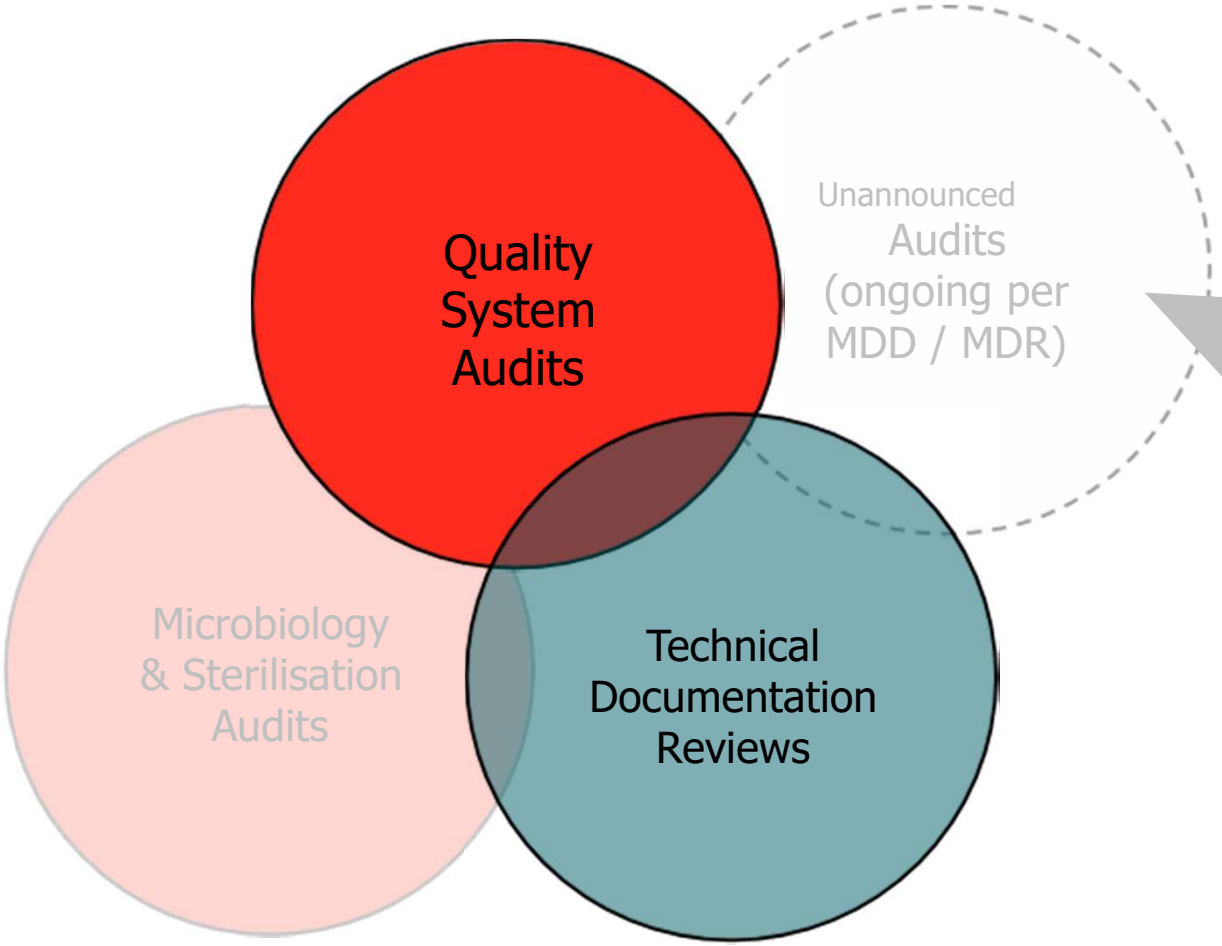
BSI Audits for MDR Certification



- No changes as a result of MDR / IVDR
- New frequencies already applied
- Once per 3 years for Class III & Implants
- Once per 5 years for rest

