



MDR & IVDR – Roles in the Regulatory System

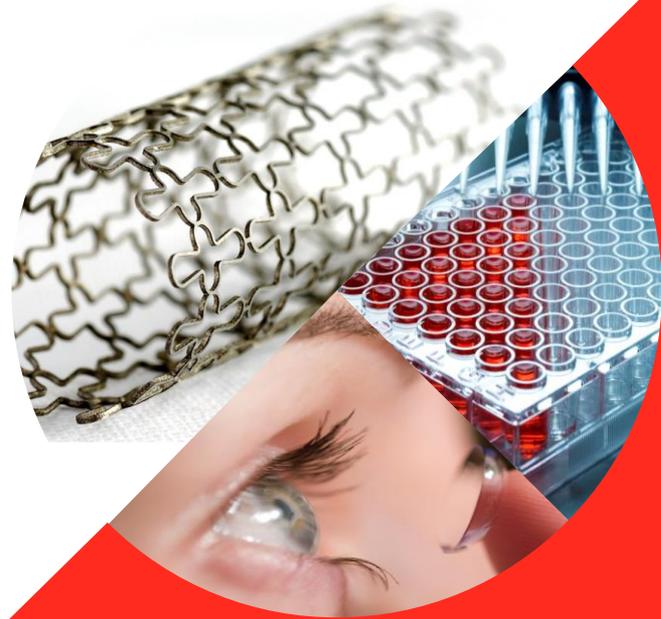
Suzanne Halliday

March 2017

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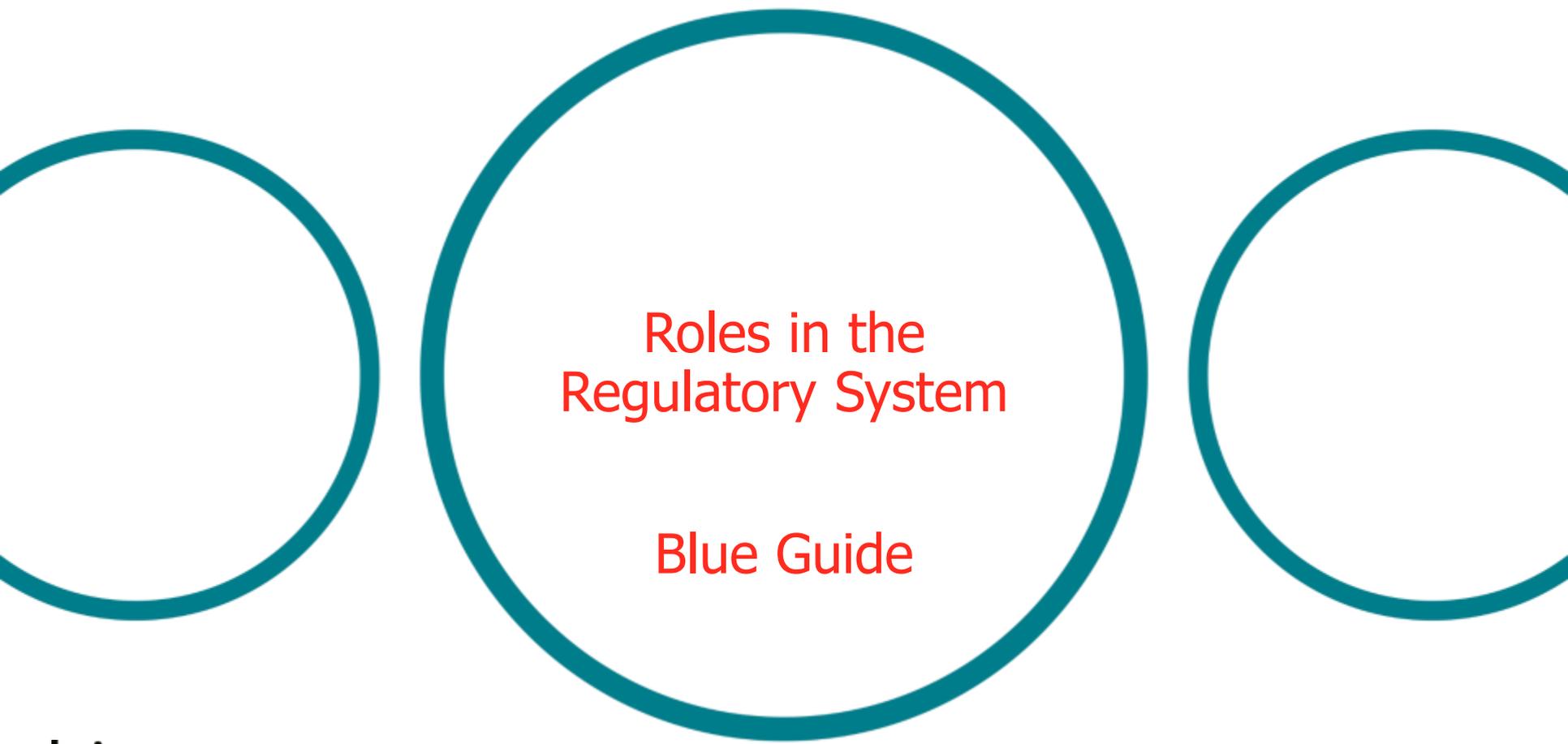
INVESTORS
IN PEOPLE



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?

