IVDR Lessons Learnt

NB view to date

12 May 2021

By Royal Charter

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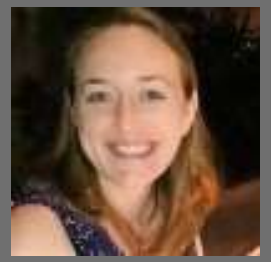
Welcome!

Dr Erica Conway
Global Head – IVD Technical Team
Regulatory Services (Medical Devices)



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Technical Team Manager – IVD
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Series of 2020 webinars available

- QMS Requirements under IVDR
- Performance Evaluation Part 1
  - Introduction to Performance Evaluation
  - Performance Evaluation Plan
  - Scientific Validity
  - Link to PE Report & conclusion
- Performance Evaluation Part 2
  - Clinical Performance as part of the PER
  - Link to PMPF
- Maintaining certification

Free Resources & Webinars can be found at: www.bsigroup.com/IVDR

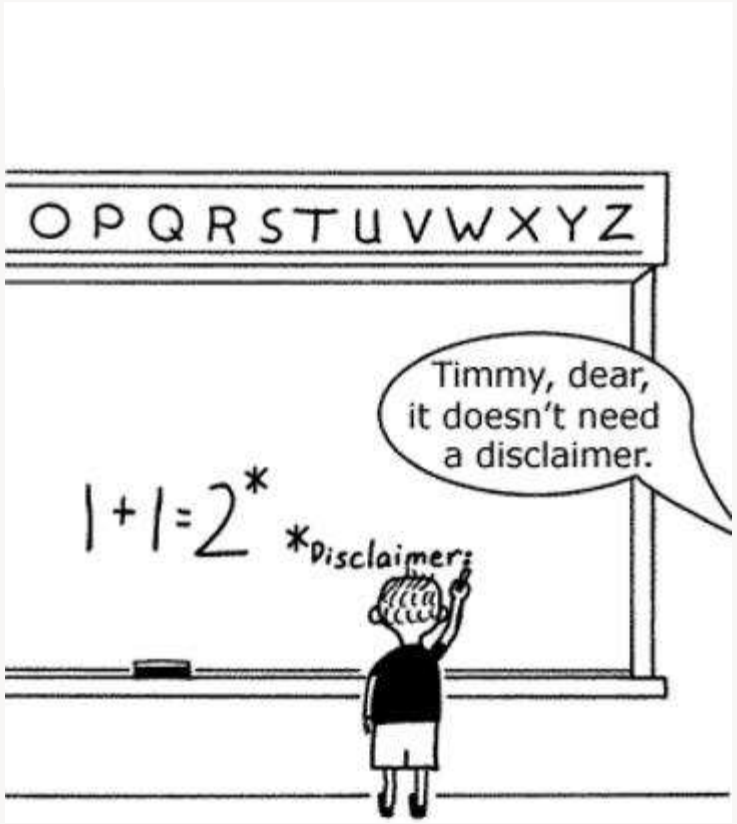
Agenda – **Our lessons learned**

- Introduction & achieving certification
- QMS audits
- Technical Documentation assessments

  --- 5 min break ---

- Performance Evaluation & Clinical Evidence
- NB updates & conclusions
- Panel Q&A

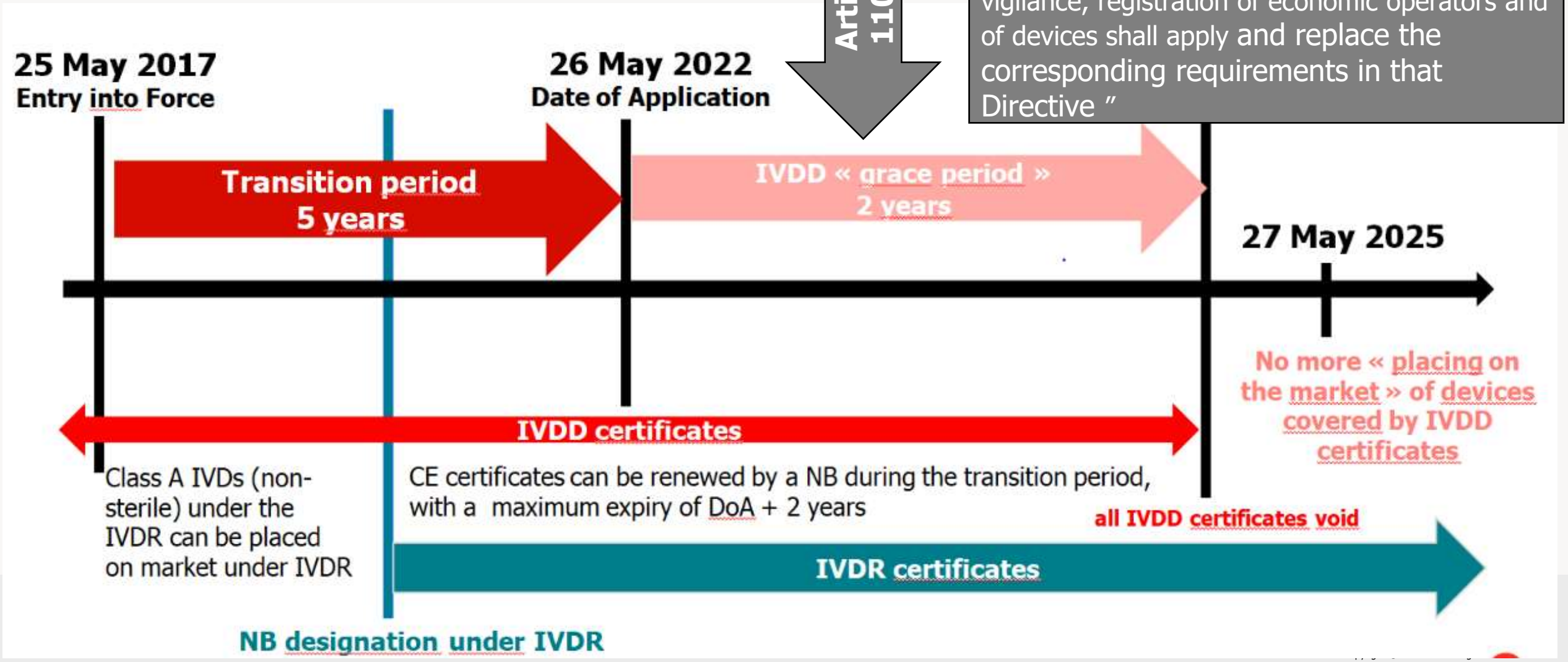
Disclaimer



- Information presented within this webinar is based on our current understanding of the IVDR
- *Subject to change*

Transitional arrangements for IVDR

Article 110.3 "…it continues to comply with that Directive, and provided there are no significant changes in the design and intended purpose…
…the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply and replace the corresponding requirements in that Directive "



