided by the UDI system

**Article 17:** “…the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device”
Similar to current process, in accordance with Annex VIII or in Part A of Annex X and may include:

- In vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];
- Any other products which are in conformity with the legislation applicable to those products only when they are used within the medical procedure or their presence in the system or procedure pack is justified.
- System or procedure pack subject to appropriate methods of internal monitoring, verification and validation
- Shall be assigned and bear their own UDI
- Notified Body still involved for sterility aspect
1  Latest News on MDR
2  General Changes
3  Definitions
4  Classification
5  Annexes and Routes to Conformity
6  Summary
“Definitions” – Article 2

Medical Device

- Definition now includes implant and reagent
- Medical Purpose now include
  - prediction and prognosis of disease
  - Investigation, replacement or modification of a pathological process or state
  - Provision of information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations

Now includes definition for “falsified device” → does not include unintentional non-compliance

Other new definitions such as
Nanomaterials
Interoperability
Compatibility
Benefit-risk determination
Fully Refurbishing
Distributor
Etc…

No Definition for State of The Art!
“Definitions” – Article 2

Economic Operators

- the manufacturer,
- the authorised representative,
- the importer,
- the distributor

“Manufacturer”: simplified rewording, but essentially the same
“Authorised Representative”: reworded, but essentially the same

New additions:
‘importer’ means any natural or legal person established within the Union who 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, who makes a device available on the market, up until the point of putting into service
ISO 13485:2016, section 4.1.1
The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.
NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.
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## Non invasive Devices: Annex VII, Chapter III, Rule 1-4

| Rule 1 | No changes  
All Non-invasive are class I unless… |
| Rule 2 | Channelling or storing for eventual administration  
No changes in classification  
Inclusion of “cells”, within the context and exclusion of blood bags  
…for use with blood, body liquids, organs, body cells and tissues – except blood bags… |
| Rule 3 | Modifying biological or chemical composition of blood, body liquids, other liquids intended for Infusion  
No changes in classification, however:  
• Expansion of scope context, infusion changed to implantation or administration  
  …biological and chemical composition of human tissues or cell, blood, other body liquids or other liquids intended for implantation or administration  
• Substances intended to be used in vitro in direct contact with human cells/tissues/organs or with human embryos before implantation/administration → Class III |
| Rule 4 | In contact with injured skin (mechanical barrier, compression, absorb exudates)  
• Now includes mucous membrane as well  
• No changes in classification  
• The rule applies to invasive devices that come into contact with injured mucous membrane |
### Invasive Devices: Annex VII, Chapter III, Rule 5-8

#### Rule 5
**Invasive in body orifice or stoma (not surgically)**

No changes to classification or wording

#### Rule 6
**Surgically invasive – Transient use**

- Intended specifically to use in direct contact with the heart / central circulatory system / central nervous system → class III
- No other changes

#### Rule 7
**Surgically invasive – Short-Term use**

- Intended specifically to use in direct contact with the heart / central circulatory system / central nervous system → class III
- No other changes

#### Rule 8
**Surgically invasive – Long-Term use and implantable**

- Now includes 4 new indents as following
- If active implantable or their accessories → Class III
- If breast implants or surgical meshes → Class III
- If are total and partial joint replacements (exception of ancillary components such as screws, wedges, plates and instruments) → Class III
- If are spinal disc replacement implants and implantable devices in contact with the spinal column (except screws, wedges, plates and instruments) → Class III
Active Devices: Annex VII, Chapter III, Rule 9-12

<table>
<thead>
<tr>
<th>Rule 9</th>
<th>Active therapeutic devices intended to administer or exchange energy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Now includes 2 new indents as following:</td>
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<tr>
<td></td>
<td>• If intended to emit ionizing radiation for therapeutic purposes or to control / monitor / influence such devices → Class IIb</td>
</tr>
<tr>
<td></td>
<td>• If for controlling / monitoring / influence active implantable → Class III</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 10</th>
<th>Active devices for diagnosis, if intended to supply energy, to image in vivo distribution of radiopharmaceuticals, or for direct diagnosis or monitoring of vital physiological processes</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>• Clarification of the following:</td>
</tr>
<tr>
<td></td>
<td>• Device intended to illuminate the patient’s body → Class I</td>
</tr>
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<td></td>
<td>• Direct diagnosis in clinical situations with immediate danger → Class IIb</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 10a</th>
<th>Software intended to provide information used to take decisions with diagnosis or therapeutic purposes</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>• Are in class IIa, unless such decision may cause:</td>
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<tr>
<td></td>
<td>• The death or irreversible deterioration of the state of health → Class III</td>
</tr>
<tr>
<td></td>
<td>• A serious deterioration of the state of health or a surgical intervention → Class IIb</td>
</tr>
<tr>
<td></td>
<td>• Software to monitor physiological processes → Class IIa</td>
</tr>
<tr>
<td></td>
<td>• Software to monitor vital parameters where variation may cause immediate danger → Class IIb</td>
</tr>
<tr>
<td></td>
<td>• All other software → Class I</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 11</th>
<th>Active devices to administer or remove medicines &amp; other substances to or from the body</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>• No Changes</td>
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<thead>
<tr>
<th>Rule 12</th>
<th>All Other Active Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• No Changes</td>
</tr>
</tbody>
</table>
## Special rules: Annex VII, Chapter III, Rule 13-23