Blue Guide



2016 Actors – What do they do?

Blue Guide





Commission &
Member States

MDR / IVDR
Draft February 2017

Whereas 82 / Whereas 83

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 \(Performance Studies\)](#)
- 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)

Annex I – Safety & Performance Requirements

Annex I – Safety & Performance Requirements

Annex XIV – Clinical Evaluation & PMCF

Annex II & III – Technical Documentation

Annex XIII – Custom Made Devices

Annex IV & V – EU DOC & CE

Annex VI – Unique Device Identification

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

Article 10 – Manufacturers – Clause 9 – QMS

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.

ISO 13485:2016

Not covered

Clause 7.3.3

Clause 5

Clause 6.1, 7.4.1

Clause 4.1.2, 7.1

Clause 7.3.7

Clause 7

Clause 7.5.8

Clause 8.2.1, 8.5.1

Clause 7.2.3, 8.2.3

Clause 8.2.2, 8.2.3

Clause 8.5.2, 8.5.3

Clause 8

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)

Annex III – Technical Documentation on PMS

Annex I – Safety & Performance Requirements

Article 87-90 – Incidents, Trends, FSCA

Article 87-90 – Incidents, Trends, FSCA

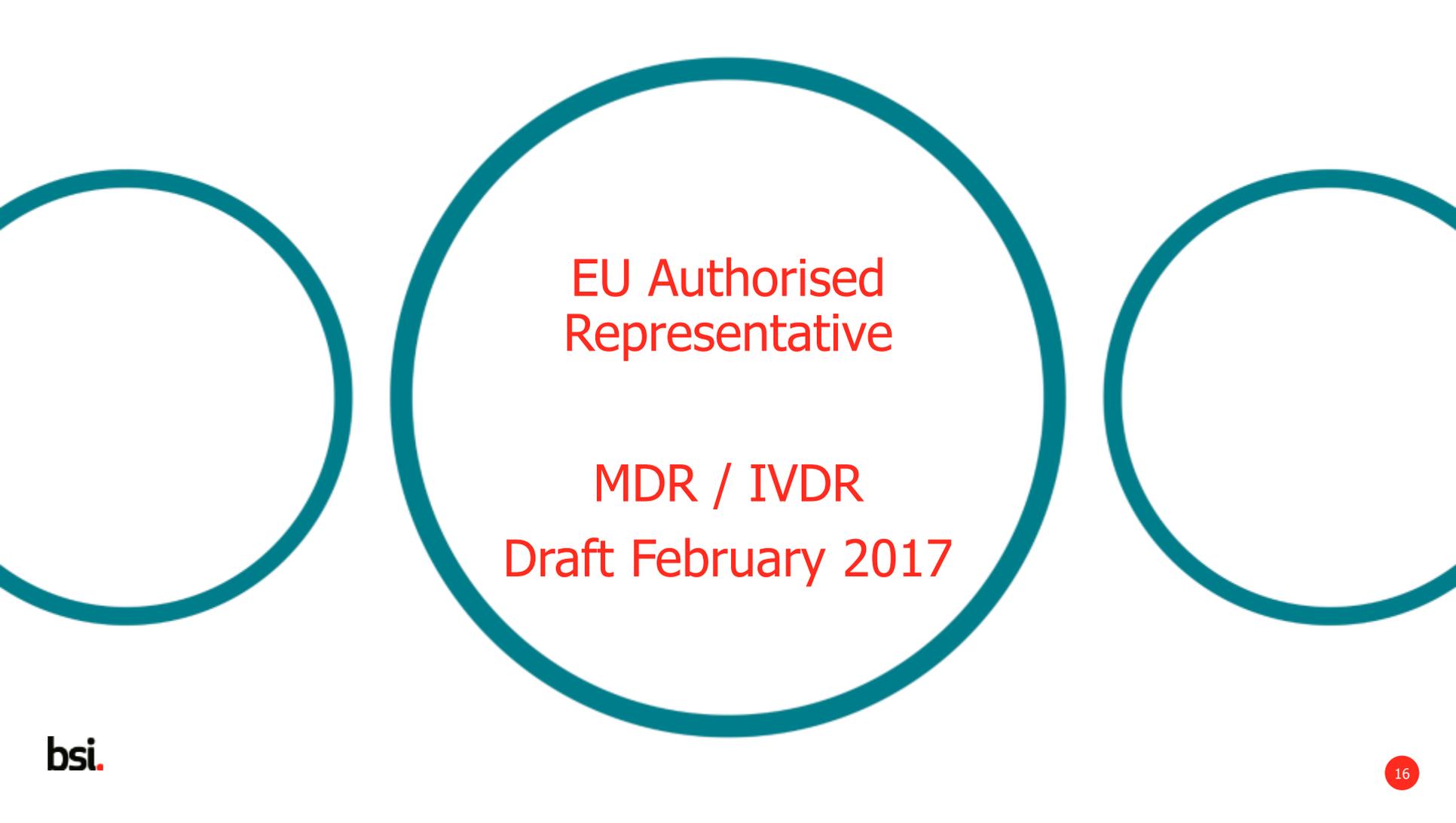
Article 10 – General Obligations of Manufacturers

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.

