QMS Aspects of the MDR (& IVDR)

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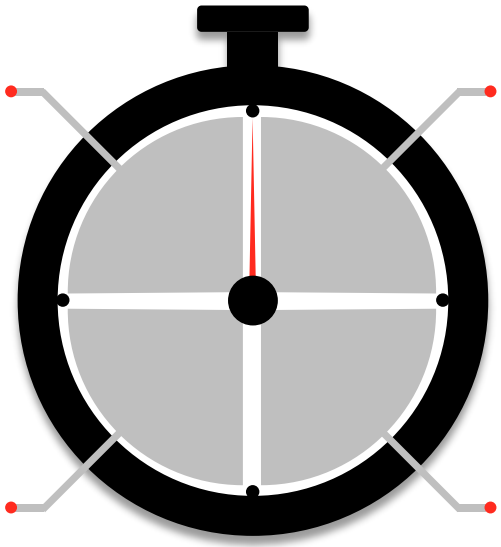
Global QMS Manager Medical Devices
27 February 2018

By Royal Charter

This Presentation

1. The clock is ticking!
2. Dates & priorities
3. BSI Assessments
4. QMS Items for MDR / IVDR
    - Immediate checks / post market
    - For full MDR / IVDR Application
5. MDD to MDR Certification
6. Next Steps...

The Clock is Ticking!



- What products currently on the EU market?
- What products on the market post 2024?
- What needs certification in 2022 / 2024?
- What is ‘in’ the MDR / IVDR that wasn’t previously? i.e. Will need CE Certification sooner?
- What is reclassified?
- What are the priority products?

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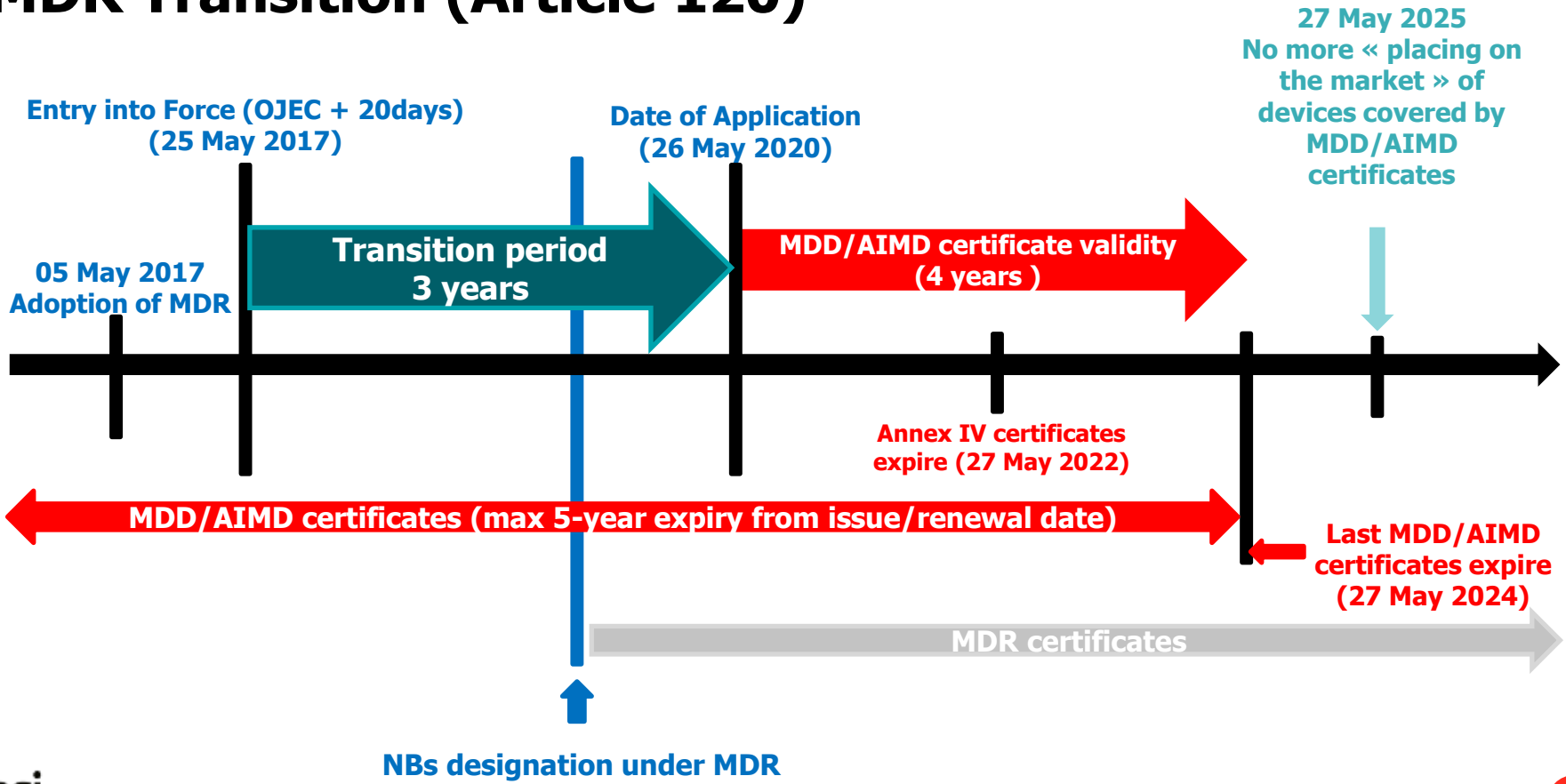
MDR Transition (Article 120)



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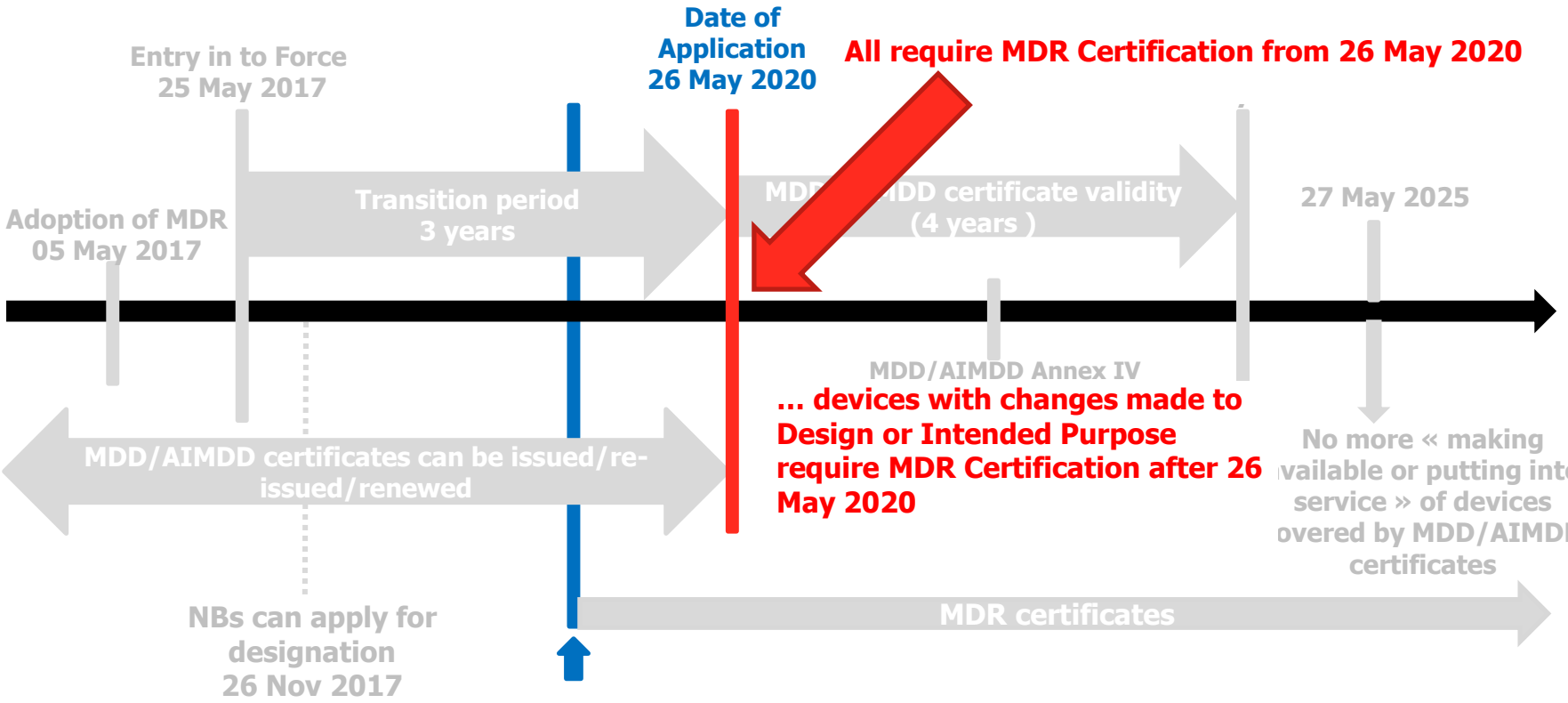
MDR Transition (Article 120)