Making an application

Annex IX – Application Documentation

2. Quality management system assessment

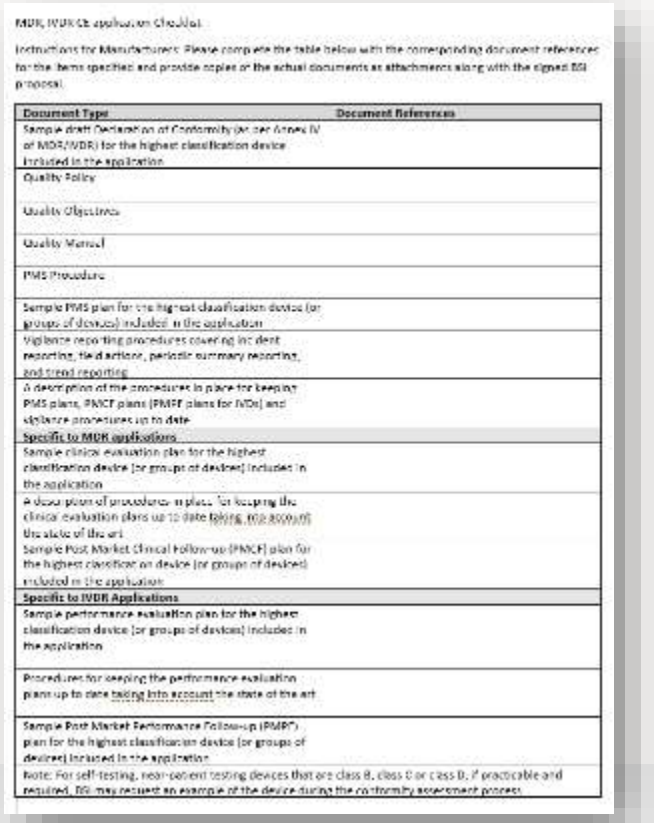
2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

- the name of the **manufacturer** and address of its registered place of business and **any additional manufacturing site** covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the **authorised representative** and the address of the authorised representative's registered place of business,
- all relevant information on the **device** or **group of devices** covered by the quality management system,
- a written declaration that **no application has been lodged with any other notified body** for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
- a draft of an **EU declaration of conformity** in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure,

Annex IX – Application Documentation

The application ***shall*** include (continued):

- a description of the **procedures in place to ensure that the quality management system remains adequate** and effective, and the undertaking by the manufacturer to apply those procedures,
- a description of the **procedures in place to keep up to date the post-market surveillance system**, and, where applicable, the **PMPF plan**, and the **procedures ensuring compliance** with the obligations resulting from the provisions on **vigilance** set out in Articles 82 to 87, as well as the **undertaking by the manufacturer to apply those procedures**,
- **documentation on the performance evaluation plan**, and
- a description of the **procedures in place to keep up to date the performance evaluation plan**, taking into account the state of the art.