Annex II & III – Technical Documentation

Article 30 – EUDAMED – Economic Operators

Directive 85/374/EEC



EU Authorised
Representative

MDR / IVDR
Draft February 2017

EU Authorised Representative – Article 11 / Article 11

- 4. The manufacturer shall not delegate the obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).



- 5. Where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, jointly and severally with, the manufacturer.

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)
6. EU DoC (Annex IV) & affix CE mark (Annex V)
7. UDI (Annex VI)
9. QMS
10. PMS (Annex III)
11. Information Supplied (Annex I – SPR#23)
12. CAPA, FSCA (Article 89)

EU Authorised Representative – Article 11 / Article 11

MDD	MDR / IVDR
<p>Article 1 (j)</p> <ul style="list-style-type: none">• 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”	<p>Article 11/11 – 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</p>
<p>No defined process or scope for designation:</p> <ul style="list-style-type: none">• 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	<p>2. & 3. The designation shall constitute the EU AR’s mandate:</p> <ul style="list-style-type: none">• 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

MDD	MDR / IVDR
	a) Mandate shall require, and the Manufacturer shall enable the EU AR to perform at least the following: <ul style="list-style-type: none"> • Verify DoC and Technical Documentation drawn up • Verify appropriate conformity assessment performed
Annex II, V, VI – Make available to CAs upon request: <ul style="list-style-type: none"> • DoC • Documentation of QMS, Technical Documentation, + Changes • NB certificates, NB audit reports • >5 / >15 years <u>after last manufacture</u> • + Article 15 – clinical investigation reports 	b) Keep available a copy of and at the disposal of the Competent Authority: <ul style="list-style-type: none"> • Technical Documentation, DoC and NB certificates • >10 / 10 years <u>after last placing on the market</u> / >15 years for implantable devices
Article 14 – Register with a Competent Authority	c) Register with SRN, within one week of any change maintain, re-confirm accuracy in first year and then every second year Verify Manufacturer has: <ul style="list-style-type: none"> • Entered UDI core data elements • Assigned / Entered Basic UDI-DI

EU Authorised Representative

MDD	MDR / IVDR
Annex II, V, VI – Provide information in response to Competent Authority request (no reference to demonstration of conformity, no language requirement)	d) Provide information / documentation to Competent Authority on request to demonstrate conformity in requested language
	e) Forward to Manufacturer Competent Authority's request for samples / access to a device and verify samples / access given
	f) Cooperate with Competent Authorities in any preventive / corrective action to eliminate / mitigate risk
Article 10 – Member States with manufacturer or EU AR assessment of incidents	g) Immediately inform Manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents
	h) Terminate mandate if Manufacturer acts contrary to its obligations under this Regulation (inform Member State & Notified Body)

Person Responsible for Regulatory Compliance Article 15 / Article 15

- 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.**

Person Responsible for Regulatory Compliance Article 15 / Article 15

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

- a) 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;
- b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;
- c) the post-market surveillance obligations in accordance with Article 10(10) / Article 10(9) are complied with;
- d) the reporting obligations referred to in Articles 87 to 91 / 82 to 86 are fulfilled;
- e) in the case of investigational devices / devices for performance studies, the statement referred to in Section 4.1 of Chapter II of Annex XV / Annex XIV is issued.



Importers &
Distributors

MDR / IVDR
Draft February 2017

Importers & Distributors – Current Directives

Directive 2001/95/EC – General Product Safety Directive

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

Distributors – Article 14 / 14

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

Importers

Distributors

Importers MDR / IVDR	Distributors MDR / IVDR
<p>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</p>	<p>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</p>
<p>Where the Importer considers the device presents a serious risk or is a falsified device, it shall inform Manufacturer, EU AR and Competent Authority</p>	<p>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</p>
<p>3. Importers shall indicate on the device, on its packaging or in a document accompanying the device:</p> <ul style="list-style-type: none">• 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	

Importers

Distributors

Importers MDR / IVDR	Distributors MDR / IVDR
<p>4. Importers shall:</p> <ul style="list-style-type: none">• Verify device is registered in UDI database• Register for SRN, within one week of any change maintain, re-confirm accuracy in first year and then every second year	
<p>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</p>	<p>3. Distributors shall ensure that while a device is under their responsibility, storage or transport conditions comply with conditions set by Manufacturer</p>
<p>6. Importers shall:</p> <ul style="list-style-type: none">• Keep register of complaints, non-conforming devices, recalls and withdrawals• Provide Manufacturer, EU AR and Distributors with any information requested in order to allow investigation of complaints	<p>5. Distributors shall:</p> <ul style="list-style-type: none">• Keep register of complaints, non-conforming devices, recalls and withdrawals• Keep Manufacturer, EU AR and Importers informed of monitoring and provide any information upon request

Importers

Distributors

Importers MDR / IVDR

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

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.

