MDR & IVDR – Roles in the Regulatory System

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March 2017

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This Presentation ...

1. Roles in the regulatory system – Blue Guide

2. Roles in the regulatory system – MDR & IVDR
   - Commission / Member States
   - Manufacturer
   - EU Authorised Representative
   - Importer / Distributor

3. UDI

4. EUDAMED
Roles in the Regulatory System

Blue Guide
2016 – Actors – Who are they?

European Commission, Parliament, Council

Member States EU, EEA, EFTA, Customs Union, MRA

Notified Bodies

Manufacturer Suppliers Subcontractors EU Authorised Representative Importer Distributor

New Legislative Framework
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
Manufacturer, Suppliers, Subcontractor

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

Market Surveillance

New Legislative Framework

bsi
Commission & Member States

MDR / IVDR
Draft February 2017
Medical Device Coordination Group (MDCG)

An expert committee, composed of persons designated by the Member States based on their role and expertise in the field of medical devices including *in vitro* diagnostic medical devices, should be established to fulfil the tasks conferred on it by this Regulation, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

The MDCG should be able to establish subgroups in order to have access to necessary in-depth technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility to involve existing groups at Union level in the field of medical devices.
# Medical Device Coordination Group

- **Article 103 / Article 98** – Each Member State shall appoint one member and one alternate in the fields of medical devices and *in vitro* diagnostic medical devices, for a three year term.

- **Article 105 / Article 99** – The MDCG shall have the following tasks:
  - contribute to assessment of applicant CABs and NBs
  - advise the Commission in matters concerning the coordination group of NBs
  - contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation (designation and monitoring of NBs, application of the safety & performance requirements, conduct of clinical / *performance* evaluations, conduct of clinical investigations / *performance studies*, assessment of NBs and vigilance activities)
  - contribute to continuous monitoring of technical progress and assessment of whether SPRs are adequate to ensure safety and performance of devices
Delegated Acts, Implementing Acts & Common Specifications

**Delegated Acts**
- Acts used to modify / amend the ‘what’ of a legislation
- Limited to the non-essential elements
- Amend list of products with no medical purpose
- Amend elements of technical documentation
- Amend implants exempt from implant card obligation
- Amend minimum content of DOC
- Amend frequency of re-assessment of Notified Bodies
- Amend minimum content of certificates
- Amend requirements for application for clinical investigation / performance studies
  
  \[= 13 / 7\]

**Implementing Acts**
- Acts used to clarify / implement the ‘how’ of a legislation
- Determine whether products fall within definition of device
- Specify procedural aspects of UDI
- Set out elements to be included in summary of safety and clinical performance
- List codes to specify scope of designation of Notified Bodies
- Set out detailed arrangements for review of technical and clinical assessments conducted by Notified Bodies
- Set out detailed arrangements for peer review, training and qualification of Notified Bodies
- Establish a model for certificates of free sale
- Ensure uniform application of clinical / performance evaluation
- Ensure uniform documentation to be submitted for clinical investigation / performance studies
  
  \[= 32 / 32\]

**Common Specifications**
- Article 9 / Article 9 – Where no harmonised standards exist or where harmonised standards are not sufficient, the Commission after having consulted the MDCG by means of implementing acts, adopt Common Specifications in respect of Annex I (SPRs), Annex II (Technical Documentation), Annex III (Technical Documentation – PMS), Annex XIV (Clinical Evaluation & PMCF) / Annex XIII (Performance Evaluation & PMPF), Annex XV (Clinical Investigation) / Annex XIII (Performance Studies)
  
  \[= 32 / 32\]
- Products with no medical purpose
- Single use devices to be reprocessed
Manufacturer

MDR / IVDR
Draft February 2017
Article 10 – General Obligations of Manufacturers

Manufacturers shall:

1. Ensure that devices have been designed and manufactured in accordance with the requirements of this Regulation
2. Establish, implement, maintain and document a system for risk management (Annex I, Section 3)
3. Conduct a clinical evaluation, including post-market clinical follow-up (Article 61 & Annex XIV)
4. Draw up and keep up to date technical documentation for the purpose of allowing assessment of the conformity of the device with the requirements of this Regulation (Annex II & III)
5. Custom made devices – technical documentation (Annex XIII)
6. Where compliance with the applicable requirements has been demonstrated, shall draw up an EU declaration of conformity (Article 19) and affix the CE marking of conformity (Article 20)
7. Comply with the obligations related to the UDI system (Article 27) and with registration obligations (Article 29 & 31)
Article 10 – General Obligations of Manufacturers