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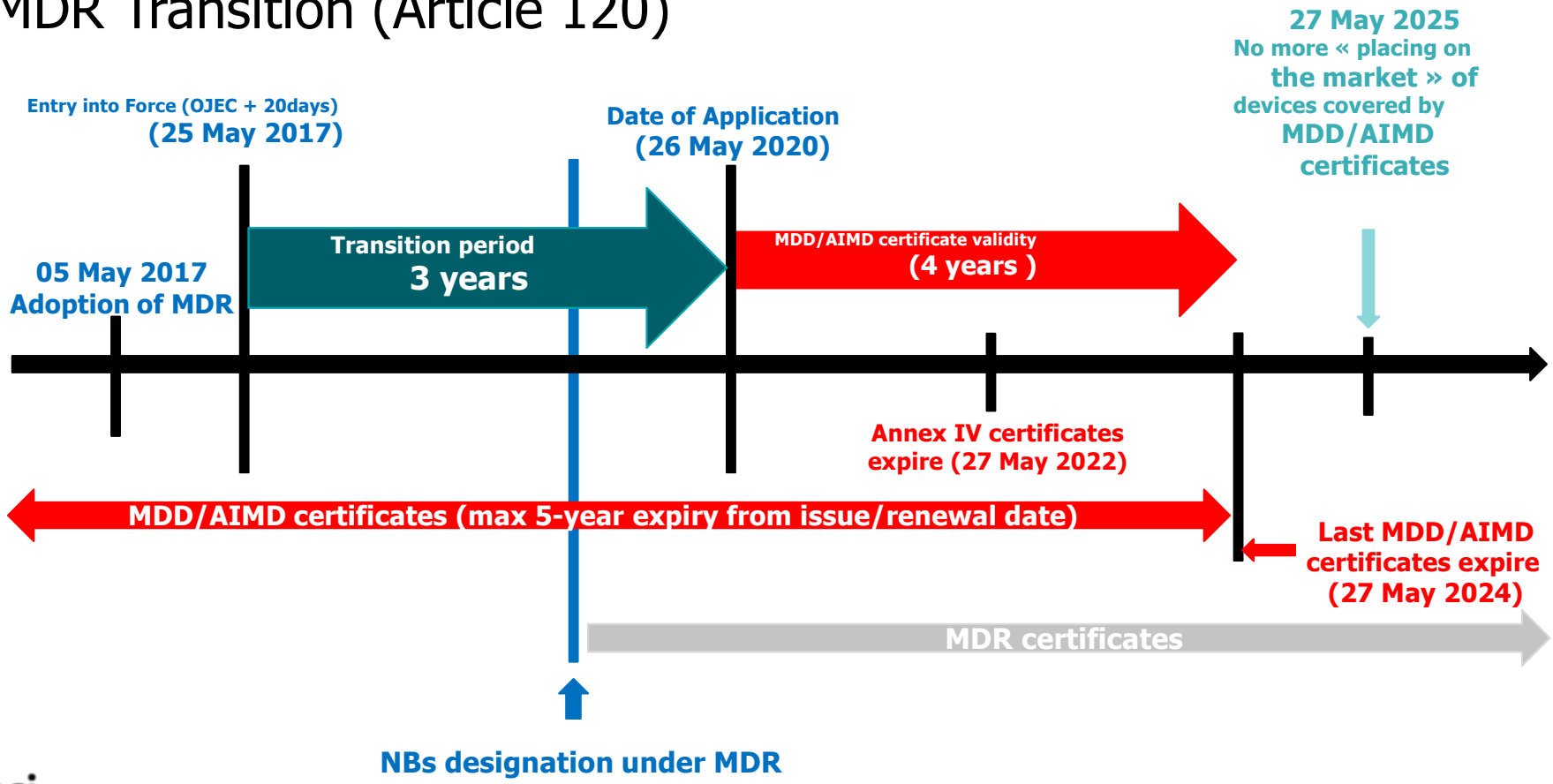
QMS Items for MDR