Distributors MDR / IVDR

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:

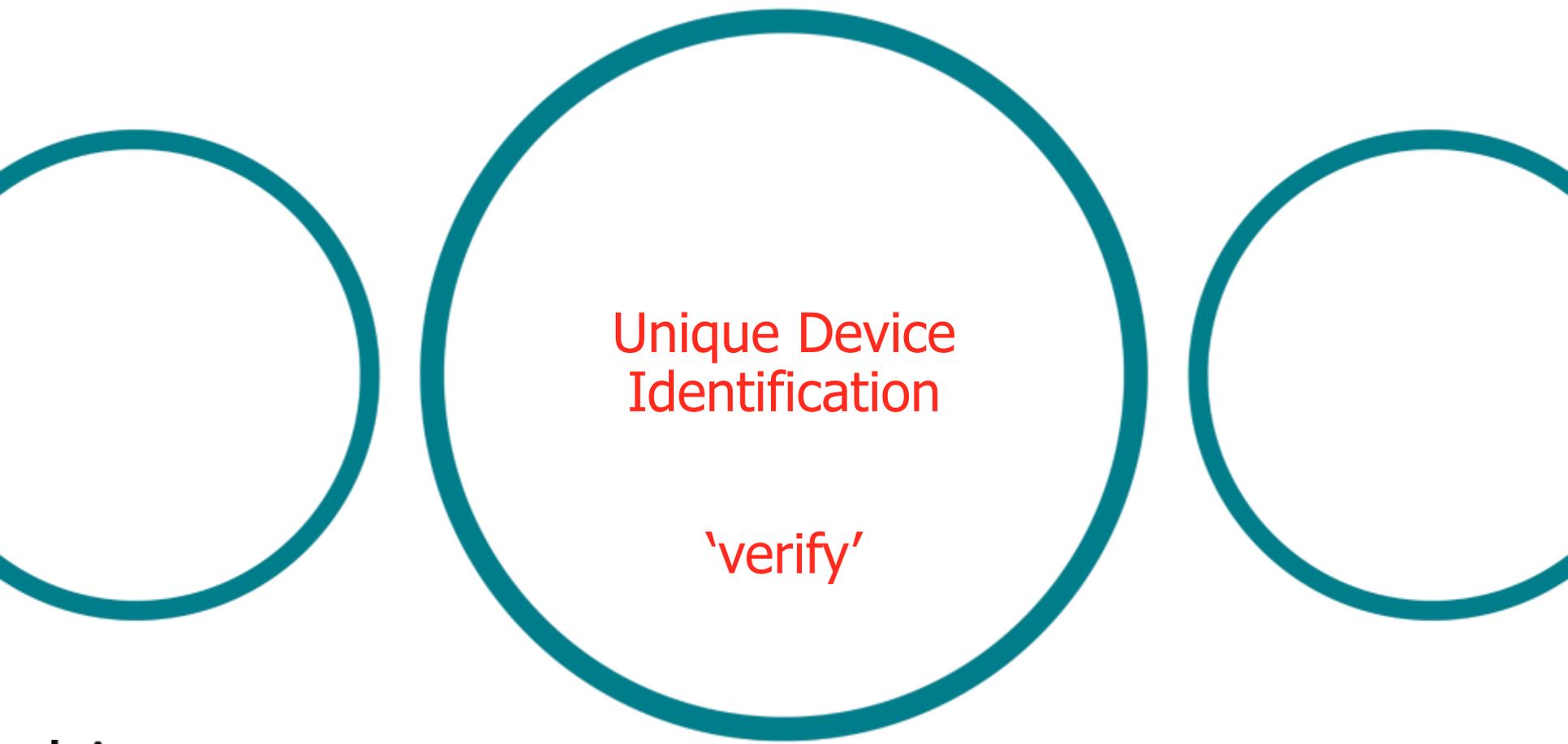
- Immediately inform the Competent Authorities of the Member States in which they made the device available and the Notified Body

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

Distributors

Importers MDR / IVDR	Distributors MDR / IVDR
9. Importers shall: <ul style="list-style-type: none">• Keep copy of DoC and NB certificates• >10 / 10 years <u>after last placing on the market</u> / >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	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'

Article 27 – Unique Device Identification

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.



Article 27 – UDI

- 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.
- The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.
- 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.
- 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.