Manufacturers shall:

8. Keep the technical documentation, DOC and relevant certificates available to the competent authorities for a period >ten years after the last device has been placed on the market / >15 years after the last implantable device has been placed on the market
   • upon request by a competent authority, provide the technical documentation in its entirety or a summary thereof
   • ensure that the authorised representative has the necessary documentation permanently available

9. Ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation
   • changes in product design, harmonised standards or common specifications shall be adequately taken into account in a timely manner
   • Establish, document, implement, maintain, keep up to date and continually improve a quality management system that ensures compliance with this regulation in the most effective manner and in a manner that is proportionate to the risk class and type of device

Annex IX, X, XI – Conformity Assessment

Annex IX, X, XI – Conformity Assessment
The quality management system shall:

- Cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions to achieve compliance with the provisions of this regulation.

The quality management system shall address at least the following aspects:

a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

b) identification of applicable safety and performance requirements and exploration of options to address these requirements;

c) responsibility of the management;

d) resource management, including selection and control of suppliers and sub-contractors;

e) risk management (Annex I Section 3);

f) clinical evaluation, including post-market clinical follow-up (Article 61 & Annex XIV);

g) product realisation, including planning, design, development, production and service provision;

h) verification of UDI assignments, ensuring consistency of information provided (Article 27 & 29);

i) setting-up, implementation and maintenance of a PMS system (Article 83);

j) handling communication with competent authorities, notified bodies, economic operators, customers and/or other stakeholders;

k) processes for reporting of serious incidents and FSCA in the context of vigilance;

l) management of corrective and preventive actions and verification of effectiveness;

m) processes for monitoring and measurement of output, data analysis and product improvement.
Article 10 – General Obligations of Manufacturers

Manufacturers shall:

10. Implement and keep up to date the post-market surveillance system (Article 83)

11. Ensure that the device is accompanied by the information set out in Annex I Section 23 in an official Union language(s) determined by the Member State in which the device is made available. The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient.

12. Manufacturers who believe that a device which they have placed on the market is not in conformity with this Regulation, immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the Distributors and, where applicable, the EU AR and the Importers accordingly.

• Where the device presents a serious risk, immediately inform the Competent Authorities of the Member States in which they made the device available and, where applicable, the Notified Body that issued a certificate for the device, of the non-compliance and of any corrective action taken.

13. Have a system for recording and reporting of incidents and field safety corrective actions (Article 87 & 88)
14. Upon request from a Competent Authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The Competent Authority of the Member State in which the Manufacturer has its registered place of business may require that the Manufacturer provide samples / grant access free of charge. Manufacturers shall cooperate with a Competent Authority, at its request, on any corrective action taken to eliminate / mitigate the risks posed by devices which they have placed on the market.

- If the Manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the Competent Authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit, restrict withdraw or recall until the manufacturer cooperates or provides complete and correct information.

15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted to EUDAMED.

16. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

- In a manner that is proportionate to the risk class, type of device and size of the enterprise have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures being taken under national law.
EU Authorised Representative

MDR / IVDR
Draft February 2017
1. Design and manufacture (Annex I – SPR#1)
2. Risk Management (Annex I – SPR#2, 3, 4 & 5)
3. Clinical evaluation, including PMCF (Annex XI)
4. Technical Documentation (Annex II & III)
5. EU DoC (Annex IV) & affix CE mark (Annex V)
6. UDI (Annex VI)
7. QMS
8. PMS (Annex III)
10. CAPA, FSCA (Article 89)
## EU Authorised Representative – Article 11 / Article 11