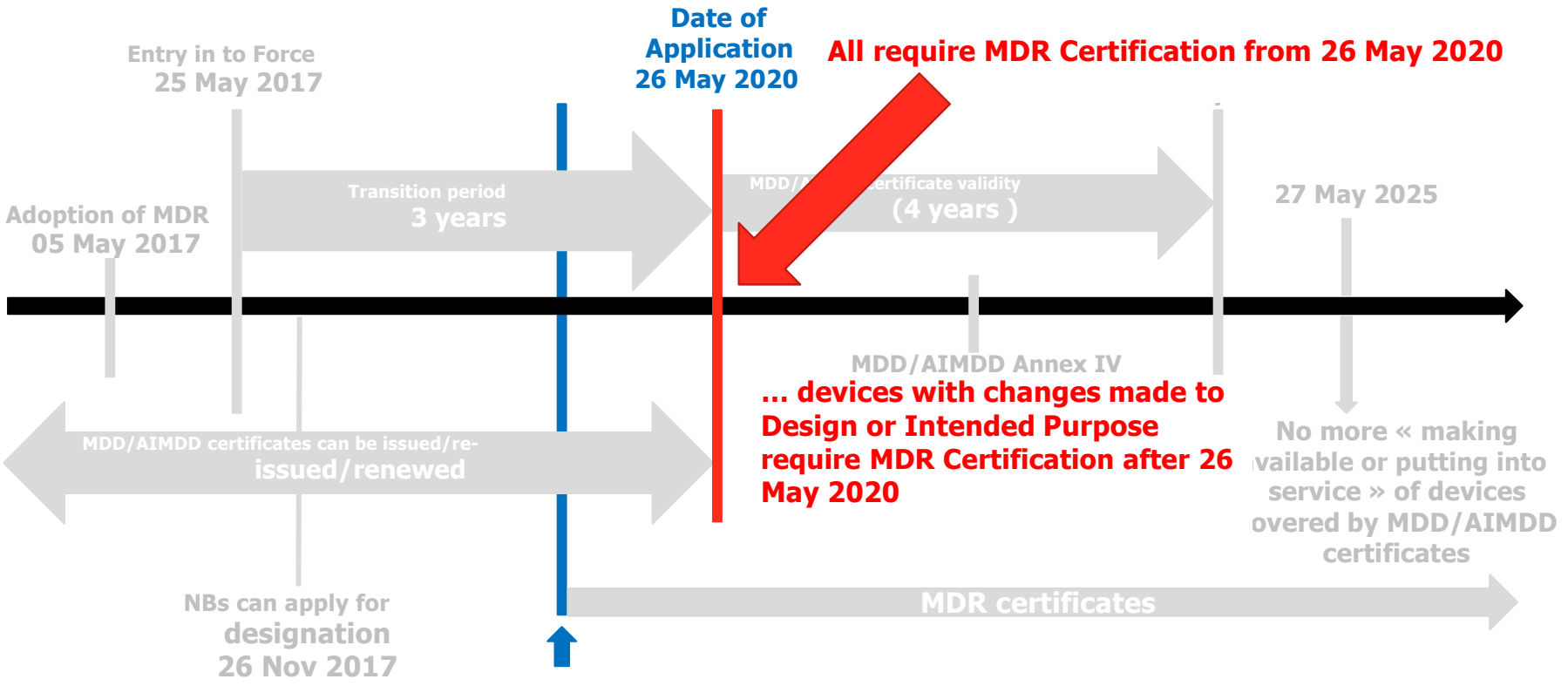
Immediate checks / post market

MDR Transition (Article 120)



MDR Transition (Article 120)

- **Class I reusable**
- **Class III custom made implantable**
- **Reclassified Software (previously Class I)**
- **Devices with no medical purpose (once CS available)**




MDR
26 May 2020


IVDR
26 May 2022

BSI QMS Audits from 26 May 2020
For All EXISTING CE Certifications – 3 Main Areas

1) Registrations
   - Devices (Article 29)
   - Economic Operators (Article 30)
   - Manufacturers, authorised representatives and importers (Article 31)

2) Post Marketing Surveillance Systems
   - For Plan (Article 84) & Report (Article 85 – Class I)
- Vigilance Reporting requirements - Systems for Serious Incident, FSCA and Trend Reports (Article 87 & 88)
   - PSUR (Article 86 – Class IIa, IIb, III) – post MDR certification

3) Market Surveillance (Article 93)
   - Provision / access to information, devices, sites by Competent Authorities

Economic Operators

Article 2 Definitions

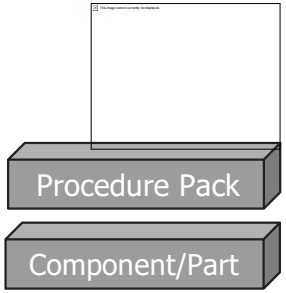
- A manufacturer
- An authorised representative
- An importer
- A distributor
- Or the person referred to in Article 22(1) and 22(3) i.e. Provider of Procedure Packs or Parts & Components

Economic Operators

Manufacturer – Article 10

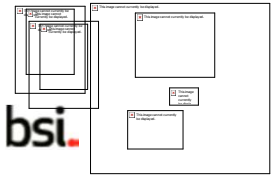
Authorised Representative – Article 11 & 12