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

import XML fix + save
fill with test data Initial
fill with test data In F
fill with test data Follow Up
fill with test data Final new case, keep base data

Version: 2.26 en
2012-12-04

1 Administrative information

Recipient (Name of MCA)	Stamp box
Address of National Competent Authority	
Date of this report	
Reference number assigned by the manufacturer	
Reference number assigned by MCA	
Type of report <input type="radio"/> Initial report <input type="radio"/> Follow-up report <input type="radio"/> Combined initial and final report <input type="radio"/> Final report	
Does this incident represent a serious public health threat? <input type="radio"/> yes <input type="radio"/> no	
Classification of incident <input type="radio"/> Death <input type="radio"/> Unanticipated Serious Deterioration in State of Health <input type="radio"/> All other reportable incident	
Identify to what other MCA's this report was also sent	

2 Information on submitter of the report

Status of submitter <input type="radio"/> Manufacturer <input type="radio"/> Authorized Representative within EEA and Switzerland and Turkey <input type="radio"/> Others (identify the role)
--

Numeric description of device

Nomenclature system (preferable GMDN) GMDN	Nomenclature code ▼
Nomenclature text	
Commercial name/brand name / make	
Model number	Catalogue number
Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
Software version number (if applicable)	

Article 27 – UDI

Annex IV

- 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.
- The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.
- 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.
- 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.

Declaration of Conformity

Manufacturer: Name, registered trade name or registered trade mark

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

EU Authorised Representative: Name and Address

Devices:

- Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered (it may include a photograph, where appropriate)
- UDI device identifier
- Risk class of the device in accordance with Annex VII

References to the relevant common technical specifications

Where applicable, additional information

Notified Body: Where applicable, name and identification number
Description of the conformity assessment procedure performed
Identification of the certificate(s) issued

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

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

Name and function of the person who signs

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

Date ____ Place and date of issue _____

Article 27 – UDI

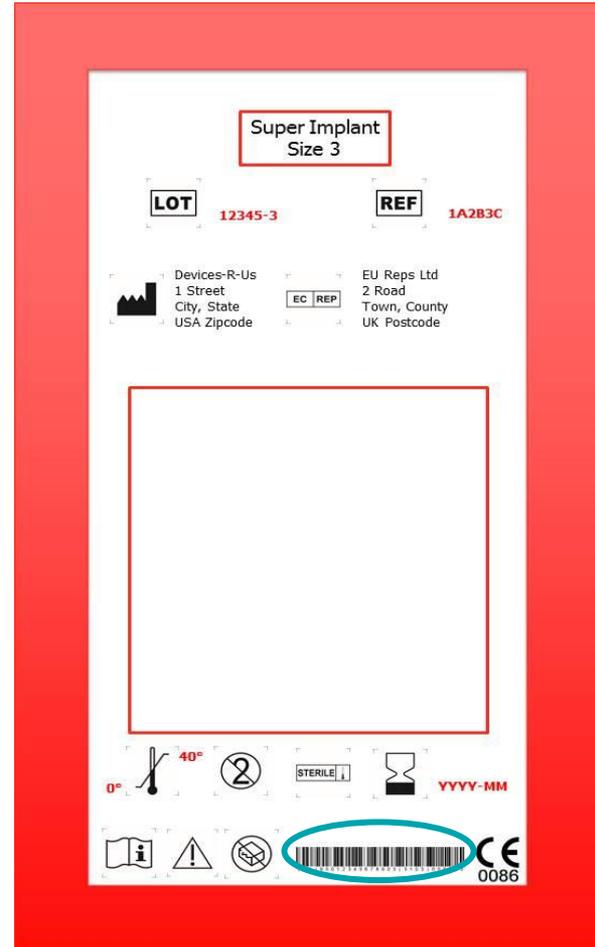
4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.
5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article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

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

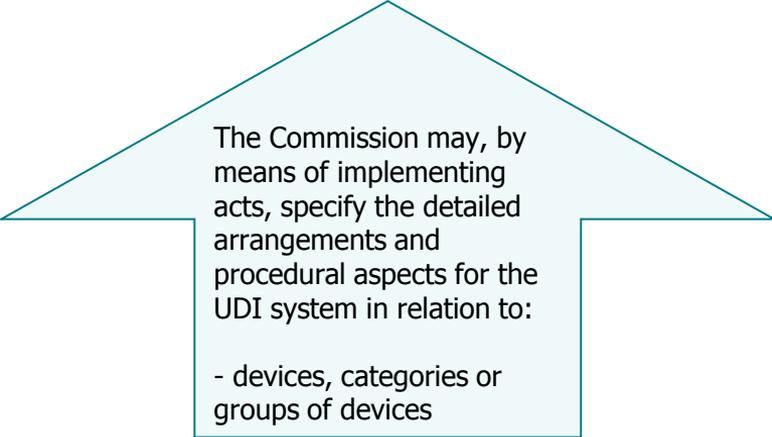
Annex I – Safety & Performance Requirements

- **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)



Article 27 – UDI

- 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.**



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

- 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.