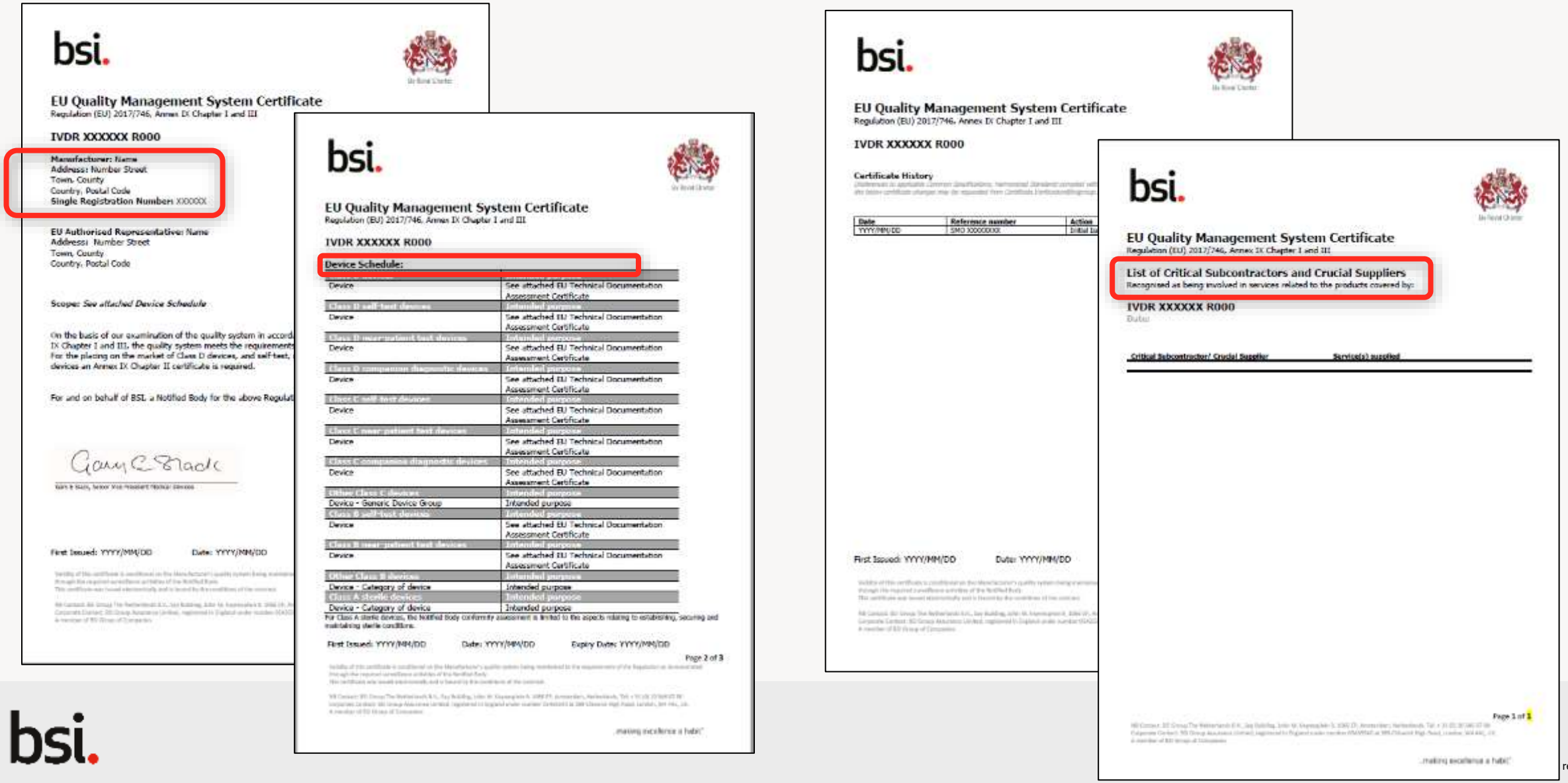


MDR, IVDR CE application Checklist

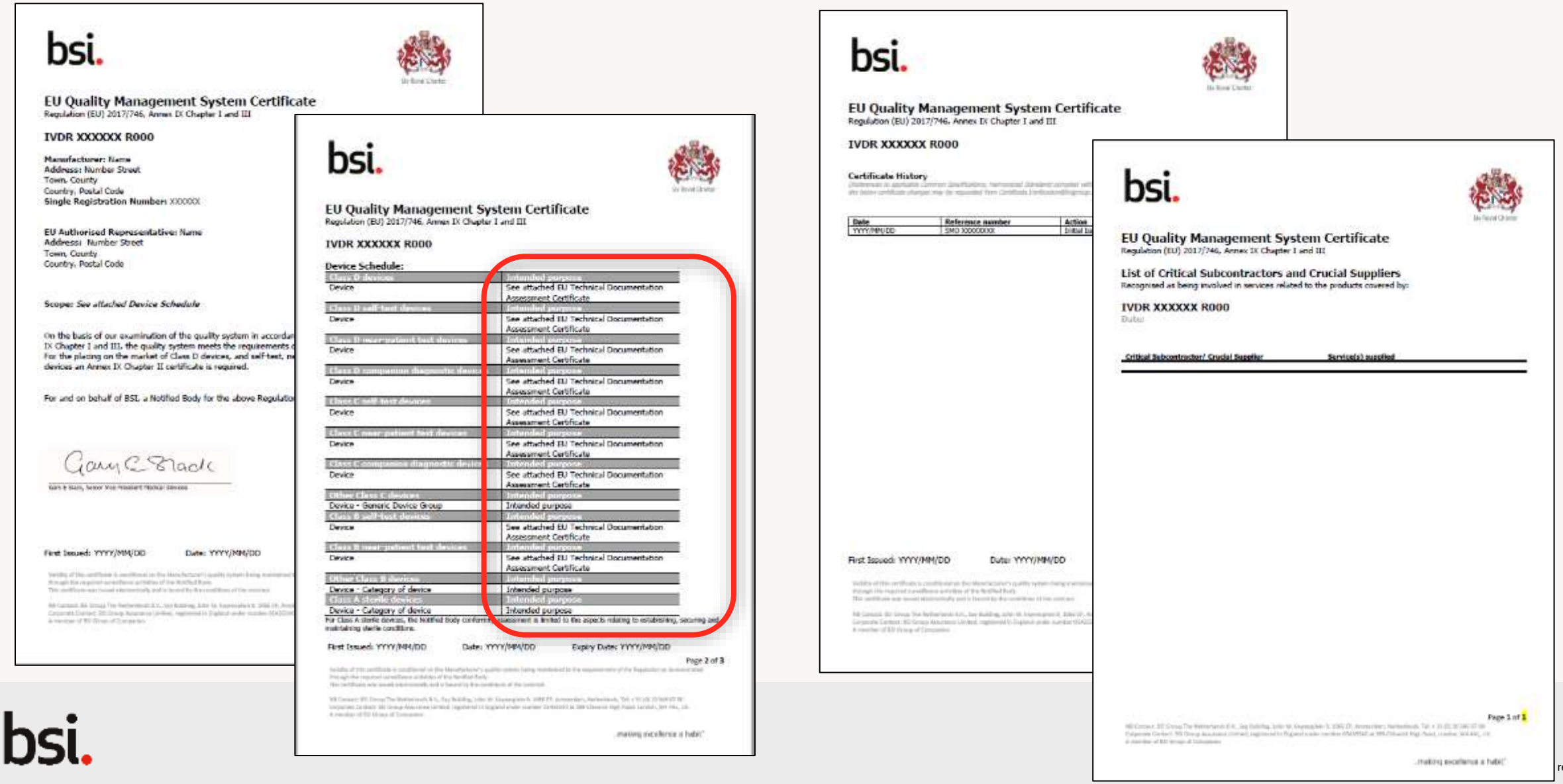
Instructions for Manufacturers: Please complete the table below with the corresponding document references for the items specified and provide copies of the actual documents as attachments along with the signed BSI proposal.

Document Type	Document References
Sample draft Declaration of Conformity (as per Annex IV of MDR/IVDR) for the highest classification device included in the application	
Quality Policy	
Quality Objectives	
Quality Manual	
PMS Procedure	
Sample PMS plan for the highest classification device (or groups of devices) included in the application	
Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting	
A description of the procedures in place for keeping PMS plans, PMCF plans (PMPF plans for IVDs) and vigilance procedures up to date	
Specific to MDR applications	
Sample clinical evaluation plan for the highest classification device (or groups of devices) included in the application	
A description of procedures in place for keeping the clinical evaluation plans up to date taking into account the state of the art	
Sample Post Market Clinical Follow-up (PMCF) plan for the highest classification device (or groups of devices) included in the application	
Specific to IVDR Applications	
Sample performance evaluation plan for the highest classification device (or groups of devices) included in the application	
Procedures for keeping the performance evaluation plans up to date taking into account the state of the art	
Sample Post Market Performance Follow-up (PMPF) plan for the highest classification device (or groups of devices) included in the application	
Note: For self-testing, near-patient testing devices that are class B, class C or class D, if practicable and required, BSI may request an example of the device during the conformity assessment process.	

IVDR Certificates – Annex IX Chapter I & III



IVDR Certificates – Annex IX Chapter I & III



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EU Quality Management System Certificate
Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR XXXXXX R000

Manufacturer: Name
Address: Number Street
Town, County
Country, Postal Code
Single Registration Number: XXXXXX

EU Authorised Representative: Name
Address: Number Street
Town, County
Country, Postal Code

Scope: *See attached Device Schedule*

On the basis of our examination of the quality system in accordance with Annex IX Chapter I and III, the quality system meets the requirements of the Regulation for the placing on the market of Class D devices, and self-test, near-patient and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation

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

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EU Quality Management System Certificate
Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR XXXXXX R000

Device Schedule:

Class D devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class D self-test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class D near-patient test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class D companion diagnostic devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class C self-test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class C near-patient test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class C companion diagnostic devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Other Class C devices	Intended purpose
Device - Generic Device Group	Intended purpose
Class B self-test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Class B near-patient test devices	Intended purpose
Device	See attached EU Technical Documentation Assessment Certificate
Other Class B devices	Intended purpose
Device - Category of device	Intended purpose
Class A sterile devices	Intended purpose
Device - Category of device	Intended purpose

For Class A sterile devices, the Notified Body confirms assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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

Page 2 of 3

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EU Quality Management System Certificate
Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR XXXXXX R000

Certificate History

Date	Reference number	Action
YYYY/MM/DD	SMO XXXXXXXX	Initial Issue

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

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EU Quality Management System Certificate
Regulation (EU) 2017/746, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers
Recognised as being involved in services related to the products covered by:

IVDR XXXXXX R000
Date:

Critical Subcontractor/ Crucial Supplier	Service(s) supplied

Page 1 of 1

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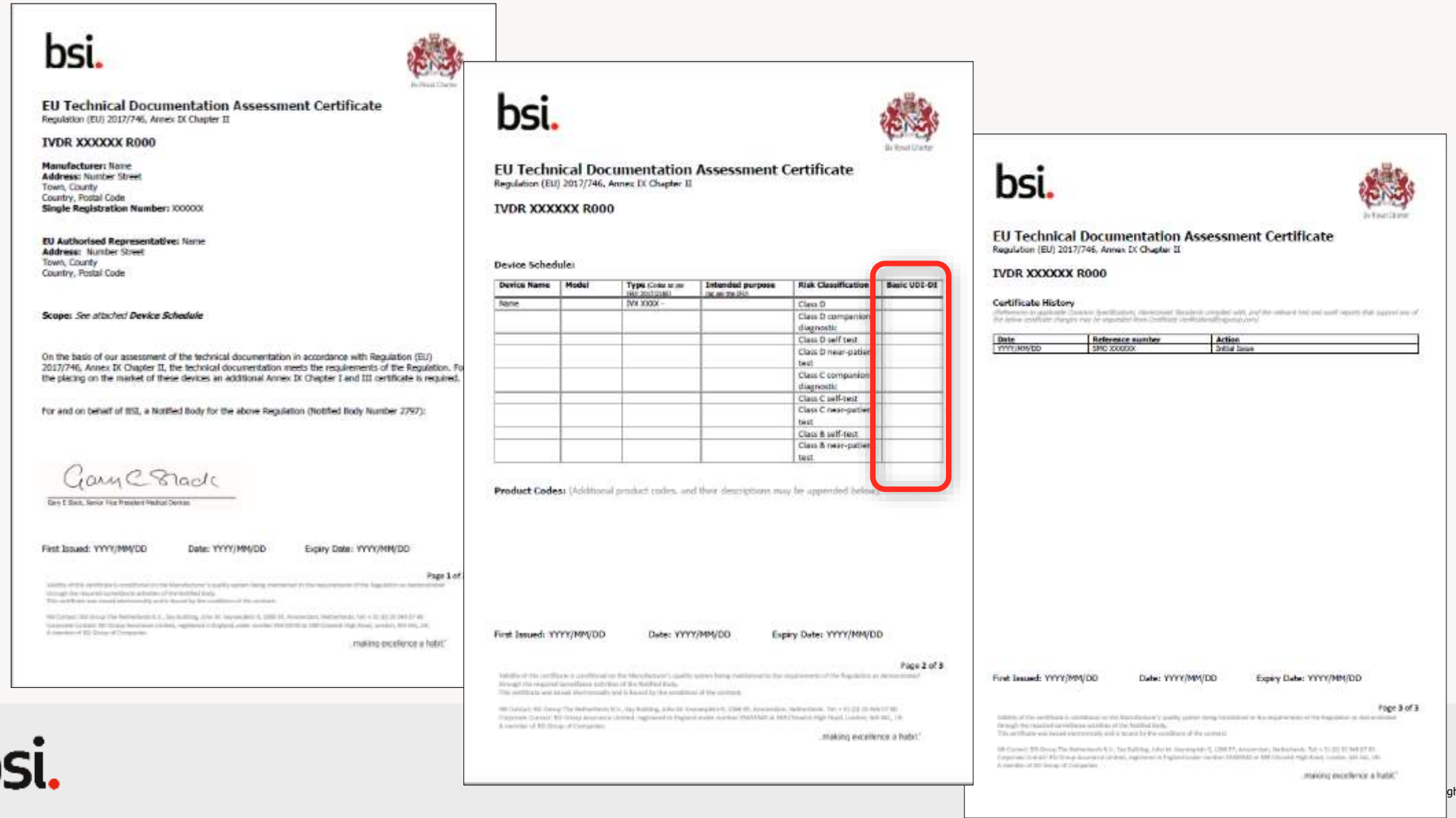
IVDR Certificates – Annex IX Chapter II



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EU Technical Documentation Assessment Certificate
Regulation (EU) 2017/746, Annex IX Chapter II

IVDR XXXXXX R000

Manufacturer: Name
Address: Number Street
Town, County
Country, Postal Code
Single Registration Number: XXXXXX

EU Authorised Representative: Name
Address: Number Street
Town, County
Country, Postal Code

Scope: *See attached* ***Device Schedule***

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. Fo
the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Black, Senior Vice President Medical Devices

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

Page 1 of

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EU Technical Documentation Assessment Certificate
Regulation (EU) 2017/746, Annex IX Chapter II

IVDR XXXXXX R000

Device Schedule:

Device Name	Model	Type (Codes as per MIR 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Name		IVX XXXX –		Class D	
				Class D companion diagnostic	
				Class D self test	
				Class D near-patie test	
				Class C companion diagnostic	
				Class C self-test	
				Class C near-patie test	
				Class B self-test	
				Class B near-patie test	

Product Codes: (Additional product codes, and their descriptions may be appended below)

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

Page 2 of 3

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EU Technical Documentation Assessment Certificate
Regulation (EU) 2017/746, Annex IX Chapter II

IVDR XXXXXX R000

Certificate History

Date	Reference number	Action
YYYY/MM/DD	SMC XXXXXX	Initial Issue

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

Page 3 of 3

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Intended Purpose

- Intended Purpose = Intended Use
- Ref: Annex I part 20.4.1 c

✓Clear statement to include medical purpose

✓Verification of classification during application

➢Classification may change during review of technical documentation

Device's intended purpose:

(i) what is detected and/or measured
(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic)
(iii) the specific information that is intended to be provided in the context:
- a physiological or pathological state
- congenital physical or mental impairments
- the predisposition to a medical condition or a disease
- the determination of the safety and compatibility with potential recipients
- the prediction of treatment response or reactions
- the definition or monitoring of therapeutic measures

(iv)whether it is automated or not
(v) whether it is qualitative, semi-quantitative or quantitative
(vi) the type of specimen(s) required
(vii) where applicable, the testing population
(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test

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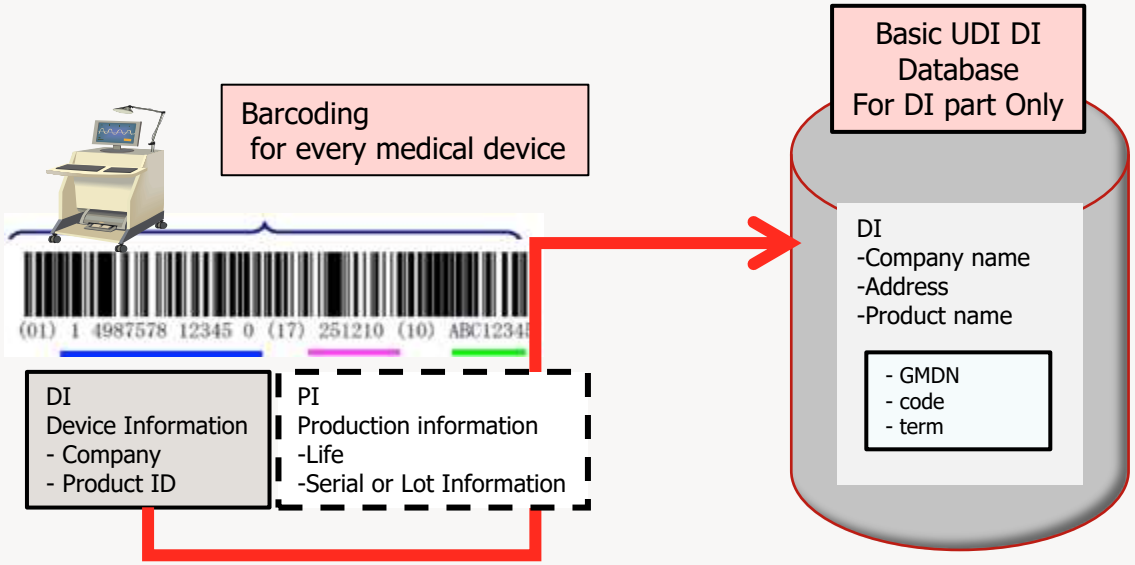
Basic UDI-DI