<table>
<thead>
<tr>
<th>MDD</th>
<th>MDR / IVDR</th>
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<tr>
<td><strong>Article 1 (j)</strong></td>
<td><strong>Article 11/11</strong> – 1. Where a Manufacturer is not established in a Member State the device may only be placed on the EU market if the manufacturer designates a sole authorised representative</td>
</tr>
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</table>
| • EU AR explicitly designated by Manufacturer  
• “acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive” | |
| **No defined process or scope for designation:** | **2. & 3. The designation shall constitute the EU AR’s mandate:** |
| • Article 15 – Clinical investigation notifications & document retention  
• Article 18 – “obliged to end CE marking infringement” when imposed by Member State  
• Annex II, V, VI – Document retention  
• Annex VII – Draw up DoC for Manufacturer | • Shall be valid only when accepted in writing by EU AR  
• Shall be effective at least for all devices of the same generic device group  
• AR shall perform the tasks specified in the mandate agreed  
• AR shall provide a copy of the mandate to the Competent Authority upon request |
## EU Authorised Representative

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<td>a) Mandate shall require, and the Manufacturer shall enable the EU AR to perform at least the following:</td>
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<td>• Verify DoC and Technical Documentation drawn up</td>
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<td></td>
<td>• Verify appropriate conformity assessment performed</td>
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<td></td>
<td>Annex II, V, VI – Make available to CAs upon request:</td>
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<tr>
<td></td>
<td>• DoC</td>
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<td></td>
<td>• Documentation of QMS, Technical Documentation, + Changes</td>
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<td></td>
<td>• NB certificates, NB audit reports</td>
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<td></td>
<td>• &gt;5 / &gt;15 years after last manufacture</td>
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<td>• + Article 15 – clinical investigation reports</td>
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<td>b) Keep available a copy of and at the disposal of the Competent Authority:</td>
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<td></td>
<td>• Technical Documentation, DoC and NB certificates</td>
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<td>• &gt;10 / 10 years after last placing on the market / &gt;15 years for implantable devices</td>
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<td></td>
<td>c) Register with SRN, within one week of any change maintain, re-confirm accuracy in first year and then every second year</td>
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<td>Verify Manufacturer has:</td>
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<tr>
<td></td>
<td>• Entered UDI core data elements</td>
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<td></td>
<td>• Assigned / Entered Basic UDI-DI</td>
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<td>Article 14 – Register with a Competent Authority</td>
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## EU Authorised Representative

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<tr>
<td>Annex II, V, VI – Provide information in response to Competent Authority request (no reference to demonstration of conformity, no language requirement)</td>
<td>d) Provide information / documentation to Competent Authority on request to demonstrate conformity in requested language</td>
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<tr>
<td></td>
<td>e) Forward to Manufacturer Competent Authority’s request for samples / access to a device and verify samples / access given</td>
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<td></td>
<td>f) Cooperate with Competent Authorities in any preventive / corrective action to eliminate / mitigate risk</td>
</tr>
<tr>
<td>Article 10 – Member States with manufacturer or EU AR assessment of incidents</td>
<td>g) Immediately inform Manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents</td>
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<td></td>
<td>h) Terminate mandate if Manufacturer acts contrary to its obligations under this Regulation (inform Member State &amp; Notified Body)</td>
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Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of *in vitro* 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.
The person responsible for regulatory compliance activities shall **at least be responsible for ensuring** that:

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<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) / <strong>Article 10(9)</strong> are complied with;</td>
</tr>
<tr>
<td>d)</td>
<td>the reporting obligations referred to in Articles 87 to 91 / <strong>82 to 86</strong> are fulfilled;</td>
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<tr>
<td>e)</td>
<td>in the case of investigational devices / <strong>devices for performance studies</strong>, the statement referred to in Section 4.1 of Chapter II of Annex XV / <strong>Annex XIV</strong> is issued.</td>
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Importers & Distributors

MDR / IVDR
Draft February 2017
Importers & Distributors – Current Directives


Regulation (EC) No 765/2008 – Requirements for accreditation and market surveillance relating to the marketing of products

- Not supply unsafe products
- Act with due care to help ensure compliance with applicable safety requirements
- Participate in monitoring safety
- Pass on product risk and traceability information
- Co-operate with Competent Authorities on action take to avoid risks (within limits of activities)
- Inform Competent Authorities if product unsafe
**Importers – Article 13 / 13**