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



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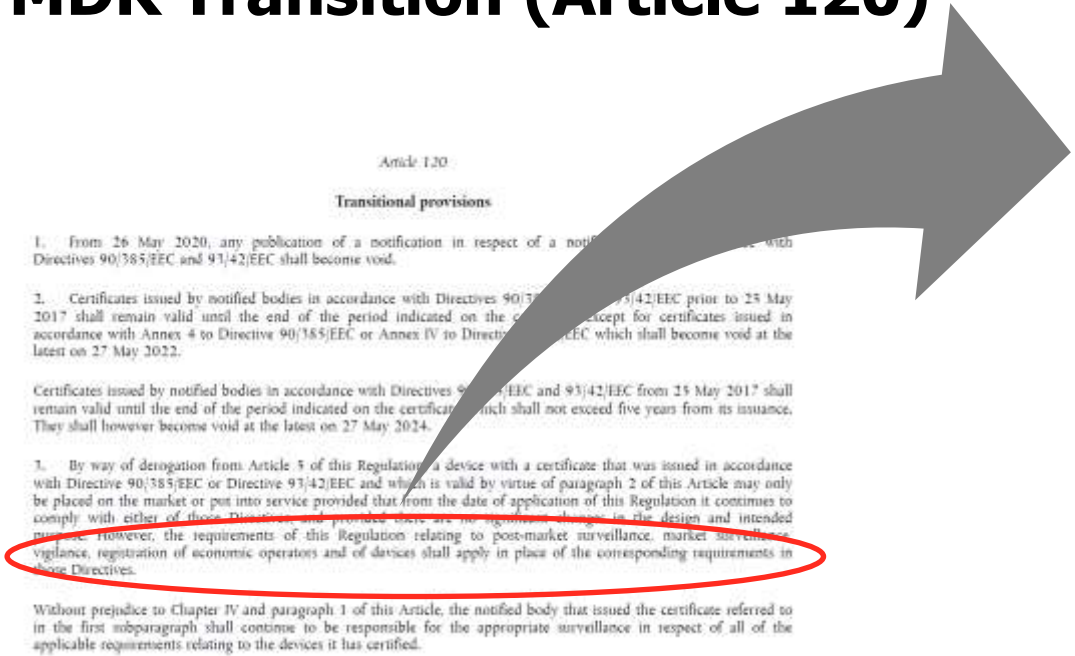
MDR Transition (Article 120)



Article 120

Transitional provisions

1. From 26 May 2020, any publication of a notification in respect of a noti… with Directives 90/385/EEC and 93/42/EEC shall become void.

2. Certificates issued by notified bodies in accordance with Directives 90/3… 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the c… except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directi… EEC which shall become void at the latest on 27 May 2022.

Certificates issued by notified bodies in accordance with Directives 9… EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificat… hich shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

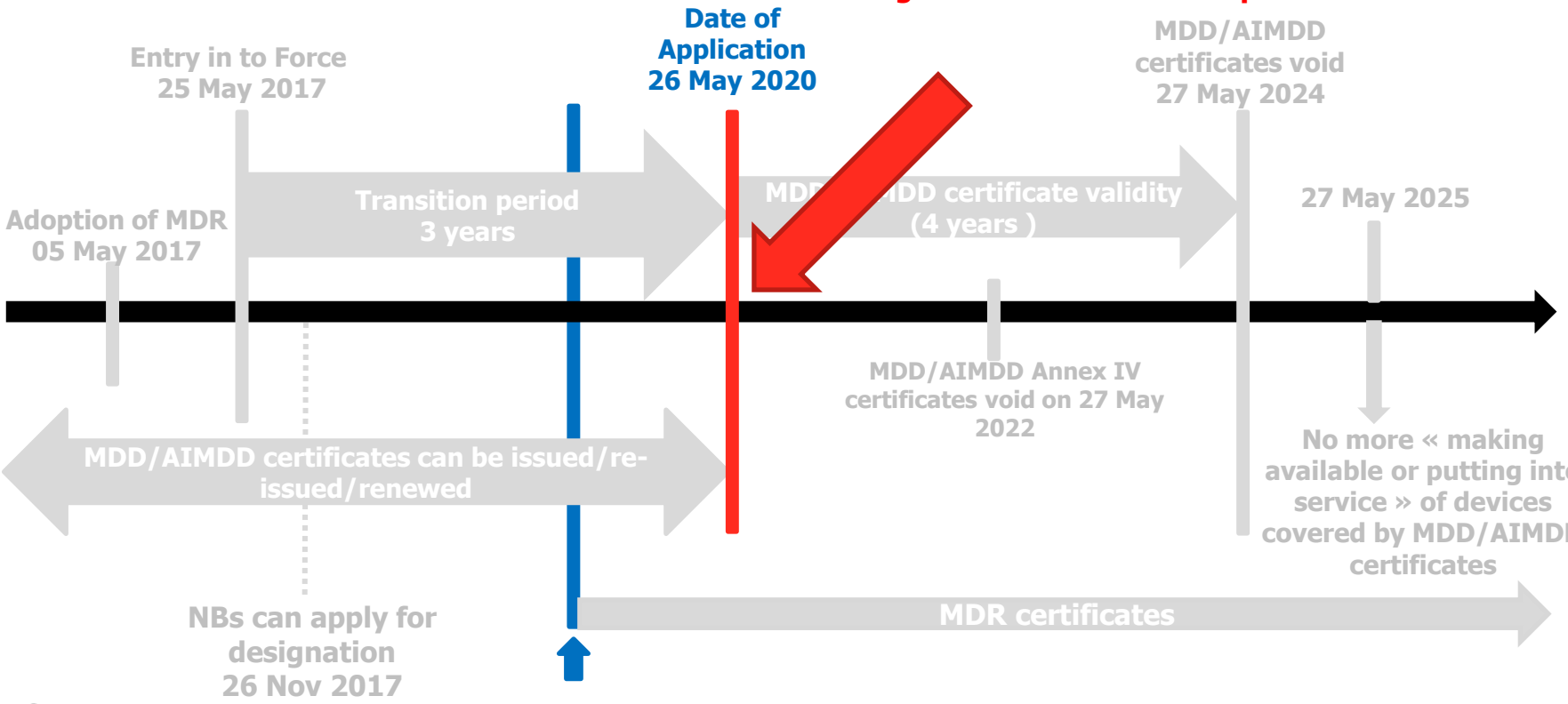
3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

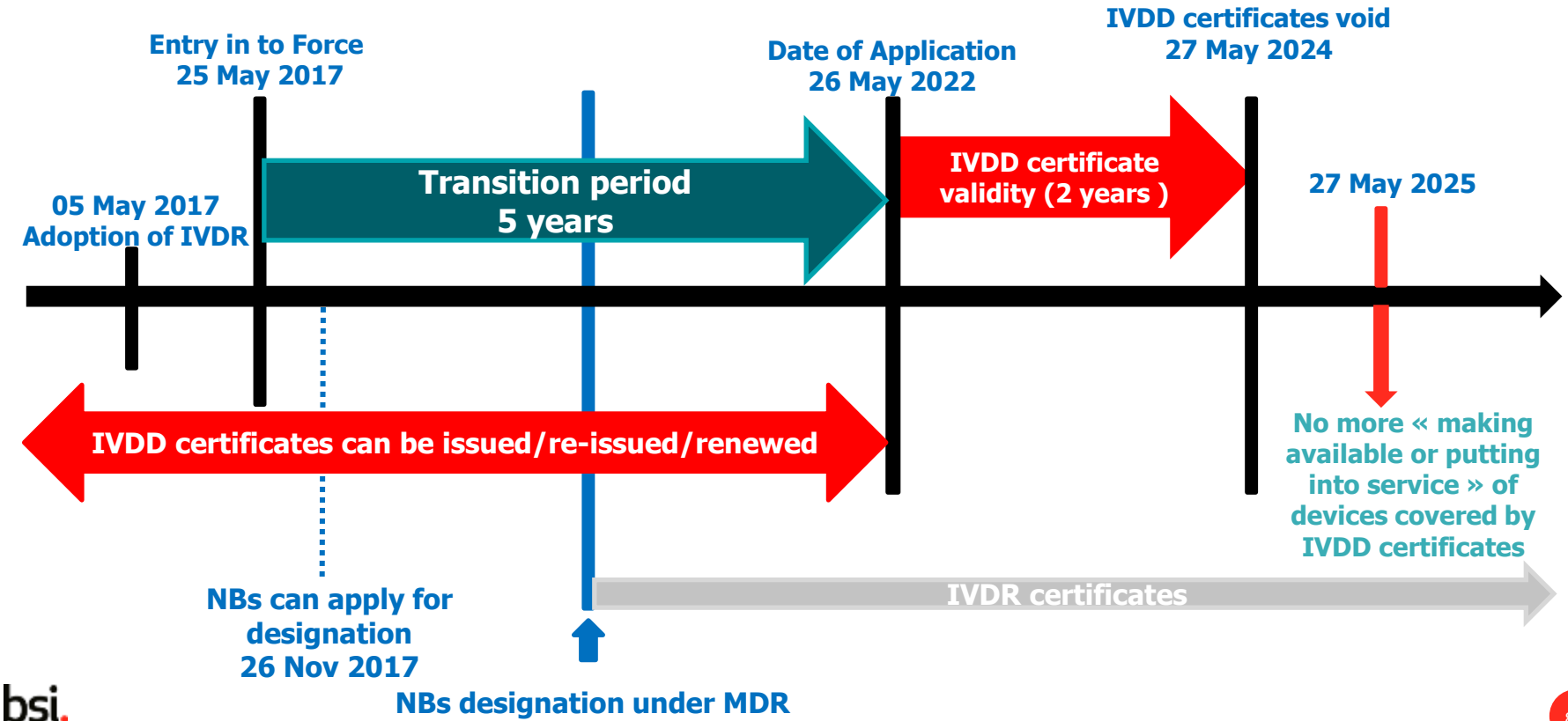
However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