- Generally poorly understood
- Guidance issued on UDI, but MDR focussed
- **Needs to be in place at application** (*definitely* for self-test, NPTs, CDx, Ds);
  - Needed at time of application for self-tests, near-patient tests, companion diagnostics, class D
    - One product certificate per one BUDI (unless kit level BUDI)
  - by QMS/Tech audit (for others, although at application preferred)
- What does BUDI look for a kit?
- **SRN** – voluntary, but will be needed when Eudamed operational!

Device Grouping – Guidance MDCG 2019-13

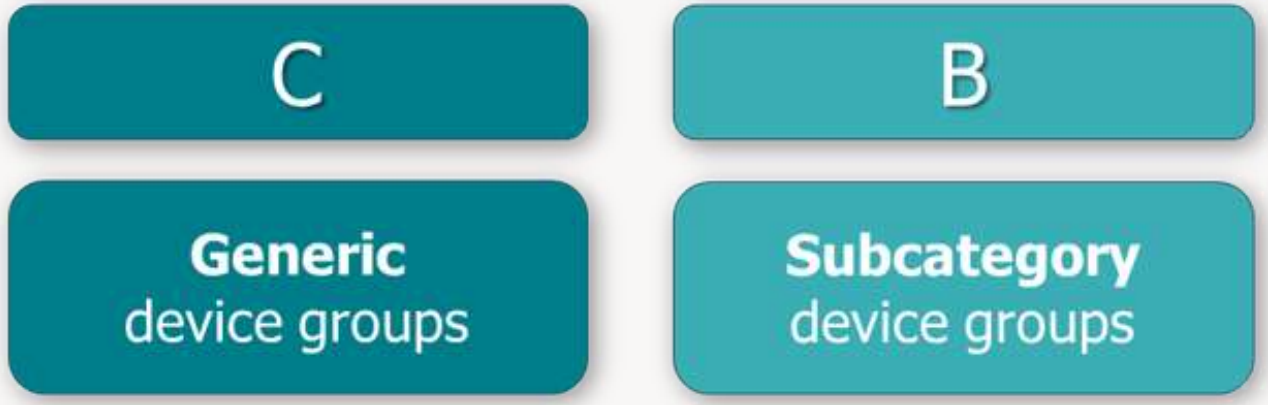
Class B – Grouping by **Subcategory** of device

MDCG 2019-13: based on **IVR** codes*

Class C – Grouping by **Generic** device groups

MDCG 2019-13: **3rd level EMDN code** (one letter + 4 digits) + **IVP** code*
(most appropriate IVP code)

OR: 4th level EMDN codes (one letter + 6 digits) + **IVP** code



✓ MDCG 2019-13 allows us to go down to the 4th level if the 3rd level is not sufficiently specific to satisfy the definition of generic device group

*Codes according to (EU) 2017/2185: *The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies*

Sampling Plans - Guidance MDCG 2019-13

NB Obligations for technical file sampling at initial & maintainance

- 15 % of devices of **each generic Class C group** and/or **each category Class B group** will be reviewed under surveillance under the certificate scope

- May be reduced to a minimum of 5% in the first certification cycle

✓ **Technical file sampling will include SSPs & PSURs during surveillance!**

Making applications – lessons learned to date

- Application information needs to be provided for your devices & QMS readiness
  - ➢Scope
  - ➢Provisional transition timings
- Intended Use – check conforms to requirements
- Classification is key!
- Assignment of codes & Basic-UDI-DI
- Your NB will confirm codes and grouping at the time of application;
  - sampling plan will be drafted by the NB with certification

Next: Lessons learned – QMS Audits

Agenda – **Our lessons learned**

- Introduction & achieving certification
- QMS audits
- Technical Documentation assessments

--- 10 min break ---

- Performance Evaluation & Clinical Evidence
- NB updates & conclusions
- Panel Q&A

Lesson learned - QMS Audits

Judith Prevoo
Regulatory Lead – BSI NL

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Requirements of the Quality Management System

a. Regulatory Compliance strategy
b. GSPRs
c. Management responsibility
d. Resource management
e. Risk Management
f. Performance evaluation
g. Product realisation
h. UDI
i. Post-market surveillance system
j. Communication with competent authorities
k. Incident reporting & FSCA
l. CAPA management
m. Monitoring & measurement

Art 10(8)

Annex IX

QMS Assurance conformity assessment process

Application to a NB

QMS certification with a scope to cover the processes/technologies /devices

- QMS assessment by a NB for the purposes of CE marking

- ISO 13485 + On-site 'upgrade' to IVDR requirements

QMS under IVDR

Submission of technical documentation for review

Dependent on the device risk and scope

Additional processes for Class D devices, Companion diagnostics

QMS Audit

- An on-site audit will be required to certify to IVDR requirements
- The audit scope must cover all devices/device groups that you wish to certify
  - ➢Consider if you are doing your device portfolio 'in stages'

➢**IVDR audit may be done at the time of a routine audit (with additional audit time) or a special audit if not an existing customer**