UDI



Article 18 – Implant Card

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

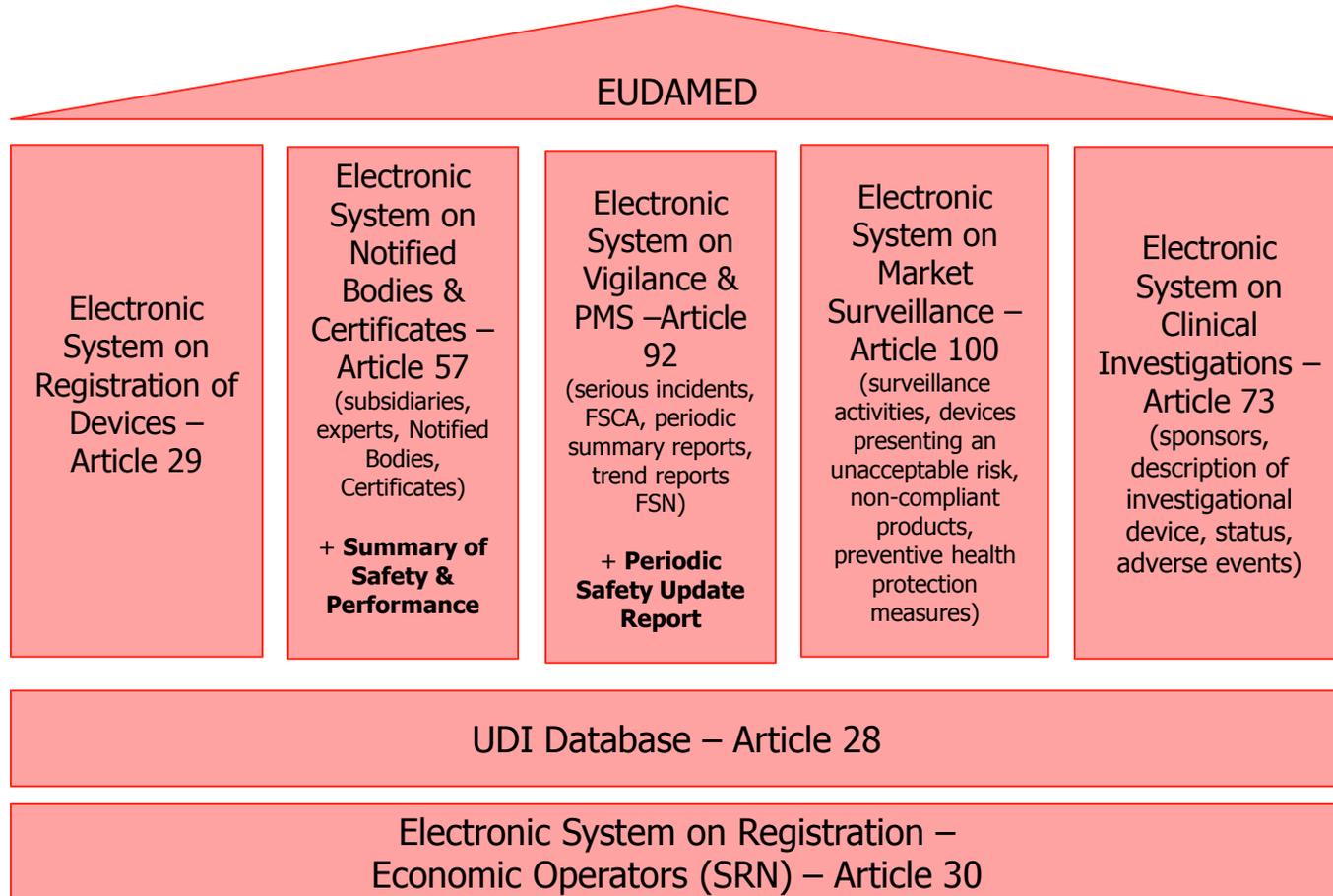
- ❑ device name
- ❑ serial number
- ❑ lot number
- ❑ **Unique Device Identification**
- ❑ device model
- ❑ manufacturer name, address and website
- ❑ any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable 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