MDR Transition (Article 120)

- Post market surveillance
- Market surveillance
- Vigilance
- Registration of economic operators and devices

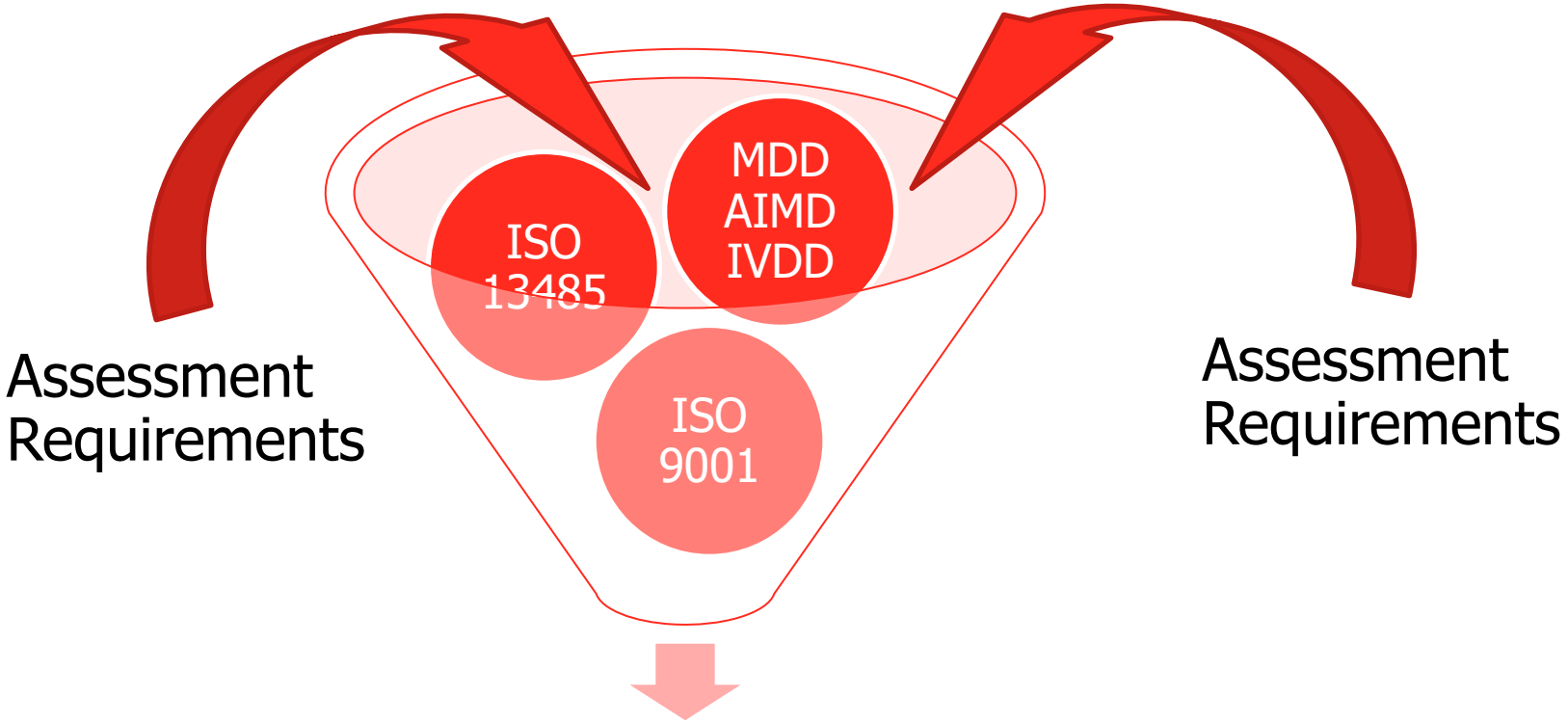


IVDR Transition (Article 110)