<table>
<thead>
<tr>
<th>Rule 13</th>
<th>Devices incorporating integral medicinal substance liable to act in ancillary way on human body</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Context now includes “…medicinal product derived from human blood or human plasma…”</td>
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<tr>
<td>• No other changes, still class III</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 14</th>
<th>Devices used for contraception or prevention of sexually transmitted diseases</th>
</tr>
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<tbody>
<tr>
<td>• No changes</td>
<td></td>
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<table>
<thead>
<tr>
<th>Rule 15</th>
<th>Specifically to be used for disinfecting medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Context extended to include…”disinfecting or sterilising medical devices…”</td>
<td></td>
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<tr>
<td>• Clarification of the following:</td>
<td></td>
</tr>
<tr>
<td>• If they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing → Class IIb</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 16</th>
<th>Devices intended for recording X-ray diagnostic images</th>
</tr>
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<tbody>
<tr>
<td>• No Changes</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 17</th>
<th>Devices utilizing non-viable animal tissues or derivatives (not devices in contact only with intact skin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Context extended to human origin as well….”tissues or cells of human or animal origin…”</td>
<td></td>
</tr>
</tbody>
</table>
### Special rules: Annex VII, Chapter III, Rule 13-23

<table>
<thead>
<tr>
<th>Rule 18</th>
<th>Blood Bags</th>
</tr>
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<tbody>
<tr>
<td>• Removed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 19</th>
<th>Devices incorporating or consisting of nanomaterial</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If present a high or medium potential for internal exposure → Class III</td>
<td></td>
</tr>
<tr>
<td>• If present a low potential for internal exposure → Class IIb</td>
<td></td>
</tr>
<tr>
<td>• If present a negligible potential for internal exposure → Class IIa</td>
<td></td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Rule 20</th>
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<tr>
<td>• Not present in the current MDR Draft</td>
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<table>
<thead>
<tr>
<th>Rule 21</th>
<th>Devices composed of substances of combination of substances intended to be introduced via a body orifice, or applied on skin (absorbed or locally dispersed in the human body)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If they or their product of metabolism are systemically absorbed as intended → Class III</td>
<td></td>
</tr>
<tr>
<td>• If intended purpose is for stomach or lower gastrointestinal tract → Class III</td>
<td></td>
</tr>
<tr>
<td>• In all other cases → Class IIb</td>
<td></td>
</tr>
<tr>
<td>• If applied on skin → Class IIa</td>
<td></td>
</tr>
<tr>
<td>• If applied to and intended for the nasal / oral cavity as far as the pharynx → Class IIa</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 22</th>
<th>Invasive devices other than surgically invasive with respect to body orifices</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If intended to administer medicinal products by inhalation → Class IIa</td>
<td></td>
</tr>
<tr>
<td>• If the above mode of action has an impact on the efficacy and safety of the product and those intended to treat life threatening conditions → Class IIb</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 23</th>
<th>Active therapeutic devices with diagnostic function</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If significantly determinates the patient management by the device → Class III</td>
<td></td>
</tr>
<tr>
<td><em>Examples: closed look systems or automated external defibrillators</em></td>
<td></td>
</tr>
</tbody>
</table>
Conformity Assessment Procedures

Annex VIII
- Chapter I: A QUALITY MANAGEMENT SYSTEM
- Chapter II: ASSESSMENT OF TECHNICAL DOCUMENTATION Applicable to Class III
- Chapter III: Administrative Provisions

Annex IX
- ... TYPE EXAMINATION

Annex X
- PART A: PRODUCTION QUALITY ASSURANCE
- PART B: PRODUCT VERIFICATION

Annex XI
- PROCEDURE FOR CUSTOM-MADE DEVICES
ER 1a / 2 define requirements for risk management (similar to ISO 14971)

ER 6 how to deal with risk/benefit of Annex XV devices (devices with no medical purposes)

ER 7.1 the impact of processes on material properties – toxicity, flammability, compatibility, mechanical, surface etc…

ER 7.4: substances in direct contact: shall only contain less then 0.1% weight of the following substances or justification is needed: carcinogenic, mutagenic, toxic to reproduction, having endocrine disrupting properties – Link to other regulations are provided

ER 7.6 risks linked to size and properties of particles / nano materials

ER 11.4 adjustment, calibration and maintenance in a safely and effective way

ER 11.5 compatibility and interoperability are reliable and safe

ER 13.4aa reference to Directive 2013/59/EURATOM for ionizing radiation

ER 14.3a deal with IT security (IT security measures, protect against unauthorized access)

ER 14.3 mobile computing platforms (size, contrast of screen, noise)

ER 15.8 minimize unauthorized access

ER 18 Risks of devices for use by lay persons

ER 19.1 information supplied has to be available on the web site of the manufacturer
Structure for Minimum Requirements now defined:

- Device Description and Specification, including the basic UDI-DI
- Reference to previous and similar generations of the device
- Information supplied by the manufacturer, such as label, IFU
- Design and manufacturing information
- General safety and performance requirements, including any CS applied, sterilization etc…
- Risk/Benefit analysis and Risk Management
- Product Verification and Validation
- Pre-clinical and clinical data
- Where applicable, application of GLP for tests on chemical substances shall be demonstrated
- PMCF plan and evaluation report
- Additional information such as medicinal product, human/animal cells/tissues, substances,

Remember:

- Term “Design Dossier” changed to “Technical Documentation”
- All the TDs have to show compliance with the new essential requirements!
- Manufacturers shall generate additional evidence!
Conformity Assessment Procedures – Article 42 - CLASS I

Article 17
Declaration of Conformity
Annex II
Technical Documentation

Sterile, measuring or reusable surgical instruments?

No
Register with the Competent Authority

Yes
Annex VIII
Chapter I (QMS) and Chapter III (Administrative provisions)
Or
Annex X (part A only Production Quality Assurance)
Verification by Notified Body limited to Sterilization and/or Measuring Features and/or aspects related to the reuse of the device
Conformity Assessment Procedures – Article 42 - CLASS IIa

Annex VIII
QMS Assurance
Except Chapter II
Surveillance

Annex X
Product conformity verification
Section 7 of Part A
(production Quality Assurance) only

Annex II
Technical Documentation

Annex X
Product Conformity Verification
Section 8 of Part B
(Production verification) only
Surveillance

CE 0123
Conformity Assessment Procedures – Article 42 - CLASS IIb

Annex VIII
QMS Assurance Except Chapter II
Surveillance

Annex IX
Type Examination

Annex X
Product Conformity Verification

CE 0123
Conformity Assessment Procedures – Article 42 - CLASS IIb
Implantable

TD Except for: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. This list may be extended by delegated acts.

Annex VIII
QMS Assurance Including Chapter II (TD)
Surveillance

Annex IX
Type Examination

Annex X
Product Conformity Verification

CE 0123
Conformity Assessment Procedures – Article 42 - CLASS III

Annex VIII
Based on a QMS Assurance Plus Chapter II (TD for Class III)

Surveillance

Annex IX
Type Examination

Annex X
Product Conformity Specification

CE 0123
Annex XI Procedure for Custom-Made Devices

Draw Up statement as per Annex XI section 1

NO CE MARK !!
Conformity Assessment Procedures – Article 42 - CLASS III
Custom-Made Implantable

Annex VIII
Based on a QMS Assurance (Chapter I)
Surveillance

Annex X
Product Conformity Specification
Part A only (Production Quality Assurance)

0123
Conformity Assessment Procedures – Article 42

- When a device incorporates medicinal product with action ancillary to that of the device
- Device that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body

**Step 1**
- Substance shall be verified by analogy to Annex I of Directive 2001/83/EC

**Step 2**
- Notified Body shall seek a scientific opinion from one of the CA designated by the Member States
- Alternatively, the NB can consult with the European Medicines Agency

**Step 3**
- When scientific opinion is favourable, the NB can express its verdict (i.e. issue of certificate)
Conformity Assessment Procedures – Article 42

- Device manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable
- Device that incorporates, as an integral part, tissues or cells of human origin or their derivatives with action ancillary to that of the device:

**Step 1**
- Notified Body shall seek a scientific opinion from one of the CA designated by the Member States

**Step 2**
- NB shall submit a summary of the preliminary conformity assessment
- CA to provide the NB its opinion within 60 days

**Step 3**
- When scientific opinion is favourable, the NB can deliver the certificate
Device that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body

**Step 1**
- Substance shall be verified by analogy to Annex I of Directive 2001/83/EC

**Step 2**
- NB shall submit a summary of the preliminary conformity assessment
- CA to provide the NB its opinion within 60 days

**Step 3**
- When scientific opinion is favourable, the NB can deliver the certificate
all or certain documents, including the technical documentation, audit, assessment and inspection reports, shall be available in an official Union language(s) determined by the Member State concerned. Otherwise they shall be available in an official Union language acceptable to the notified body.
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Take Away Message and Summary

- Check if your device(s) fall(s) under the new Medical Devices Regulation
- Check if a re-classification is needed
- Regardless of the classification, strictly follow the new Conformity Route Assessment options and requirements, including Annex I
- Be aware of timelines, transition period etc., for a smooth and planned change
- Discuss with both the Competent Authority and Notified Body about the changes
- Assess your Organization and Quality System for any changes, i.e. liability insurance, new contracts in place, resources, qualified person etc...
- Update the Technical Documentation accordingly
- Understand that changes cannot be implemented overnight, so “time”, information and resources are essential
To Learn More...

TUV SUD UK Training Courses

http://www.tuv-sud.co.uk/uk-en/activity/training-people-certification

TUV SUD UK Webinars

http://www.tuv-sud.co.uk/uk-en/resource-centre/webinars/webinar-downloads
Thank you

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