Importer – Article 13



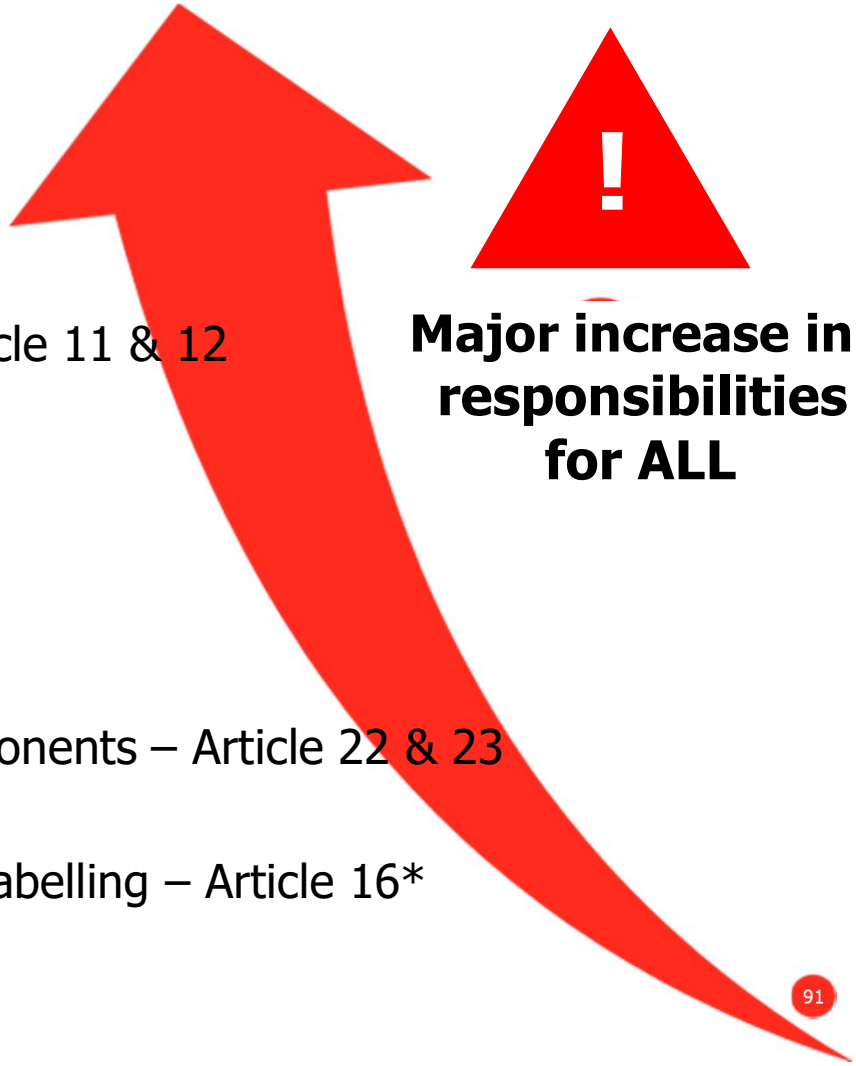
Distributor – Article 14

Procedure packs or parts / components – Article 22 & 23



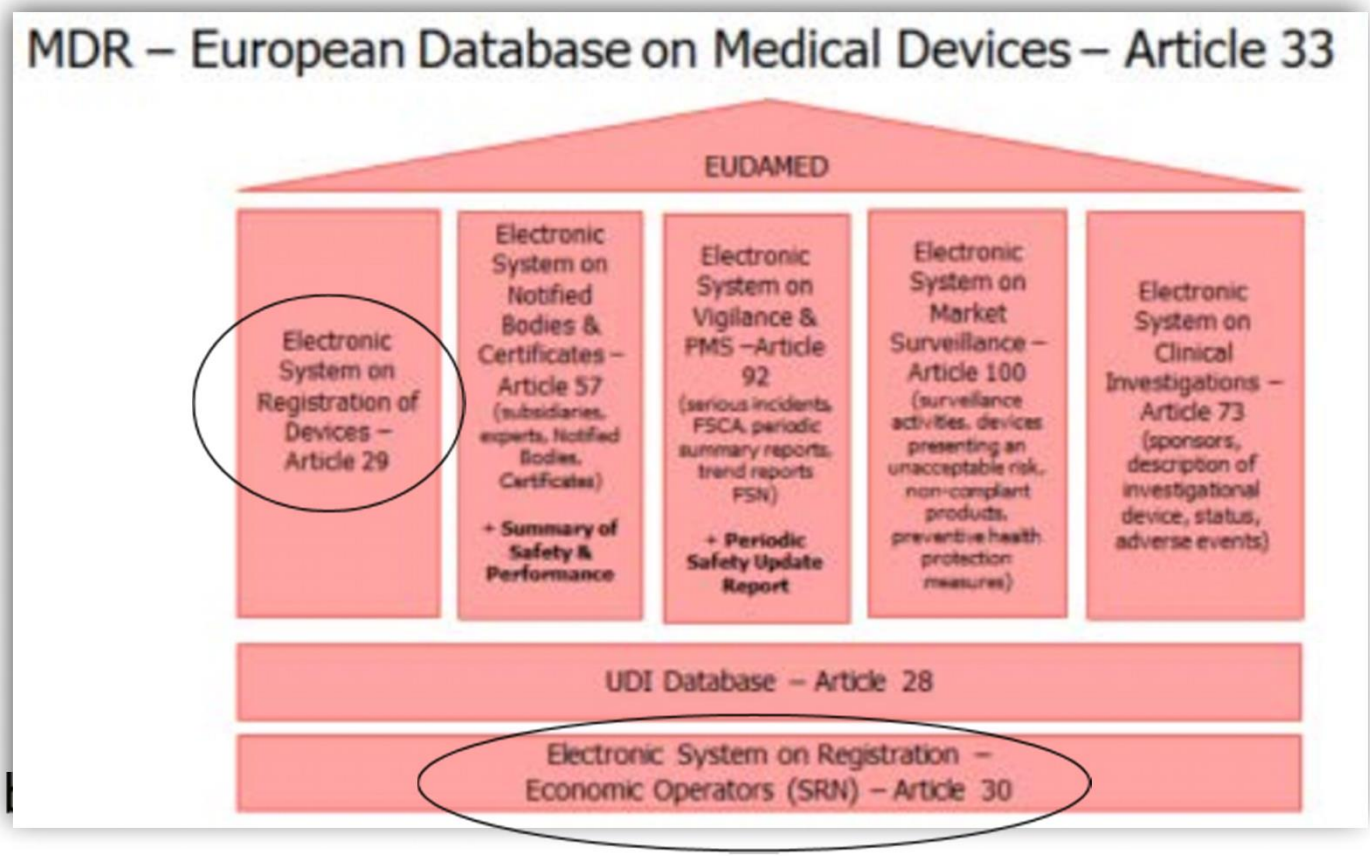
Translation / Re-packaging / Re-labelling – Article 16*