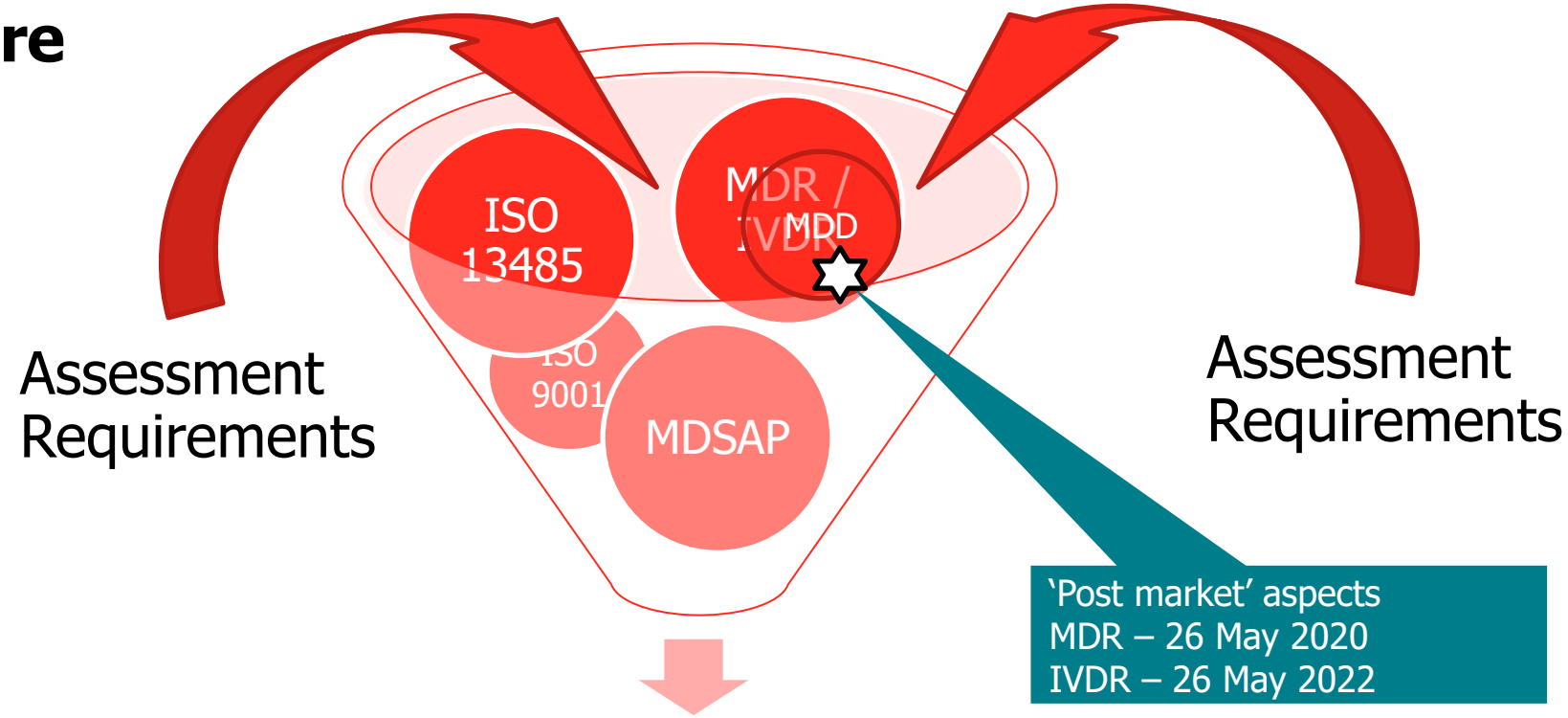
BSI Assessments

Now



BSI QMS AUDIT

Future

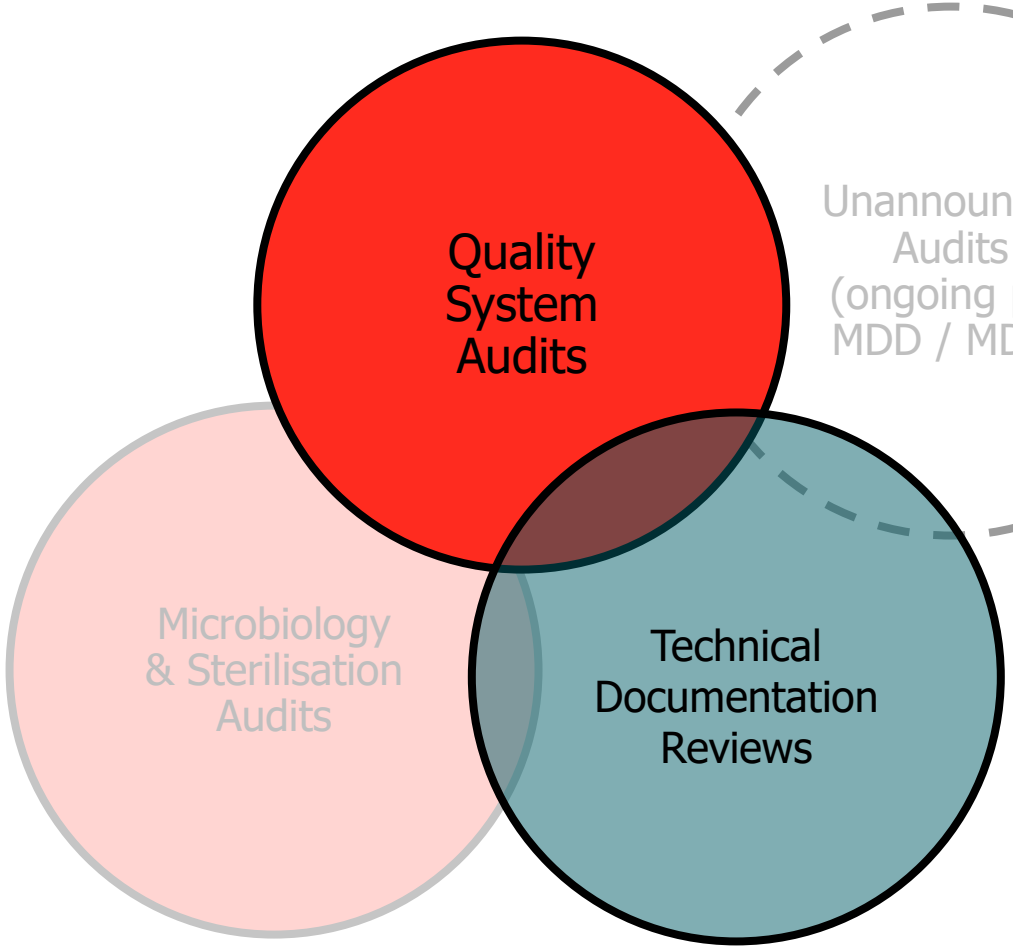


BSI QMS AUDIT

BSI QMS Audits

- What is the procedure?
- Show me the process
- What is the defined and documented system for…
- Do you have evidence of?

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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IVDR Pilot Audits - Volunteers Required!

Charge at standard rates

Pilot IVDR QMS Audits

- Not a full formal audit, could be:
  - Sections of site / systems
  - Section of QMS
  - One product range
  - Several sub-systems

BSI Draft MDR / IVDR Processes and Procedures:

- DRAFT MDR / IVDR Assessment Procedures
- DRAFT MDR and IVDR Checklist (Approx. 100 items dependant on Devices, Conformity Assessment Route etc)

- No non-conformities (observations)
- Assessment will **not** count (i.e. full formal QMS assessment required at later date)
- Audit of process / systems and evidence as far as is reasonable / possible
- **BSI accept full implementation will not be possible in all cases (e.g. SRN, UDI, EUDAMED etc)**

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QMS Items for MDR / IVDR

- Immediate checks / post market


MDR
26 May 2020


IVDR
26 May 2022

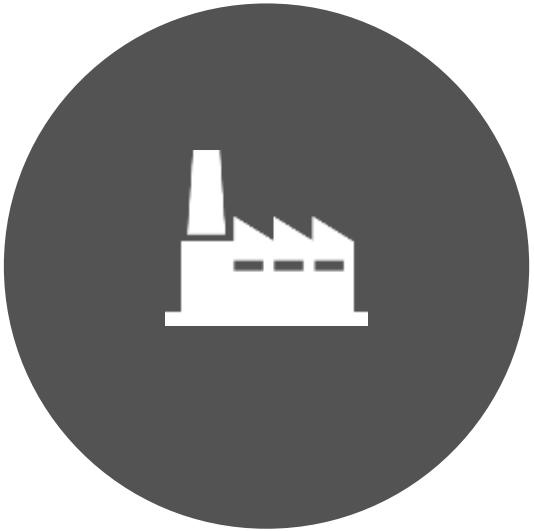
BSI QMS Audits from 26 May 2020 / 2022
For All EXISTING CE Certifications – 3 Main Areas

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

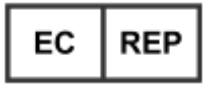


Article 2 Definitions

- *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

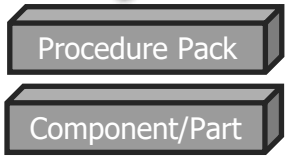
Manufacturer – Article 10



Authorised Representative – Article 11 & 12

Importer – Article 13

Distributor – Article 14



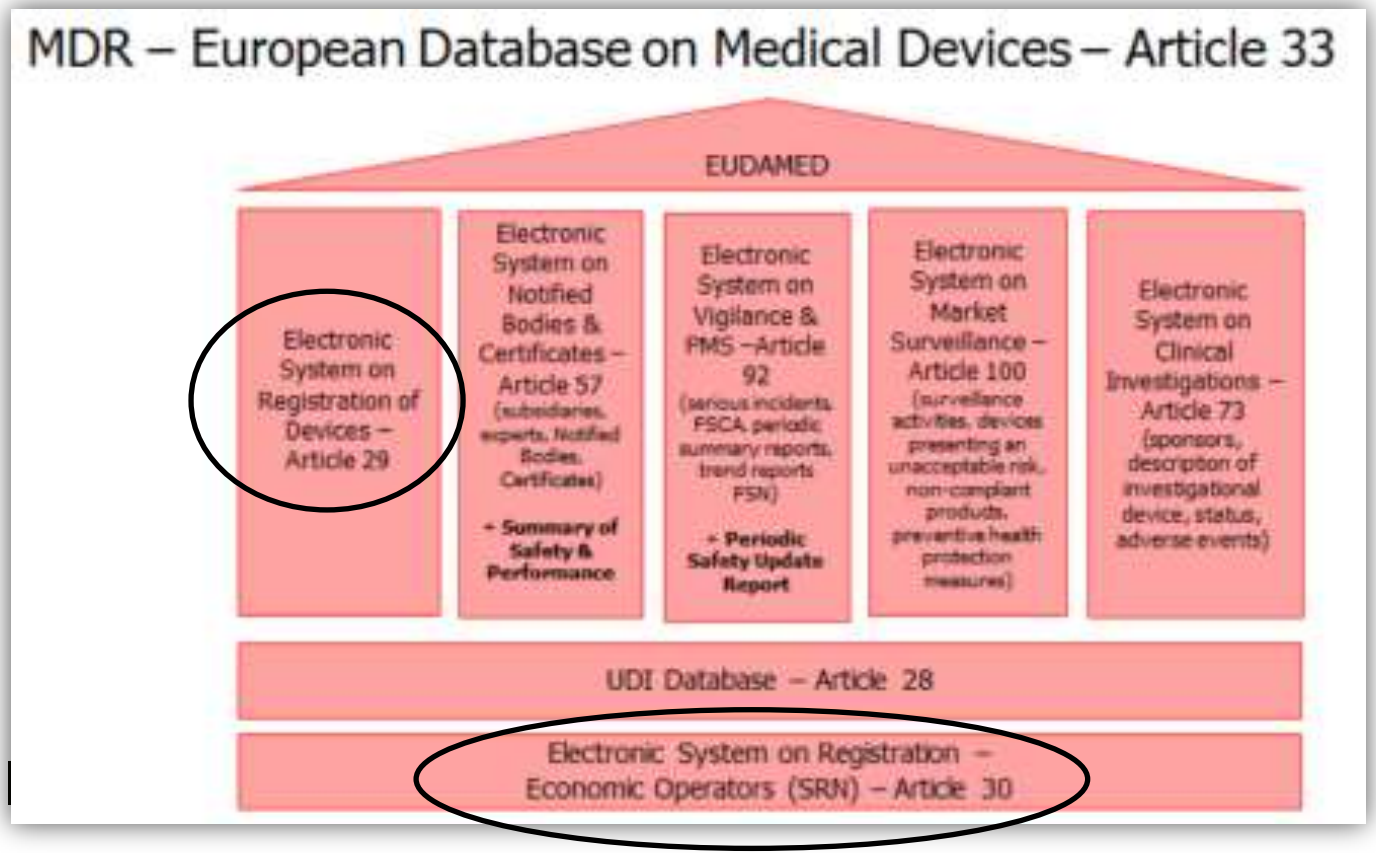
Procedure packs or parts / components – Article 22 & 23