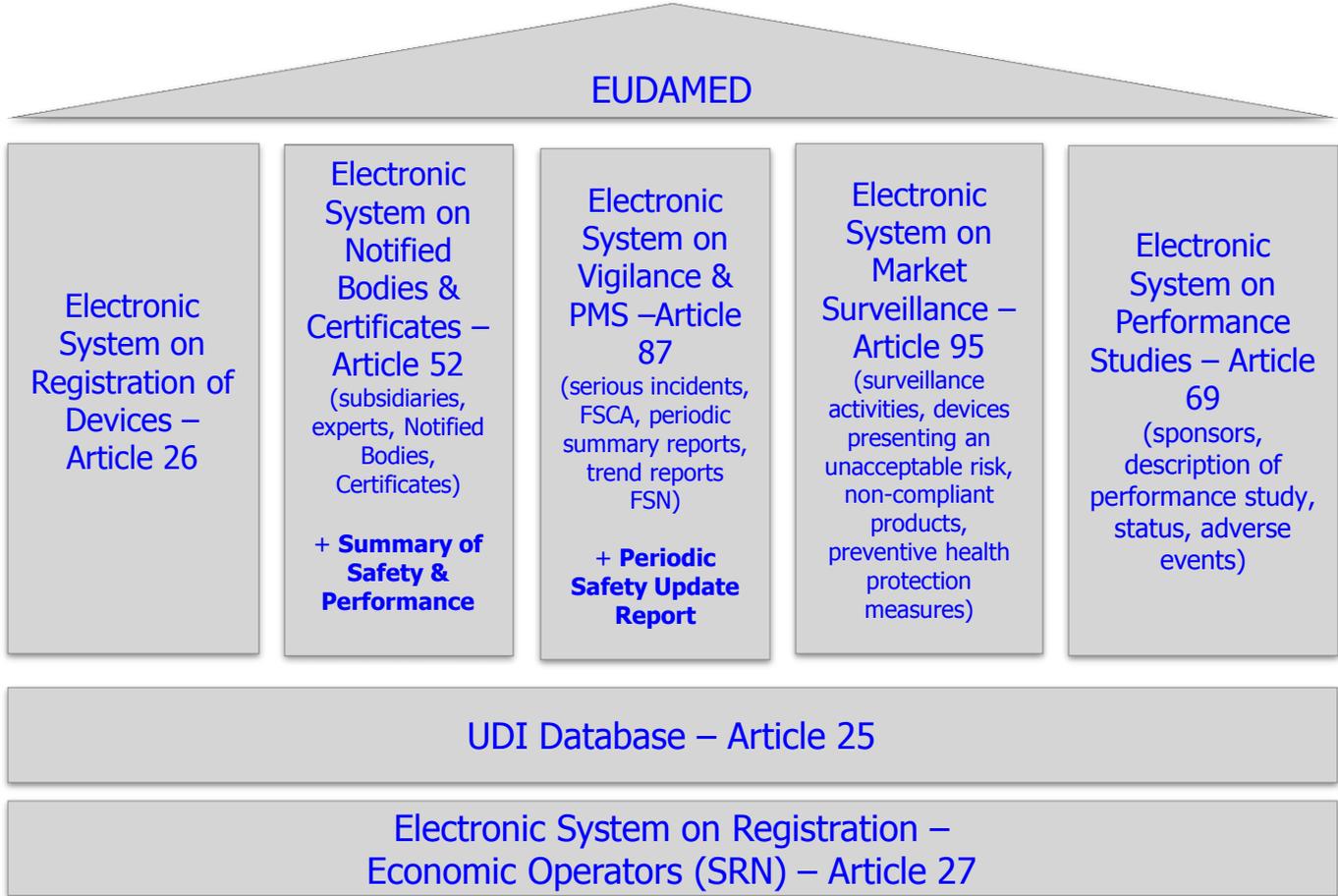
EUDAMED

'register'