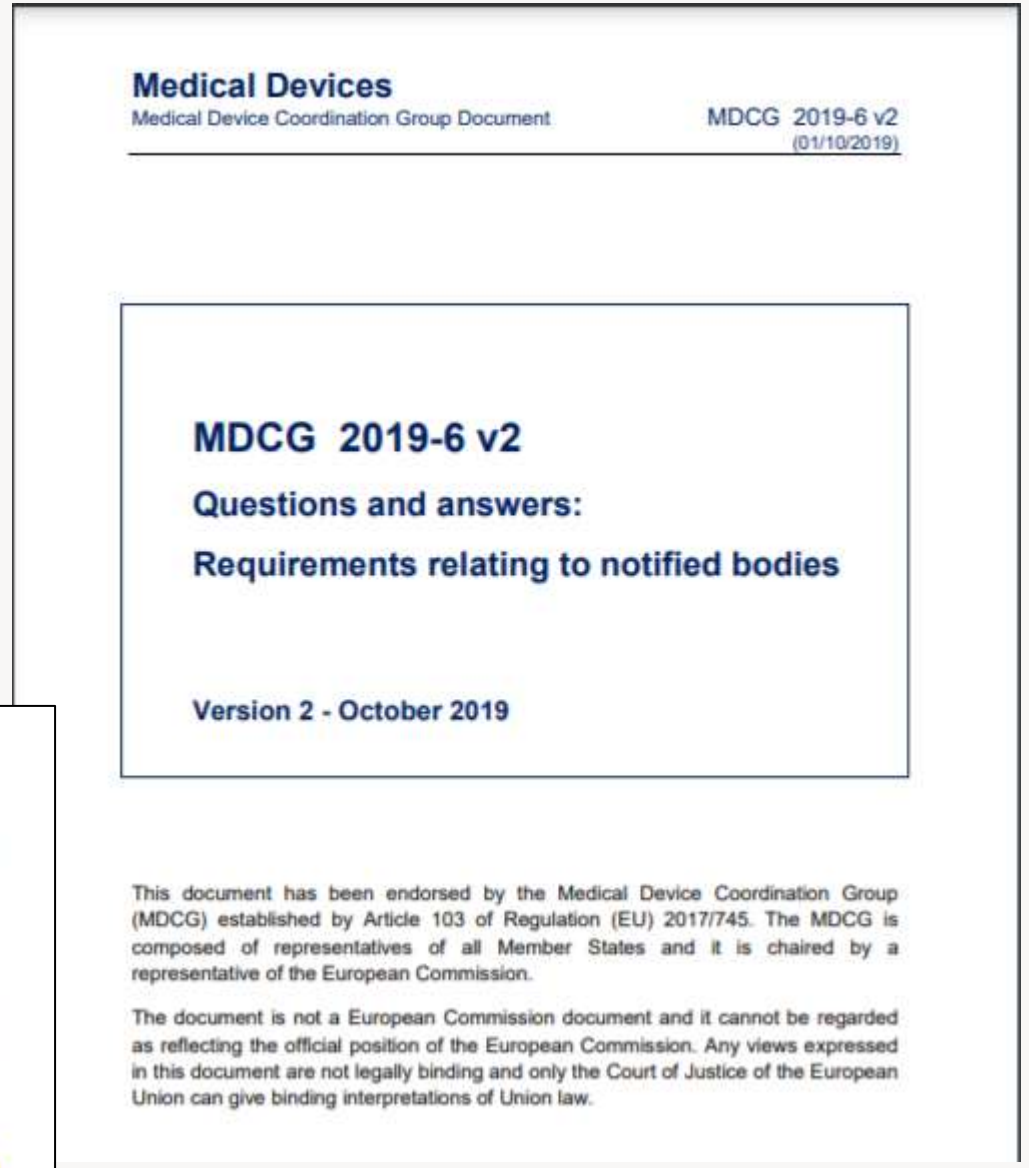
QMS audit

IVDR initial audits, not gap analysis to existing directive

IV. PROCESS REQUIREMENTS

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The conformity assessment activities described under Article 52 / Article 48 apply to any certificate issued under the new regulations. As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore, all devices to be certified under the MDR / IVDR should be subject to an initial certification according to the applicable annex. The notified body should ensure that all requirements under the MDR / IVDR are fulfilled. It may not restrict its procedures to gap audits or gap file reviews.



Medical Devices
Medical Device Coordination Group Document
MDCG 2019-6 v2
(01/10/2019)

MDCG 2019-6 v2

Questions and answers:

Requirements relating to notified bodies

Version 2 - October 2019

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

QMS Audits & COVID-19

MDCG 2020-4

Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions

April 2020

IAF Mandatory Document

IAF MANDATORY DOCUMENT FOR THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) FOR AUDITING/ASSESSMENT PURPOSES

Issue 2

(IAF MD 4:2018)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment

(Text with EEA relevance)

(2021/C 8/01)

MDCG 2020-17

Questions and Answers related to MDCG 2020-4

December 2020

Internal Audit process

04 Ensure objectivity and impartiality of the audit process

03 Audit plan and schedule need to include IVDR

02 Internal auditors need to be trained & qualified for IVDR (and ISO 13485:2016)

01 Ensure that the IVDR is listed as an audit criterion

IX ch I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system, as described in Article 10(8), and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2, and shall be subject to audit as laid down in Sections 2.3 and 2.4 and to surveillance as specified in Section 3.

IX 2.2 b

— the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

IX 2.1

Critical Subcontractors and Crucial Suppliers

1. Resourcing:
Score of product impact needs to be clearly defined

2. Selection and Monitoring:
CAPA plan required for supplier/subcontractor audit

3. Control of subcontractors and suppliers:
Quality agreements available

Risk Management

Output

to reduce risk
as far as possible

Risk Management Documentation

Required throughout product realization, must be maintained

Specifically required in
- 7.1 Planning of product realization
- 7.2 Customer related processes
- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring devices

- Risk management plan
- Risk analysis
- Risk evaluation (as defined in the standard)
- Risk control decision and proposed control measures
- Verification of risk control measures (effectiveness and implementation)
- Assessment of residual risk
- Risk/benefit analysis and report
- Risk management report
- Results of an nonconformities, investigations, or CAPA activities in manufacturing and/or post marketing that impact product safety and any changes resulting from these activities *

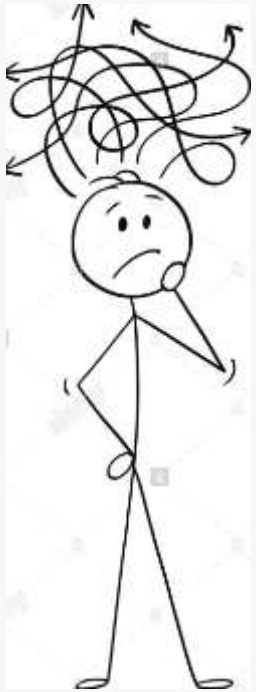
* This section is often missing.
Must be part of the system.

Communication with Competent Authority

The Manufacturer or its authorised representative:

Bankruptcy:
A process to retain documentation in the event the company becomes bankrupt or ceases its activity prior to the required retention period for documents and records.

How will the NB/CA interaction work?