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)

QMS processes and Economic Operators

	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

- Systems
- Process
- Procedures
- Evidence

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

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

Much already covered in ISO 13485:2016

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;

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

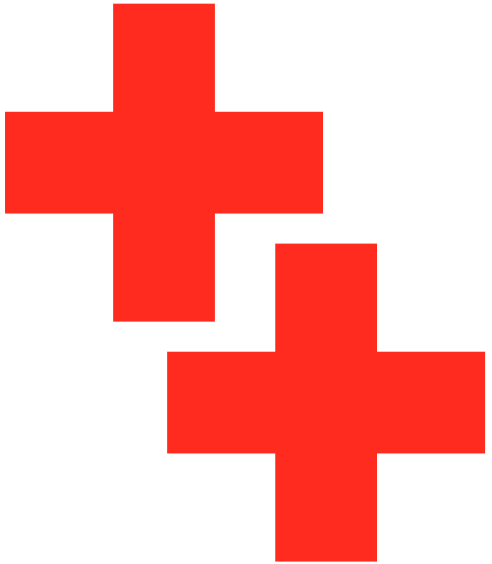
ISO 13485:2016 – 8.2.2, 8.2.3

ISO 13485:2016 – 8.5.2, 8.5.3

ISO 13485:2016 – 8

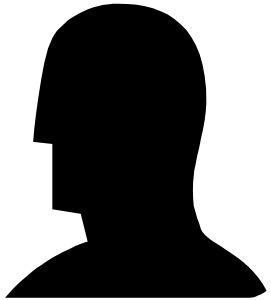
Initial Assessment to MDR / IVDR
… Some key areas we will be covering in BSI QMS Audits

- 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



Person Responsible for Regulatory Compliance Article 15

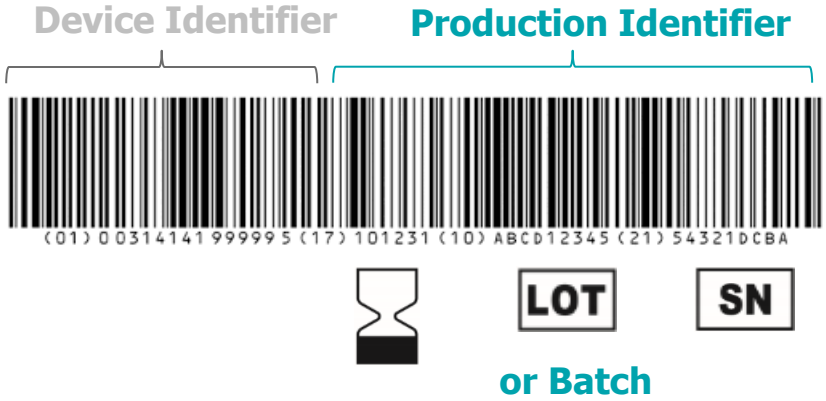
- Required for both Manufacturers and Authorised Representatives
- Must have expertise in medical devices, including degree and four years' professional experience
- Responsible for ensuring:
  - ⇨ Product conformity checked via appropriate QA release
  - ⇨ Technical documentation and DoC maintained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

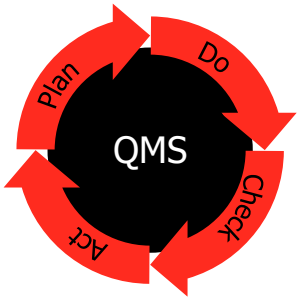


- Note the concessions for small or micro enterprises with respect to requirements

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

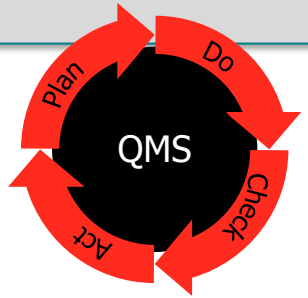
- ❑ any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- ❑ any information about the expected lifetime of the device and 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 t… risk determination
- Main findings
- Volume of Sales
- 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

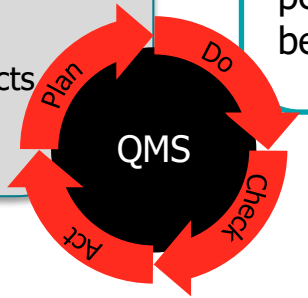


- Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices
- Manufacturers of class IIb and III devices shall …date the report at least annually
- …s IIa devices shall update …t least every two
- For class III o… submit PSUR reports by means … 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



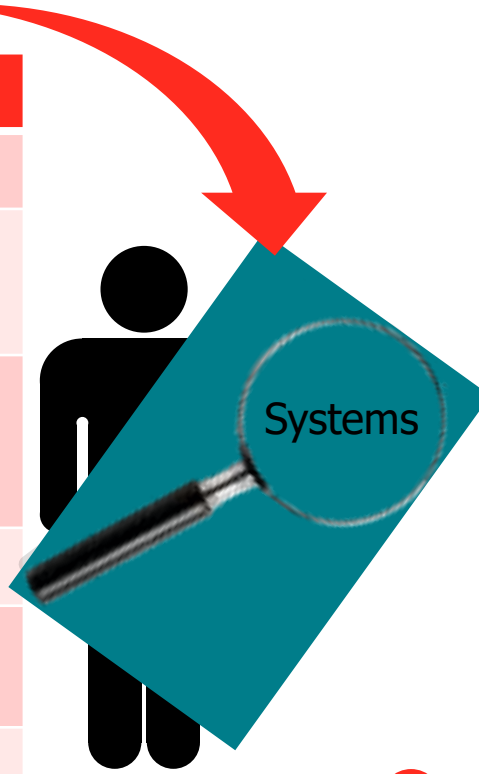
- For implantable devices and for class III devices, the manufacturer shall draw up a summary of safety and clinical performance
- The SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via EUDAMED

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.

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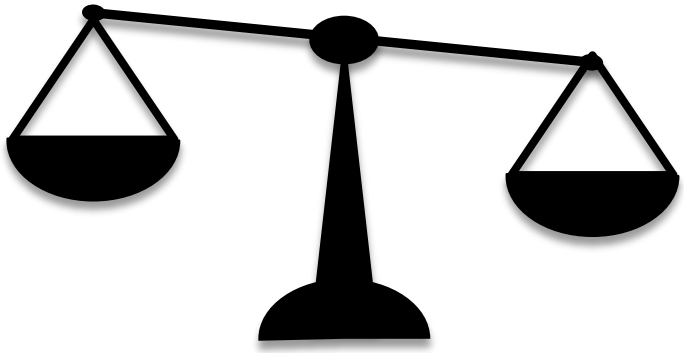
Witness Testing & Reconciliation



- 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 Management** 
4. Risk Control
5. Risk of **Use Error** 

6. Lifetime  
7. Packaging, Transport, Storage
8. Undesirable side-effects minimised & Risks<Benefits
9. Annex XVI "no risk at all" or "no more than the maximum acceptable risk" 