*Need EC Certificate



Major increase in responsibilities for ALL

Registration of Devices & Economic Operators



- Devices (Article 29)
- Economic Operators (Article 30)
- Manufacturers, authorised representatives and importers (Article 31)

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QMS processes and Economic Operators

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	Manufacturer (Article 10)	Authorised representative (Articles 11 and 12)	Importer (Article 13)	Distributor (Article 14)	Assembler (Article 22)
Eudamed registration	■	■	■		
Technical documentation	■	■	■		■
Design and development, Manufacture or assembly	■				■
Handling, storage and distribution	■		■	■	■
Nonconformities	■	■	■	■	■
FSCA	■	■	■	■	■
UDI/Labelling	■	■	■	■	■
Complaints	■	■	■	■	■
PMS	■	■		■	■
Person responsible for RC	■	■			

Vigilance

Requirements for Reporting Serious Incidents & FSCAs – Article 87

- New regulation wording on 'Causal' relationship between device and incident

Type of incident	Directives	Regulations
Serious Public Health Threat	2 days	2 days
Death or Unanticipated Serious Deterioration in the State of Health	10 days	10 days
Others	30 days	15 days

- Systems
- Process
- Procedures
- Evidence

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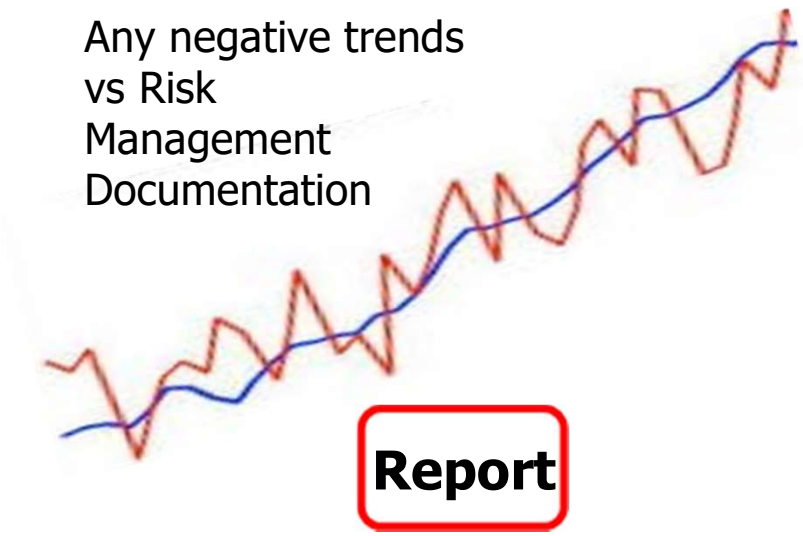
Vigilance
Requirements for Trend Reporting – Article 88

Any negative trends vs Risk Management Documentation



Report

- any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side- effects that could have a significant impact on the benefit-risk analysis … and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.
- The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information

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QMS Items for MDR / IVDR

Following application for certification

- For Brand New Initial Applications – Normal Initial Assessment Durations Apply
- For Manufacturers 'Transitioning' from MDD / AIMD to MDR likely 1 – 4 days Initial Assessment (in addition to current MDD durations)

Article 10/10 – Manufacturers

Clause 9 – 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;
f) clinical / performance evaluation, including PMCF / PMPF;
g) product realisation, including planning, design, development, production and service provision;

Much already covered in ISO 13485:2016

ISO 13485:2016 – not covered

ISO 13485:2016 – 7.3.3

ISO 13485:2016 – 5

ISO 13485:2016 – 6.1, 7.4.1

ISO 13485:2016 – 4.1.2, 7.1

ISO 13485:2016 – 7.3.7

ISO 13485:2016 – 7

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Article 10/10 – Manufacturers

- Clause 9 – The quality management system shall address at least the following aspects:
- verification of UDI assignments, ensuring consistency of information provided;
- setting-up, implementation and maintenance of a PMS system;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
- processes for reporting of serious incidents and FSCA in the context of vigilance;
- management of corrective and preventive actions and verification of effectiveness;
- processes for monitoring and measurement of output, data analysis and product improvement.