MDR – European Database on Medical Devices – Article 33



IVDR – European Database on Medical Devices – Article 30

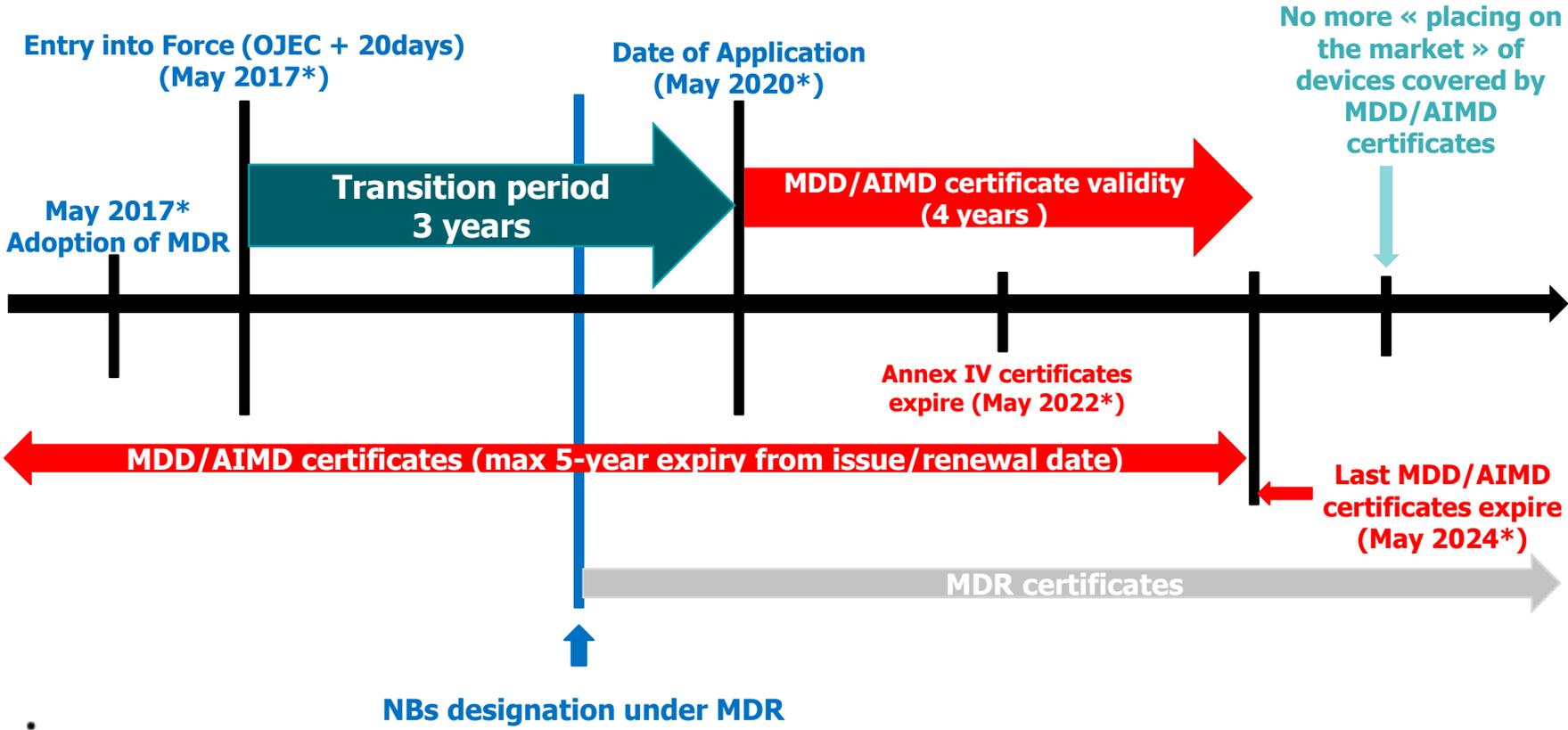


Questions & Answers

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)



* Dates are « best guess » based on our current understanding on the process/steps to be completed

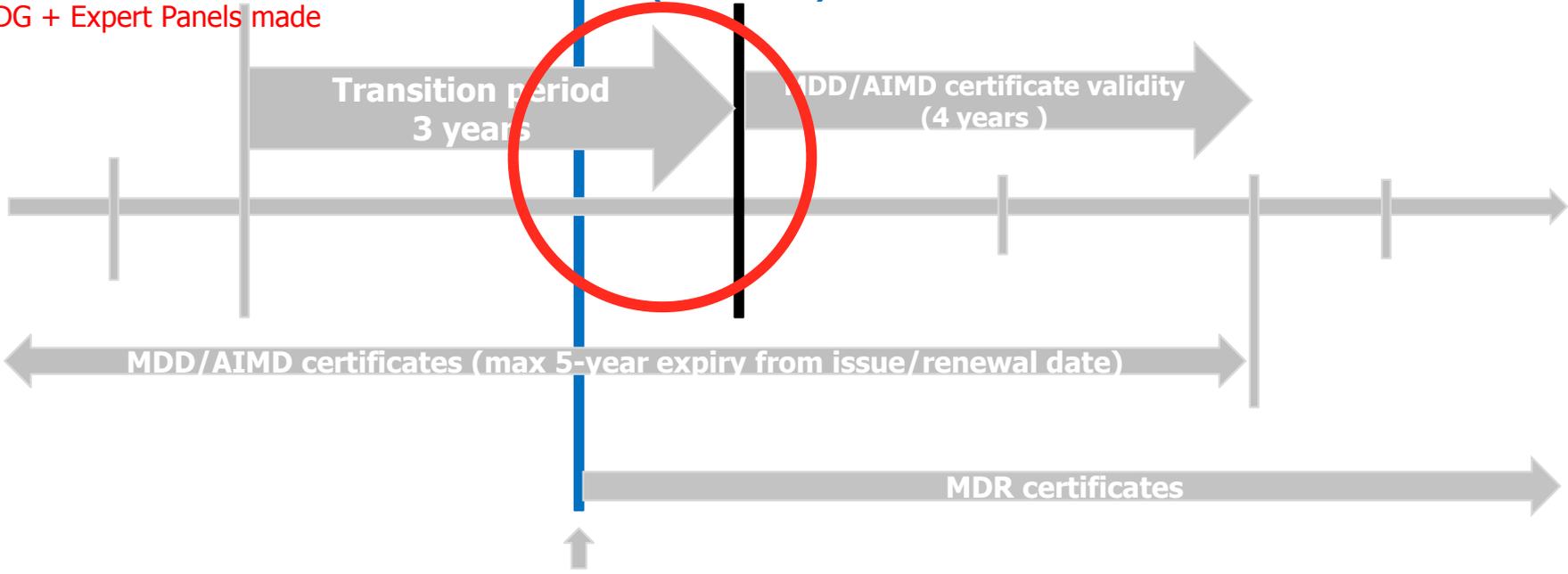
MDR Transition (Article 120)

“No significant changes in design and intended purpose”

No devices subject to scrutiny until MCDG + Expert Panels made

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

Date of Application (June 2020*)



NBs designation under MDR