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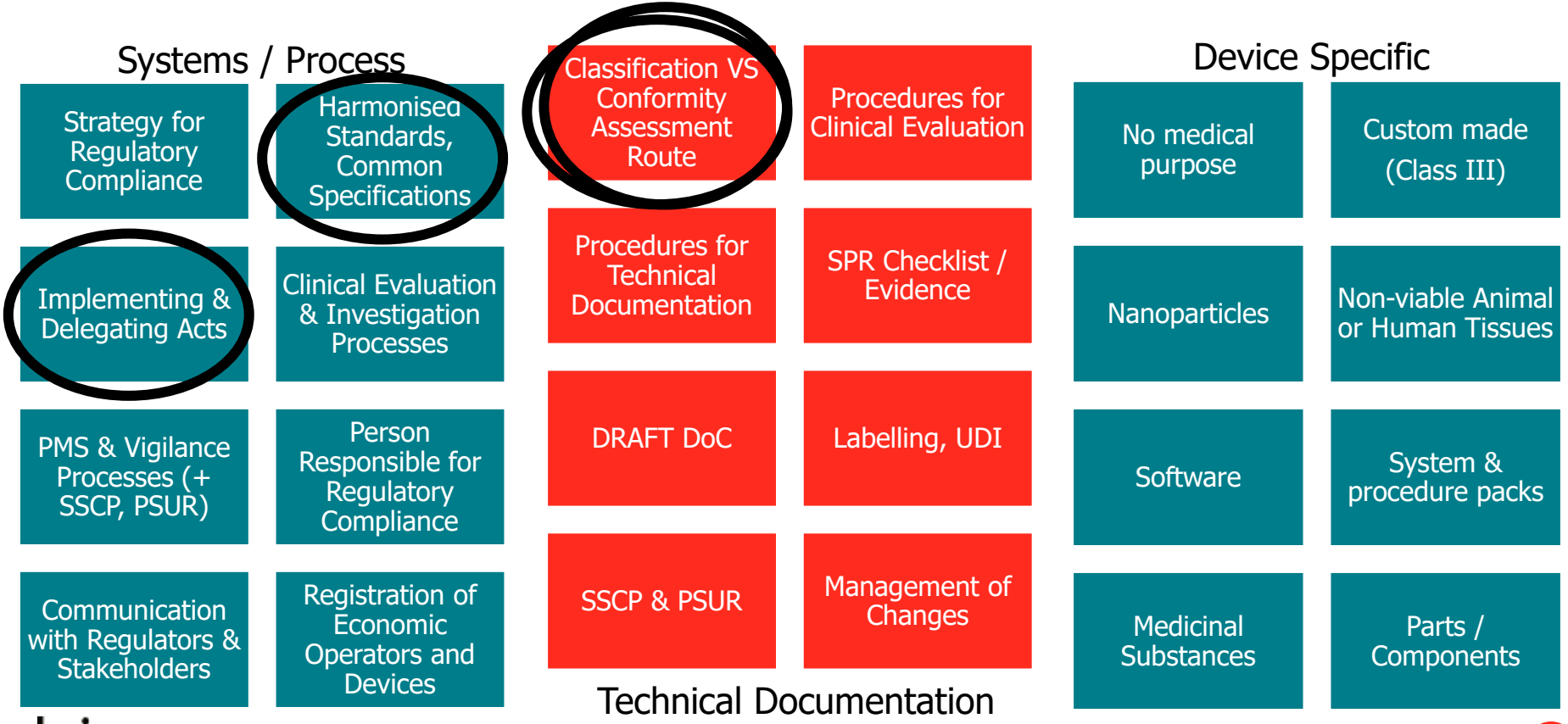
10. **Chemical, Physical & Biological** Properties 
11. Infection & Microbial Contamination 

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 **interaction 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 risks posed by medical devices intended for use by lay persons 
23. **Information Supplied**  

Summary of Key Changes Impacting QMS Processes



Route from MDD to MDR Certification

Manufacturers Route from MDD to MDR Certification

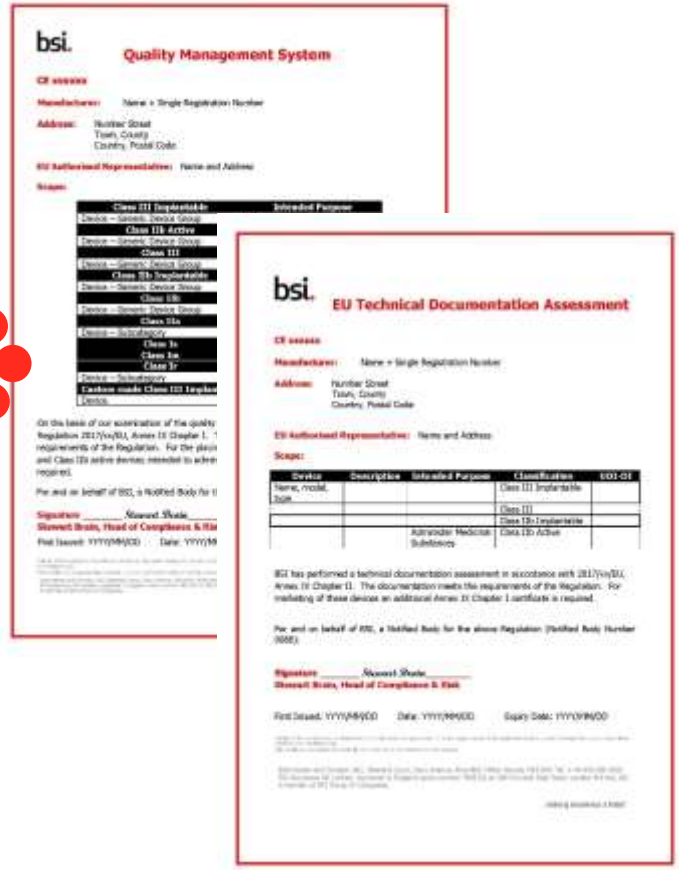
Formal MDR Application

QMS MDR Audit

MDR Technical Documentation review

MDR Microbiology & Sterilisation Review*

Recommendation(s) for MDR Certification



MDD to MDR Certification – QMS Certificates

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Quality Management System

CE xxxxxx

Manufacturer: Name + Single Registration Number

Address: Number Street
Town, County
Country, Postal Code

EU Authorised Representative: Name and Address

Scope:

Class III Implantable	Intended Purpose
Device – Generic Device Group	Intended purpose as per IFU
Class IIb Active	
Device – Generic Device Group	Intended to administer medicines
Class III	
Device – Generic Device Group	Intended purpose as per IFU
Class IIb Implantable	
Device – Generic Device Group	Intended purpose as per IFU
Class IIb	
Device – Generic Device Group	Intended purpose as per IFU
Class IIa	
Device – Substances	—
Class Is	
Class Im	
Class Ir	
Device – Substances	—
Custom made Class III Implantable	
Device	—

On the basis of our examination of the quality management system under the requirements of Regulation 2017/745/EU, Annex IX Chapter I. The quality management system meets the requirements of the Regulation. For the placing on the market of Class IIE, Class IIb implantable and Class IIb active devices intended to administer medicines an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 0086)

Signature: _____ Steward Brain_____

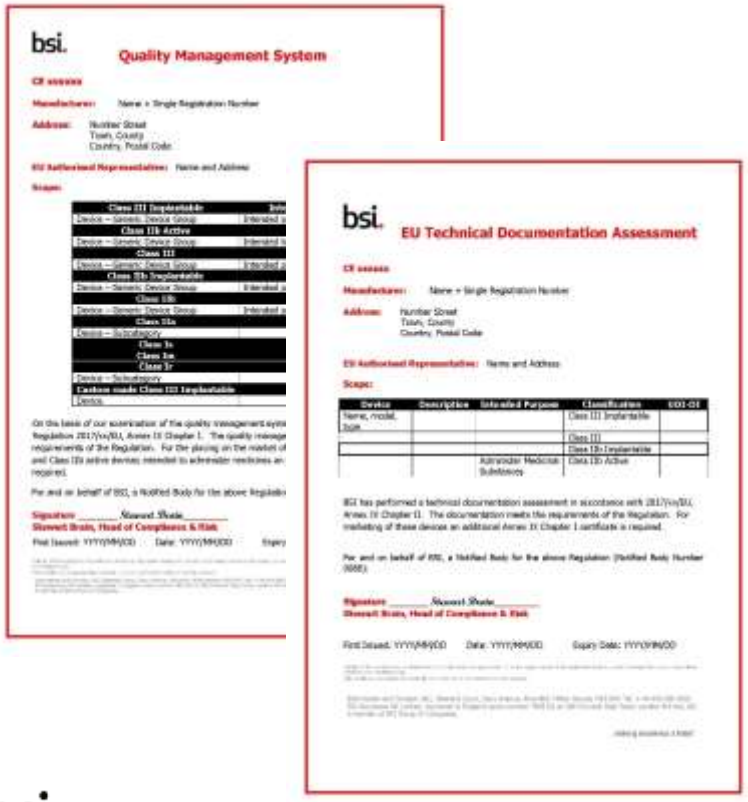
Steward Brain, Head of Competence & Risk

First Issued: YYYY/MM/DD Date: YYYY/MM/DD Expiry Date: YYYY/MM/DD

- MDR QMS Certificate (Annex IX Chapter I or Annex XI Part A) must be issued first (or concurrently with a corresponding product certificate)

- MDR QMS Certificate first issue will include in scope only devices / ranges with:
  - ✓ Successfully completed MDR QMS Audit
    AND
  - ✓ Successfully completed MDR Technical Documentation Review