Much already covered in ISO 13485:2016

ISO 13485:2016 – 7.5.8

ISO 13485:2016 – 8.2.1, 8.5.1

ISO 13485:2016 – 7.2.3, 8.2.3

ISO 13485:2016 – 8.2.2, 8.2.3

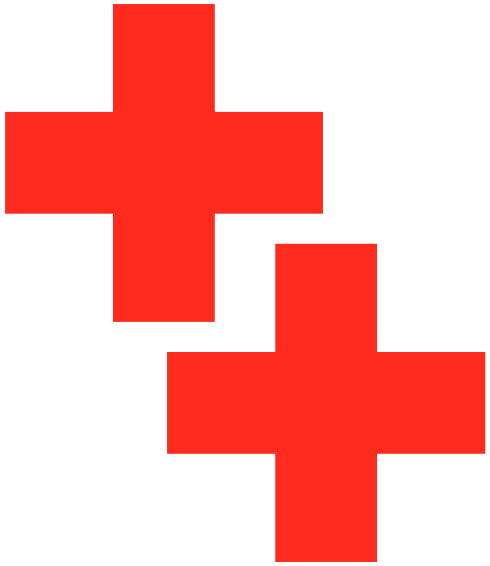
ISO 13485:2016 – 8.5.2, 8.5.3

ISO 13485:2016 – 8

Initial Assessment to MDR

… Some key areas we will be covering in BSI QMS Audits

- General QMS Requirements
  - Continual Improvement
  - Strategy for Regulatory Compliance
- Person Responsible for Regulatory Compliance
- UDI (+ Implant Card)
- Clinical processes – evaluation and investigation
- Post Market Processes – PMS Systems, PSUR, SSCP
- Technical Documentation Processes and Procedures



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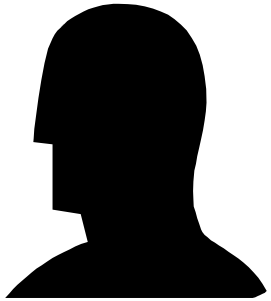
Person Responsible for Regulatory Compliance

Article 15

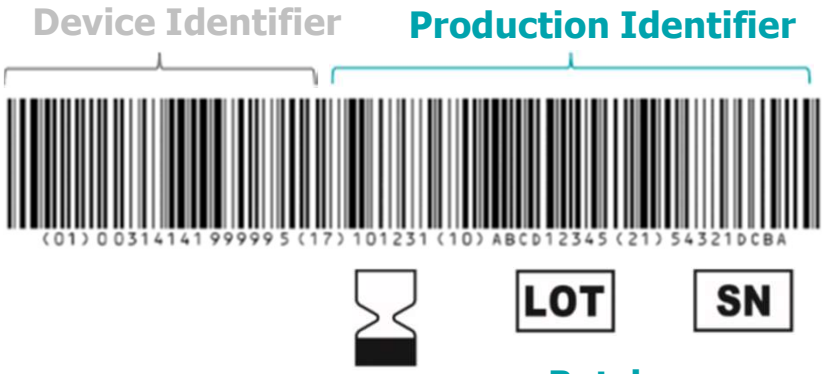
- Required for both Manufacturers and Authorised Representatives
- Must have expertise in medical devices, including degree and four years' professional experience
- Responsible for ensuring:
  - ⇨ Product conformity checked via appropriate QA release
  - ⇨ Technical documentation and DoC maintained
  - ⇨ PMS & reporting obligations are met
  - ⇨ Investigational devices: statement of safety and compliance with SPRs

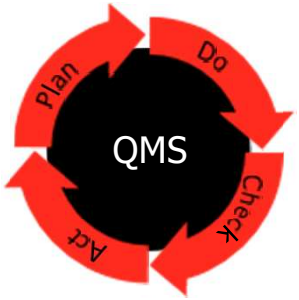


- Note the concessions for small or micro enterprises with respect to requirements

UDI – Article 27 (24)

- On the label (not shipping containers)
- On vigilance reports … the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.
- EU declaration of conformity - the Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the Doc referred to in Article 19.
- Technical documentation - Annex II
- Implant Card – Article 18
- Notified Body CE Certificate – Annex XII