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<tr>
<th>Importers MDR / IVDR</th>
<th>Distributors MDR / IVDR</th>
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<tbody>
<tr>
<td>1. Importers shall place on the Union market only devices that are in conformity with this Regulation</td>
<td>1. When making a device available on the market, Distributors shall, act with due care in relation to applicable requirements</td>
</tr>
<tr>
<td>2. In order to place a device on the market Importers shall verify:</td>
<td>2. Before making a device available on the market Distributors shall verify the following requirements are met:</td>
</tr>
<tr>
<td>a) Device CE marked and DoC drawn up</td>
<td>a) Device CE marked, DoC drawn up</td>
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<tr>
<td>b) Manufacturer identified &amp; that an EU AR has been designated</td>
<td>b) Device accompanied by the information to be supplied by the Manufacturer</td>
</tr>
<tr>
<td>c) Device labelled in accordance with MDR + accompanied by IFU</td>
<td>c) For imported devices, the Importer name and address is on the label</td>
</tr>
<tr>
<td>d) UDI assigned by Manufacturer</td>
<td>d) UDI has been assigned by the Manufacturer</td>
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Distributor may apply a sampling method to perform verification (except for c) Importer labelling)
### Importers

<table>
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<tr>
<th>Importers MDR / IVDR</th>
<th>Distributors MDR / IVDR</th>
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<tr>
<td>Where an Importer believes that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market + inform Manufacturer and EU AR</td>
<td>Where a Distributor believes that a device which they have made available is not in conformity with the requirements of this Regulation, it shall not make the device available + inform Manufacturer, EU AR and Importer</td>
</tr>
<tr>
<td>Where the Importer considers the device presents a serious risk or is a falsified device, it shall inform Manufacturer, EU AR and Competent Authority</td>
<td>Where the Distributor considers the device presents a serious risk or is a falsified device, it shall inform Manufacturer, EU AR, Importer and Competent Authority</td>
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3. Importers shall indicate on the device, on its packaging or in a document accompanying the device:
   - Name, registered trade name or registered trade mark
   - Registered place of business and address at which they can be contacted and location established
   - Ensure no additional label obscures any information
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<td>4. Importers shall:</td>
<td>3. Distributors shall ensure that while a device is under their responsibility, storage or transport conditions comply with conditions set by Manufacturer</td>
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<tr>
<td>• Verify device is registered in UDI database</td>
<td></td>
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<tr>
<td>• Register for SRN, within one week of any change maintain, re-confirm accuracy in first year and then every second year</td>
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<tr>
<td>5. Importers shall ensure that while a device is under their responsibility, storage or transport conditions do not jeopardise device compliance with General Safety and Performance Requirements [Annex I] + comply with conditions set by Manufacturer</td>
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<tr>
<td>6. Importers shall:</td>
<td>5. Distributors shall:</td>
</tr>
<tr>
<td>• Keep register of complaints, non-conforming devices, recalls and withdrawals</td>
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<tr>
<td>• Provide Manufacturer, EU AR and Distributors with any information requested in order to allow investigation of complaints</td>
<td>• Keep Manufacturer, EU AR and Importers informed of monitoring and provide any information upon request</td>
</tr>
<tr>
<td>Importers MDR / IVDR</td>
<td>Distributors MDR / IVDR</td>
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| 7. Importers who believes that a device which they have placed on the market is not in conformity with the requirements of this Regulation shall:  
  • Co-operate with the Manufacturer, the manufacturer’s EU AR and the Competent Authorities to ensure that the necessary corrective action, withdrawal or recall is taken  
Where the device presents a serious risk, they shall also:  
  • Immediately inform the Competent Authorities of the Member States in which they made the device available and the Notified Body | 4. Distributors who believes that a device which they have placed on the market is not in conformity with the requirements of this Regulation shall:  
  • Co-operate with the Manufacturer, the manufacturer’s EU AR, Importer and the Competent Authorities to ensure that the necessary corrective action, withdrawal or recall is taken  
Where the device presents a serious risk, they shall also:  
  • Immediately inform the Competent Authorities of the Member States in which they made the device available and the Notified Body |
| 8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the Manufacturer and its EU AR. | 5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have made available shall immediately forward this information to the Manufacturer, EU AR and Importer. |
## Importers

### Importers MDR / IVDR

9. Importers shall:
   - Keep copy of DoC and NB certificates
   - >10 / 10 years after last placing on the market / >15 years for implantable devices

10. Importers shall cooperate with Competent Authorities, on any action taken to eliminate / mitigate the risks posed by devices which they have placed on the market

## Distributors

### Distributors MDR / IVDR

6. Distributors shall, upon request from a Competent Authority, provide information and documentation necessary to demonstrate the conformity of a device (unless the Manufacturer or EU AR has done so)

Distributors shall cooperate with Competent Authorities, on any action taken to eliminate / mitigate the risks posed by devices which they have placed on the market

Importers, upon request of a Competent Authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge / grant access to the device

Distributors, upon request of a Competent Authority, shall provide samples of the device free of charge / grant access to the device
Unique Device Identification

‘verify’
4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.
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5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.