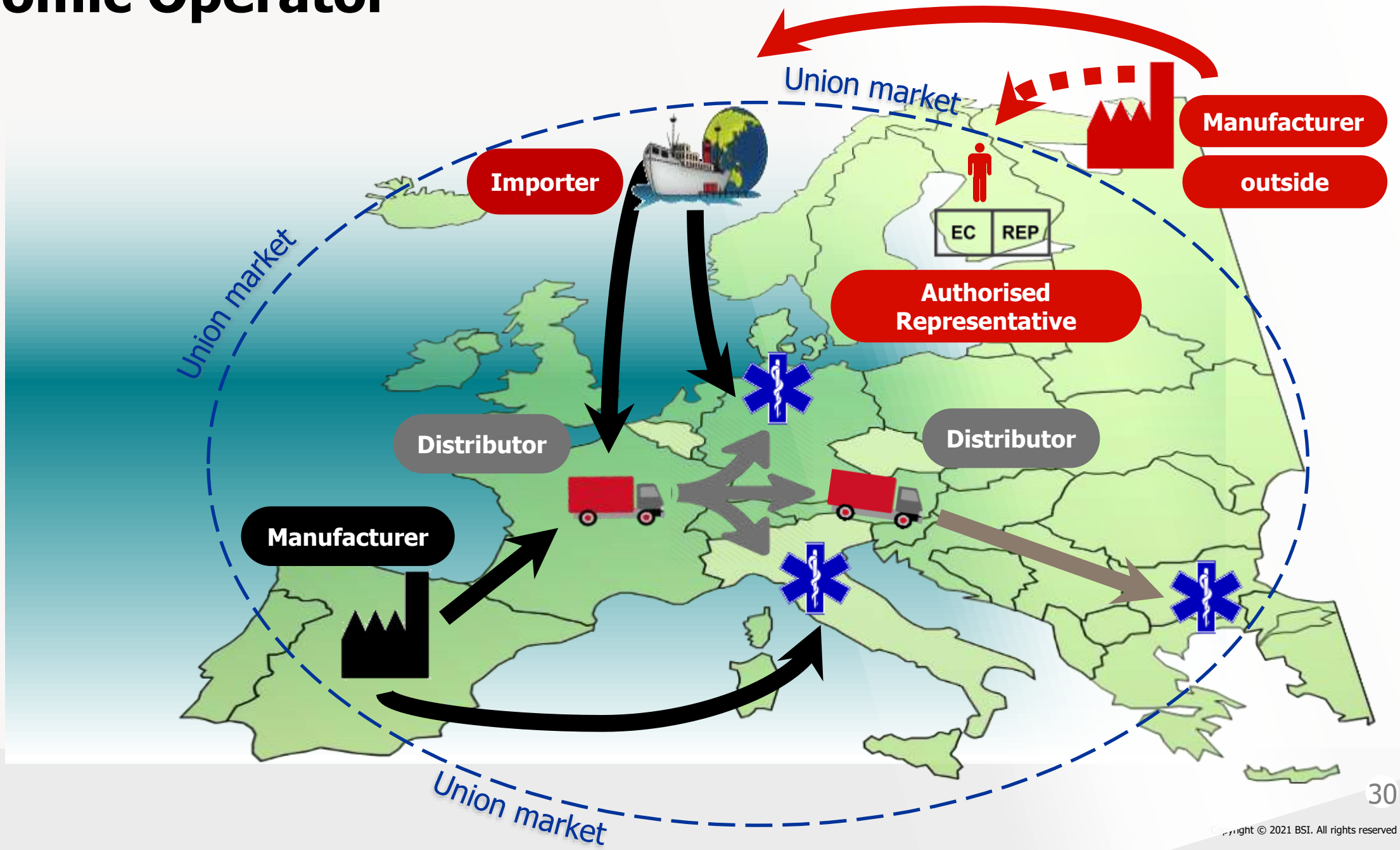


Annex IX chapter III 7

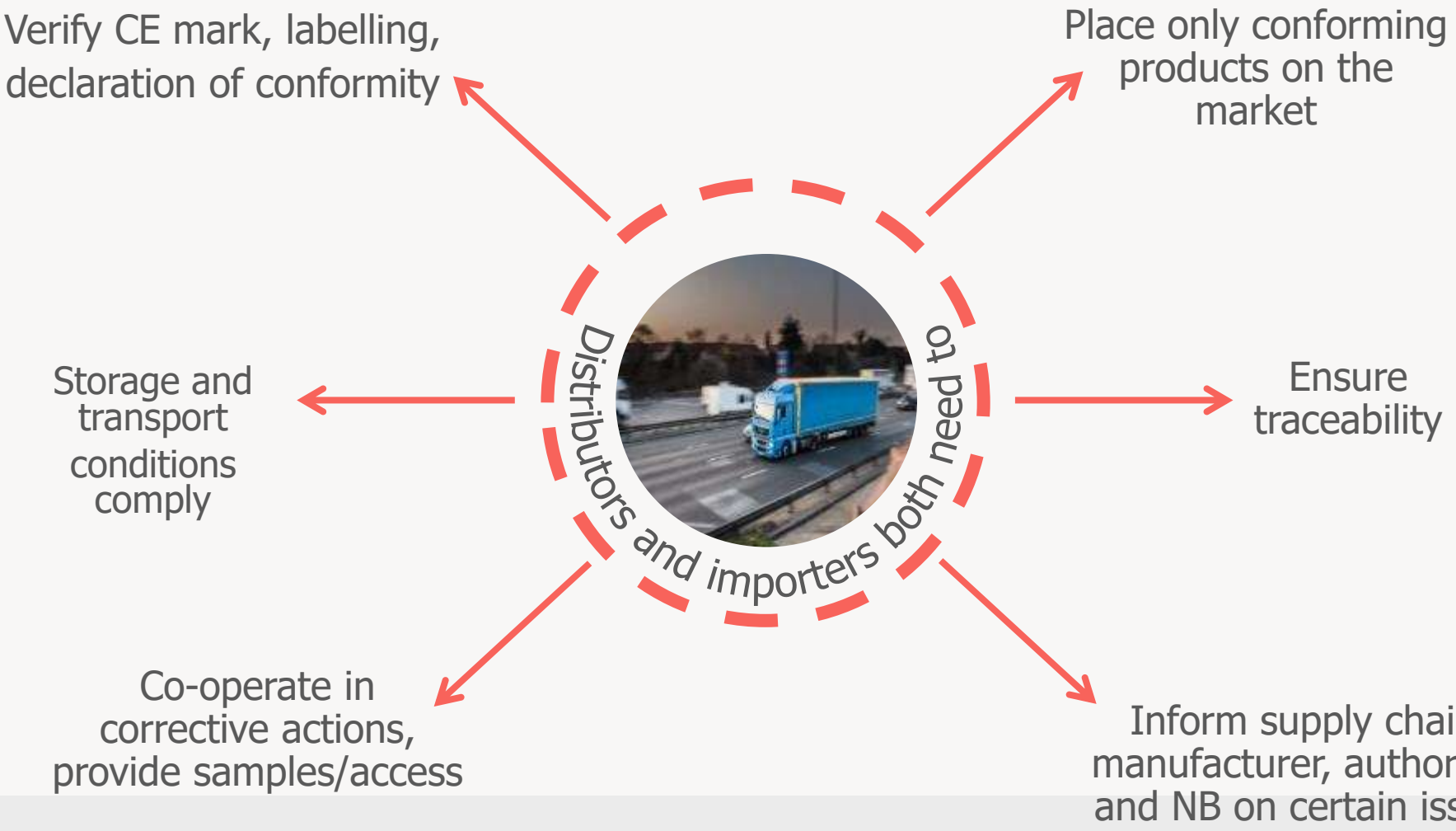
Annex XIV chapter II 3

CA – competent authority; NB – Notified Body

Economic Operator



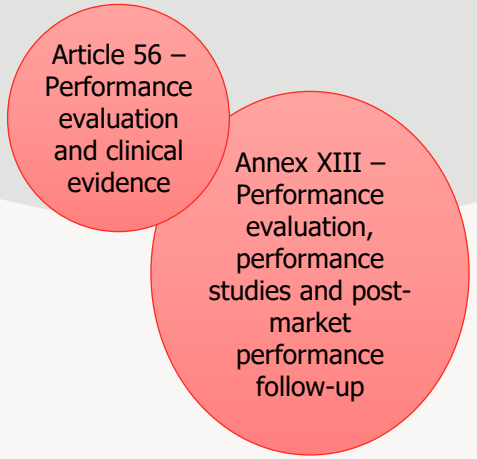
Responsibilities of distributor and importer