UDI Dates

GS1, HIBCC and ICCBBA designated UDI issuing entities (Article 123,3i; Article 113,3h)	• **May 26, 2019**
UDI carrier on the label and higher levels of packaging (Article 123,3f; Article 113,3e)	• May 26, 2021 - Implantable devices and Class III devices; • May 26, 2023 - Class IIa and IIb (non-implantable) devices and Class D devices • May 26, 2025 - Class I devices, Class B and Class C devices • May 26, 2027 - Class A devices
UDI carrier on reusable devices (Article 123,3g)	• May 26, 2023 - Reusable Class III devices • May 26, 2025 - Reusable Class IIa and reusable IIb (non-implantable) devices • May 26, 2027 - Reusable Class I devices

Implant Card - Article 18

- The manufacturer of an implantable device (**not** sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors), shall provide together with the device the following:

- device name, serial number, lot number
- Unique Device Identification, device model
- manufacturer name, address and website

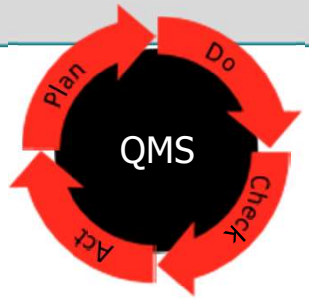
} Available to patient on implant card

- any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- any information about the expected lifetime of the device and any necessary follow-up;
- any other information to assure a safe use of the device by the patient
- including the information in Annex I, Section 23.4 (u) – qualitative and quantitative information on the materials and substances to which patients can be exposed

Periodic Safety Update Report - Article 86

- **Throughout the lifetime of the device concerned the PSUR shall set out:**
- Conclusions of determinatio
- Main finding
- Volume of Sale
- Estimate of the size and other characteristics of the Population that use the device
- Where practicable usage frequency of the device

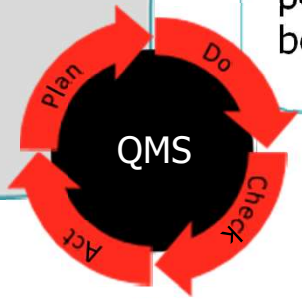
BSI QMS Audit Check of Systems, Procedures etc – Detail in Technical Documentation Reviews



- Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices
- Manufacturers of class IIb and III devices shall te the report at least annually
- lass IIa devices shall update d at least every
- For clas submit PSUR reports by c system to the notified body
- Notified Body shall review, add its evaluation with details of any action taken, and make available to the Competent Authorities through the electronic system

Summary of Safety & Clinical Performance - MDR Article 32

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



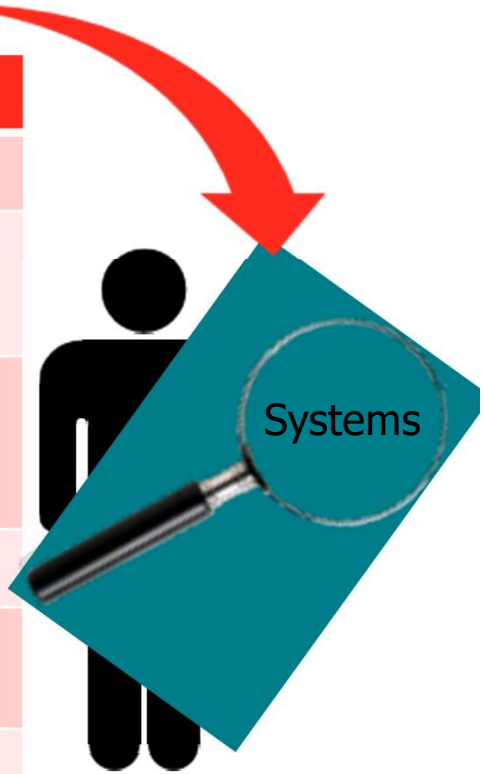
- For implantable devices and for class III devices, the manufacturer shall draw up a summary of safety and clinical performance
- The SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via EUDAMED

Article 61 – Clinical Evaluation

For class III devices **and** implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance (referred to in Article 32) shall be updated at least annually with such data.

Summary Safety & Clinical Performance SSCP- Article 32
Periodic Safety Update Report PSUR - Article 86

	PSUR	SSCP
Class I	Strictly N/A however Article 85 – Class I PMS Report updated 'when necessary'	-
Class Is / Im / Ir		-
Class IIa	As necessary and at least every 2 Years	-
Class IIb	Annual	-
Class IIb Implantable	Annual to NB (via EUDAMED)	Annual to NB (to EUDAMED)
Class III	Annual to NB (via EUDAMED)	Annual to NB (to EUDAMED)



Witness Testing & Reconciliation

- Annex IX Chapter I – 3.3 + 3.5
- Class IIa, IIb, III
- … At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly.