6. 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 19.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up to date a list of all UDIs that it has assigned.
4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

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Article 27 – UDI

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6. 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 19.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up to date a list of all UDIs that it has assigned.

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

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6. **PRODUCT VERIFICATION AND VALIDATION**
   - Pre-clinical and clinical data
   - Additional information in specific cases
Annex I – Safety & Performance Requirements

- **SPR#23.2 Information on the label**
- The label shall bear all of the following particulars:
  - (a)
  - (h) the unique device identification (UDI) carrier referred to in Article 27 and Part C of Annex VII.
  - (s)
8. **Economic operators** shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or they have been supplied with, if those devices belong to:
   - class III implantable devices;
   - the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. **Health institutions** shall store and keep preferably by electronic means the UDI of the devices which they have supplied or they have been supplied with if those devices belong to **class III implantable devices**.

   - For devices **other than class III implantable devices**, Member States shall encourage, and may require, **health institutions** to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with.
   - Member States shall encourage, and may require, **health care professionals** to store and keep preferably by electronic means, the UDI of the devices which they have been supplied with.

The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects for the UDI system in relation to:

- devices, categories or groups of devices
Article 18 – Implant Card

The manufacturer of an implantable device shall provide together with the device the following:

- device name
- serial number
- lot number
- **Unique Device Identification**
- device model
- manufacturer name, address and 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 point (u) Annex I, Section 23.4 – Instructions for Use
EUDAMED

‘register’
MDR – European Database on Medical Devices – Article 33

Electronic System on Registration of Devices – Article 29

Electronic System on Notified Bodies & Certificates – Article 57
(subsidiaries, experts, Notified Bodies, Certificates)

+ Summary of Safety & Performance

Electronic System on Vigilance & PMS – Article 92
-serious incidents, FSCA, periodic summary reports, trend reports FSN)

+ Periodic Safety Update Report

Electronic System on Market Surveillance – Article 100
(surveillance activities, devices presenting an unacceptable risk, non-compliant products, preventive health protection measures)

Electronic System on Clinical Investigations – Article 73
(sponsors, description of investigational device, status, adverse events)

UDI Database – Article 28

Electronic System on Registration – Economic Operators (SRN) – Article 30
IVDR – European Database on Medical Devices – Article 30

Electronic System on Registration of Devices – Article 26

Electronic System on Notified Bodies & Certificates – Article 52 (subsidiaries, experts, Notified Bodies, Certificates)

+ Summary of Safety & Performance

Electronic System on Vigilance & PMS – Article 87 (serious incidents, FSCA, periodic summary reports, trend reports FSN)

+ Periodic Safety Update Report

Electronic System on Market Surveillance – Article 95 (surveillance activities, devices presenting an unacceptable risk, non-compliant products, preventive health protection measures)

Electronic System on Performance Studies – Article 69 (sponsors, description of performance study, status, adverse events)

UDI Database – Article 25

Electronic System on Registration – Economic Operators (SRN) – Article 27
Questions & Answers

1. Roles in the regulatory system – Blue Guide

2. Roles in the regulatory system – MDR & IVDR
   • Commission / Member States
   • Manufacturer
   • EU Authorised Representative
   • Importer / Distributor

3. UDI

4. EUDAMED
MDR Transition (Article 120)

Entry into Force (OJEC + 20days) (May 2017*)

May 2017* Adoption of MDR

Transition period 3 years

Date of Application (May 2020*)

MDD/AIMD certificate validity (4 years )

Annex IV certificates expire (May 2022*)

Last MDD/AIMD certificates expire (May 2024*)

MDR certificates

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

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

NBs designation under MDR

* Dates are « best guess » based on our current understanding on the process/steps to be completed
MDR Transition (Article 120)

“No significant changes in design and intended purpose”

Date of Application (June 2020*)

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

Post market surveillance, market surveillance, vigilance, registration of economic operators

No devices subject to scrutiny until MCDG + Expert Panels made