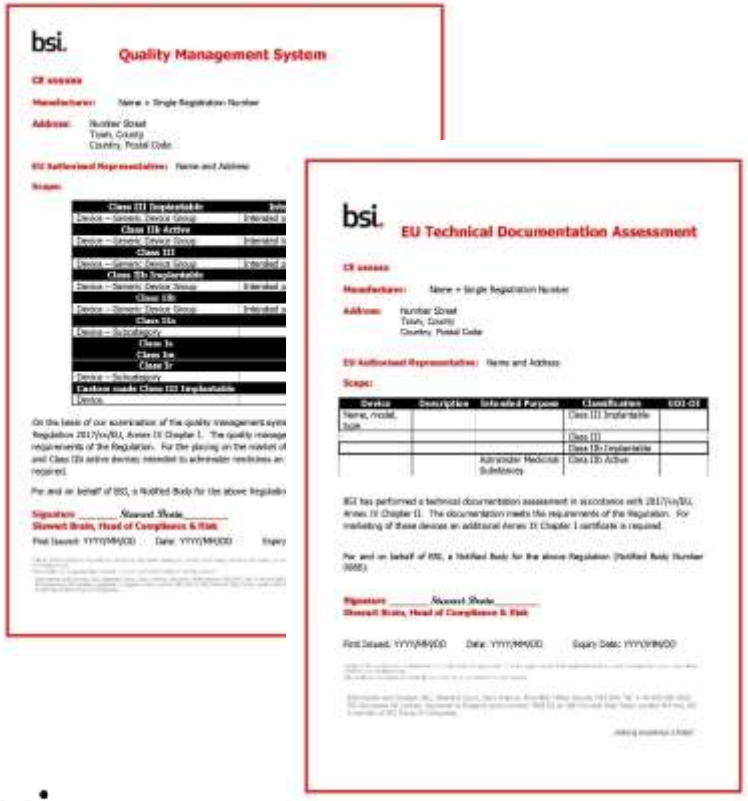
MDD to MDR Certification – Product Certificates



- For devices requiring product certificates will require concurrent certificate issue / reissue once
  - ✓ Successfully completed MDR QMS Audit AND
  - ✓ Successfully completed MDR Technical Documentation Reviews

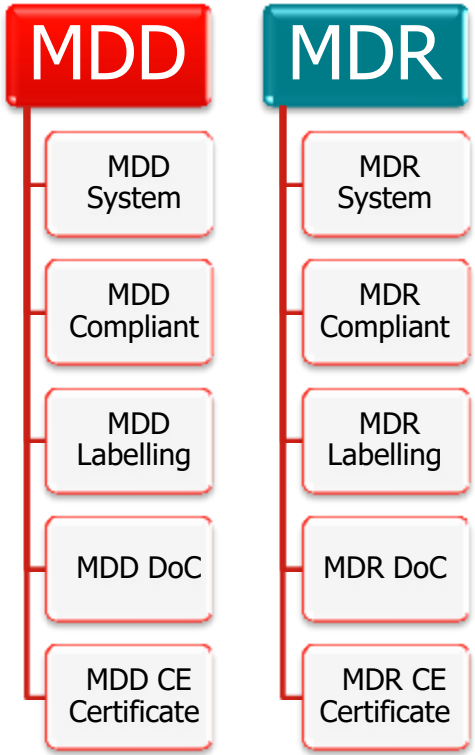
=> Certificate decision process for review for issue of
- Annex IX Chapter I QMS certificate
- Annex IX Chapter II Product certificate

MDD to MDR Certification – Larger Manufacturers & Scopes



- For larger manufacturers / scopes - as further Technical Documentation reviews completed and Product Certificates ready to be issued, the MDR QMS Certificate can be re-issued to 'add-in' additional devices or range
- Where possible, aim is to conduct one initial QMS MDR certification audit / recommendation (i.e. not multiple MDR initial QMS visits to same manufacture).
- MDR activity and compliance will be verified annually as part of normal QMS surveillance

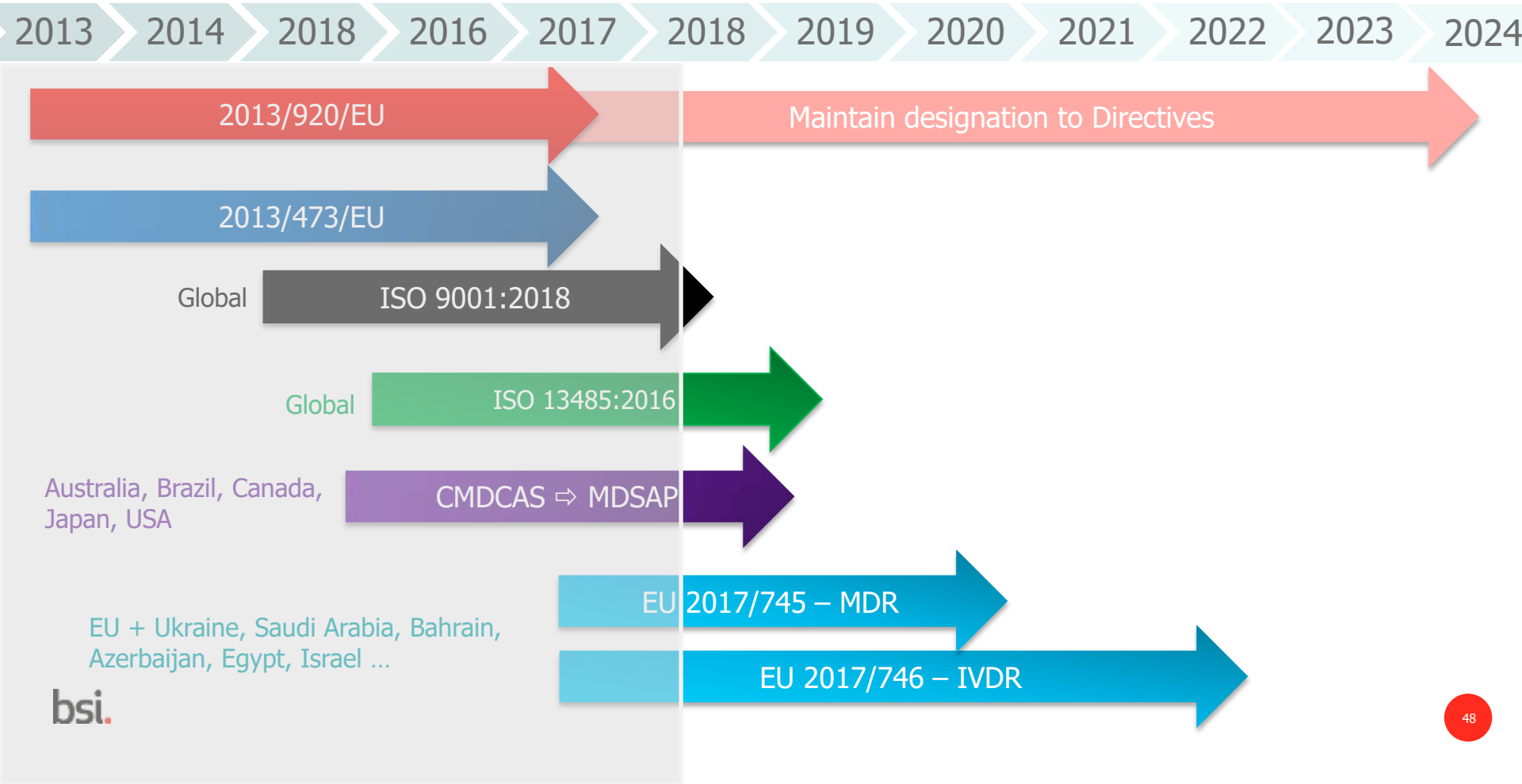
Concurrent MDD & MDR Certificates



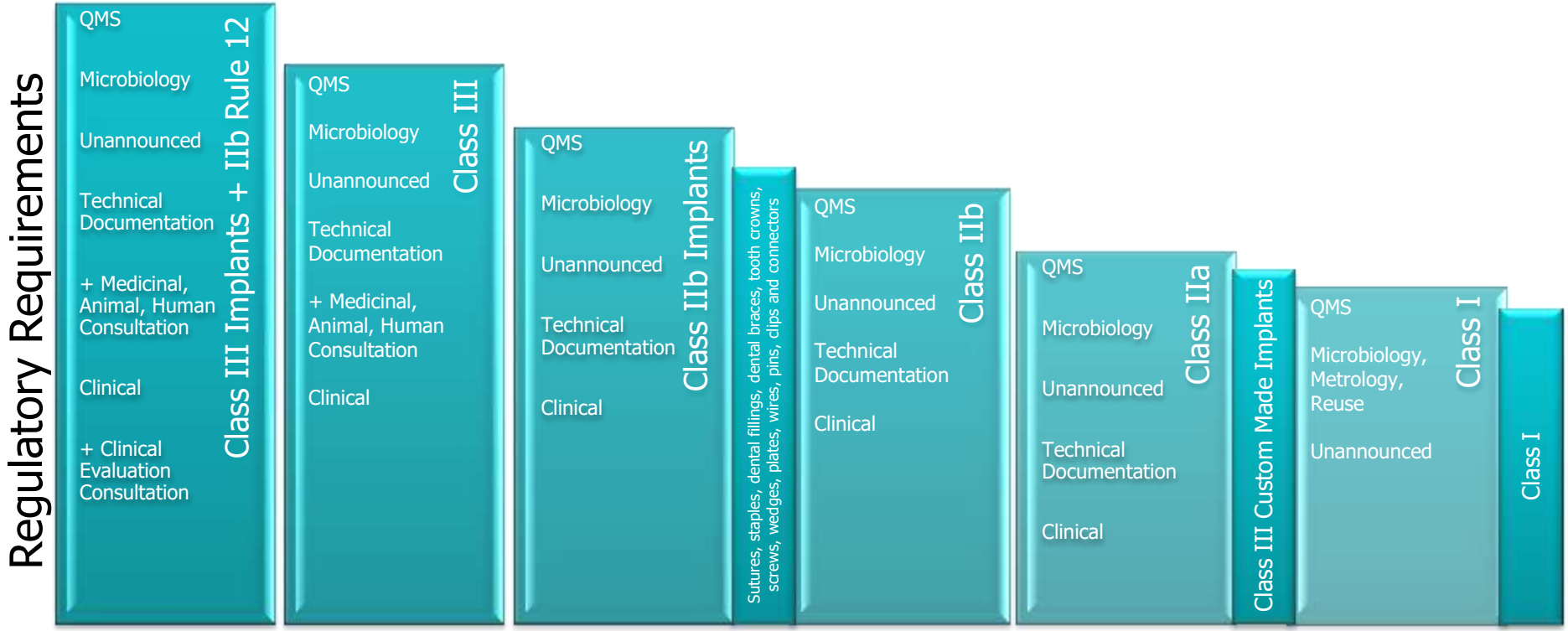
- Devices must be within respective certificate scopes
- Must be clear and traceable what product / batch has been produced under what system
- Look out for upcoming BSI communications on deadlines for applications for early renewals of MDD / AIMD / IVDD certificates