- For class III devices surveillance assessment shall include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

Witness Testing & Reconciliation

- New / strengthened requirement to perform or request tests to verify proper functioning of the QMS
- Currently routine in Unannounced Audits
- BSI Policy to witness where possible
- Focus on inprocess and / or final product inspection
- Reconciliation of materials for class III

Safety & Performance Requirements

1. Safe, Perform as Intended, State of the Art
2. Risk reduction as far as possible
3. **Risk Manageme**
4. Risk Control
5. Risk of **Use Erro**
6. Lifetime
7. Packaging, Transport, Sto
8. Undesirable side-effects minimised & Risks<Benefits
9. Annex XVI "no risk at all" or "no more than the maximum acceptable risk"

10. **Chemical, Physical & Biological** Propertie
11. Infection & Microbial Contamination
12. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body
13. Devices incorporating **materials of biological origin**
14. Construction and **interacti with the environment**
15. Devices with a diagnostic or measuring function
16. Protection against radiation

17. **Electronic programmable systems**
18. Active devices and devices connected to them
19. Requirements for AIMD
20. Protection against mechanical and thermal risks
21. Protection against the risks posed to the patient or user by supplied energy or substances
22. Protection against the r posed by medical devices intended for use by lay persons
23. **Information Supplied**

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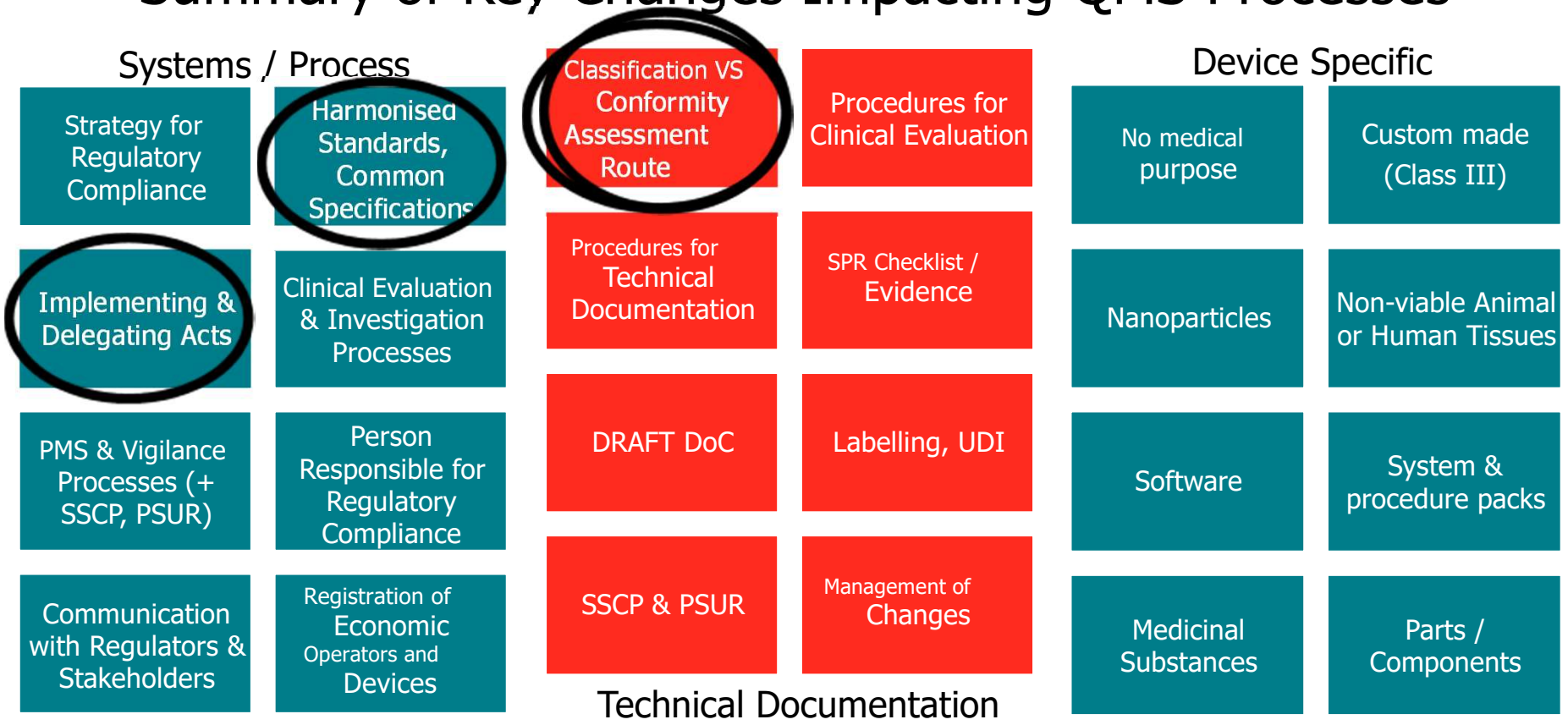
Summary of Key Changes Impacting QMS Processes



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