bsi.

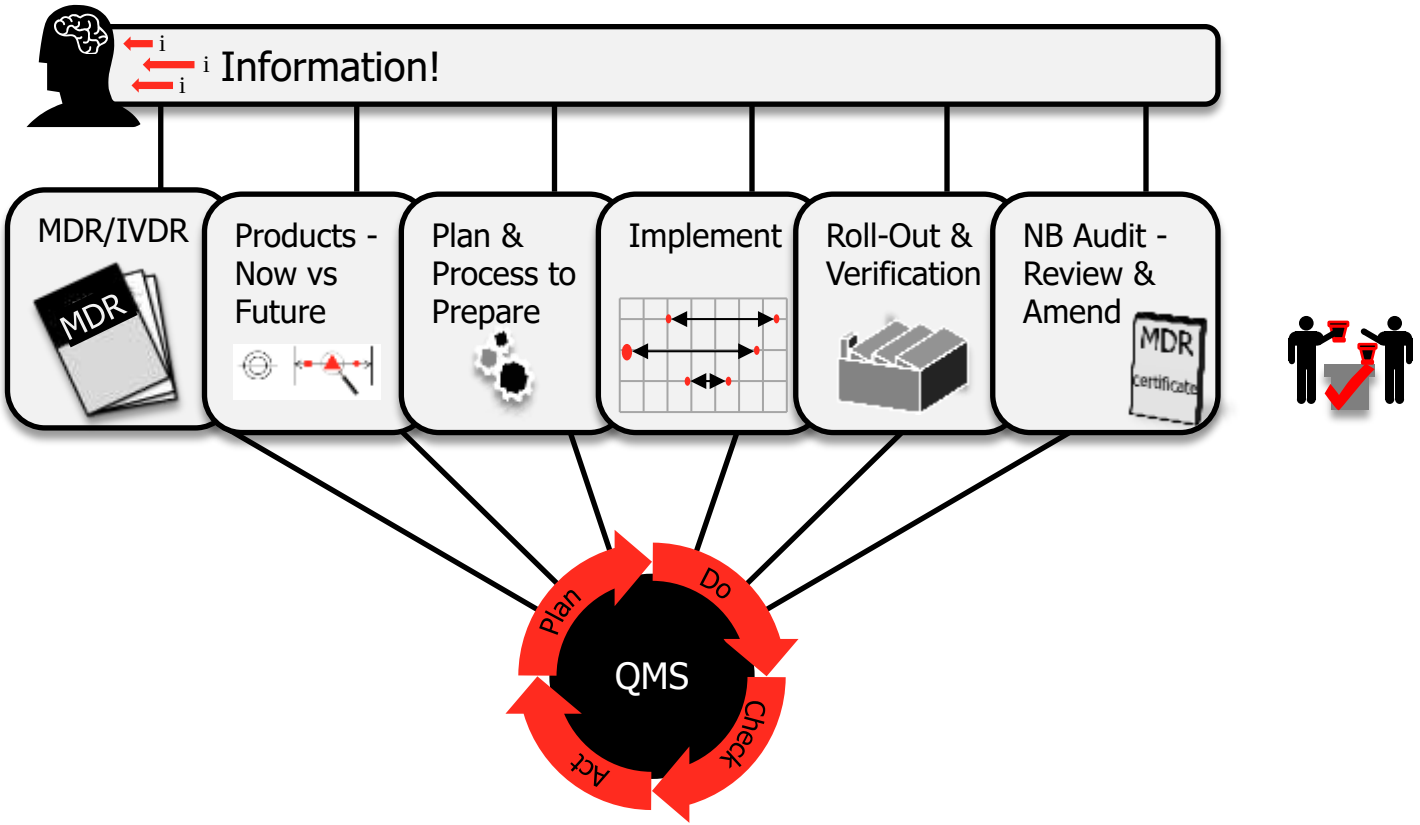
Next Steps


2013
2014
2018
2016
2017
2018
2019
2020
2021
2022
2023
2024
2013/920/EU
Maintain designation to Directives
2013/473/EU
Global
ISO 9001:2018
Global
ISO 13485:2016
Australia, Brazil, Canada, Japan, USA
CMDCAS ⇨ MDSAP
EU
2017/745 – MDR
EU + Ukraine, Saudi Arabia, Bahrain, Azerbaijan, Egypt, Israel …
EU 2017/746 – IVDR
bsi.

MDR Assessment Type by Device Classification



Approaching the MDR & IVDR

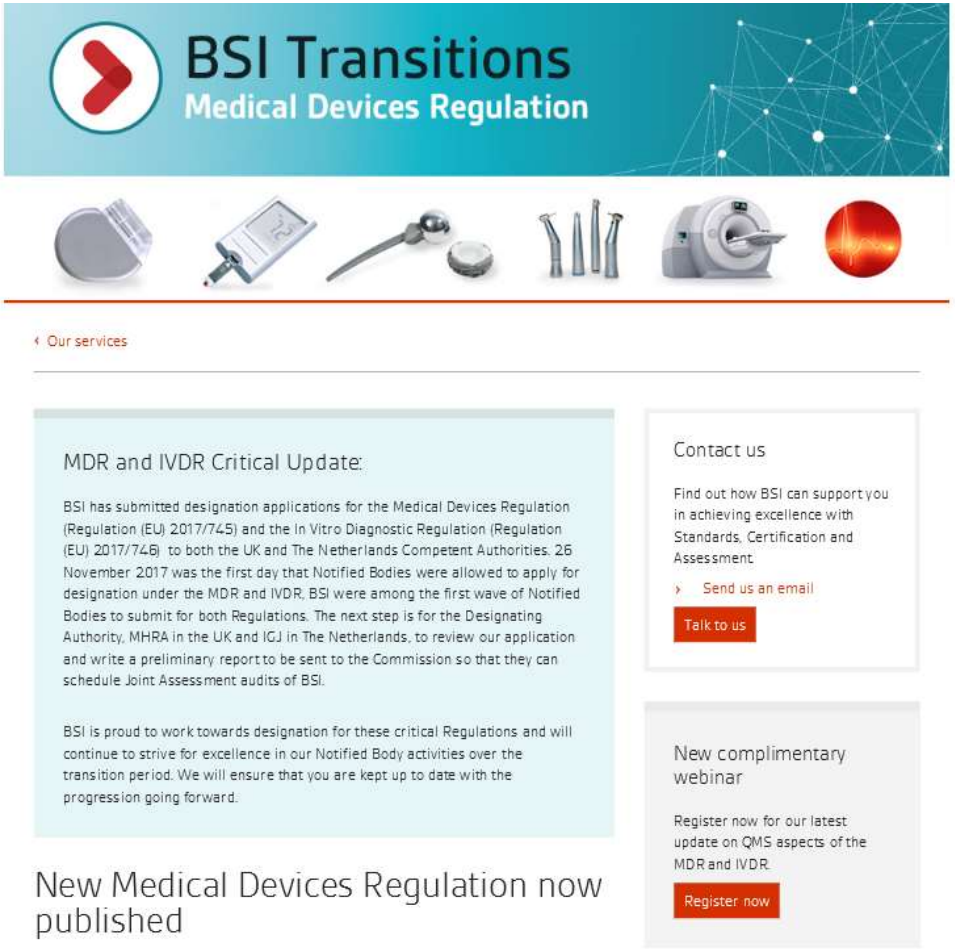


Resources

bsigroup.com/MDR-Revision

bsigroup.com/IVDR-Revision

bsigroup.com/iso13485revision



Questions & Answers

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