Post-Market Surveillance

Performance Evaluation and Clinical Performance

- Performance evaluation is a **continual** process
- The stated Intended use/purpose statement is critical for setting the clinical evidence required
- Driven by a Performance Evaluation **Plan** which needs to include:
  - An outline of the different development phases
  - The sequence and means of determination of the scientific validity
  - Analytical and clinical performance
  - Indication of milestones
  - Description of potential acceptance criteria
  - PMPF planning



Summary of safety and performance

For class C and D devices
(not performance evaluation)

Publicly available in the internet

for

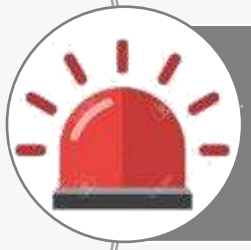
Users

If relevant, patient

Actionable events

Complaint:

- Communication about:
- Related to deficiency of a device,
- Which is outside manufacturer's control



Adverse event:

- Untoward, unintended, abnormal
- Regardless of any relation to device
- In a clinical investigation (only!)

Incident:

- Malfunction, deterioration, inadequate information, undesirable side-effect
- of a device which is made available

Complaints and Vigilance reporting

Timeframes need to be documented:

- Events reporting timelines:
  - 2 days
  - 10 days
  - 15 days
- Timeframes of complaint notification from distributor to Legal Manufacturer

Article 82.6:

- Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed by a complete report

Article 82.7:

- If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required.

Complaints and Vigilance reporting

Performance Study

Recording and reporting of adverse events that occur during performance studies:

- Procedure needs to cover all requirements of the IVDR **including responsibility of the sponsor**

Art 76 & Recital 70

Field Safety Notice Process

- Recall procedure need to include the req for FSN to be edited in the official Union Language or languages determined by the member state

- FSN Form needs:
  - correct identification of the device such as UDIs, SRN
  - the means for making it publicly available

Trend Reporting

Trend reporting process need to include the statistical methods that applied and the means of the reporting of any significant increase needs to be acknowledged.

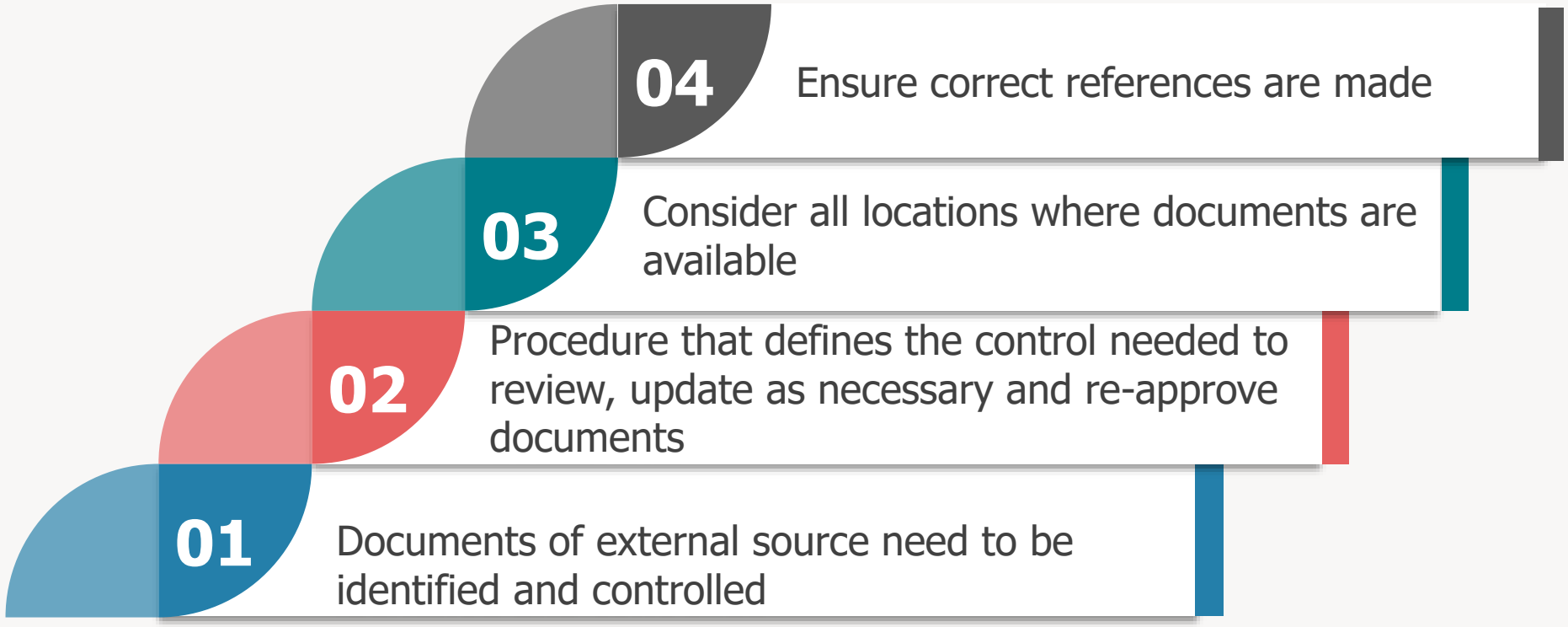
Art 83

Analysis of Data

Procedure for analysis of data on serious incidents and field safety corrective actions.

Art 84 & Art 85

Document and Record Control



Change Control

Procedure needs to be in place related to:

- Mnf shall inform the NB of any plan for substantial changes to the QMS, or the device-range covered

Annex IX section 2.4

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether, after those changes, the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

Significant changes

For QMS

- Reportable to NB

For Design and Internal Purpose

- Reportable to NB
- Approval before implementation

For Design and Intended Purpose

- For “legacy” devices
- Will end “Grace period”

Clearly present Annex I / GSPR Compliance

Possible Questions

Have applicable and non-applicable requirements been clearly noted with appropriate and relevant rationales?

It may be that certain sub-parts apply while others do not – consider the need for addressing applicability individually

Has the "precise identity of the controlled documents offering evidence of conformity" (annex II, Section 4d) been identified for each including document location?

e.g. "Design Verification Testing, Tech Doc Section 8" is not precise and is not fully applicable to each GSPR where it might be listed.

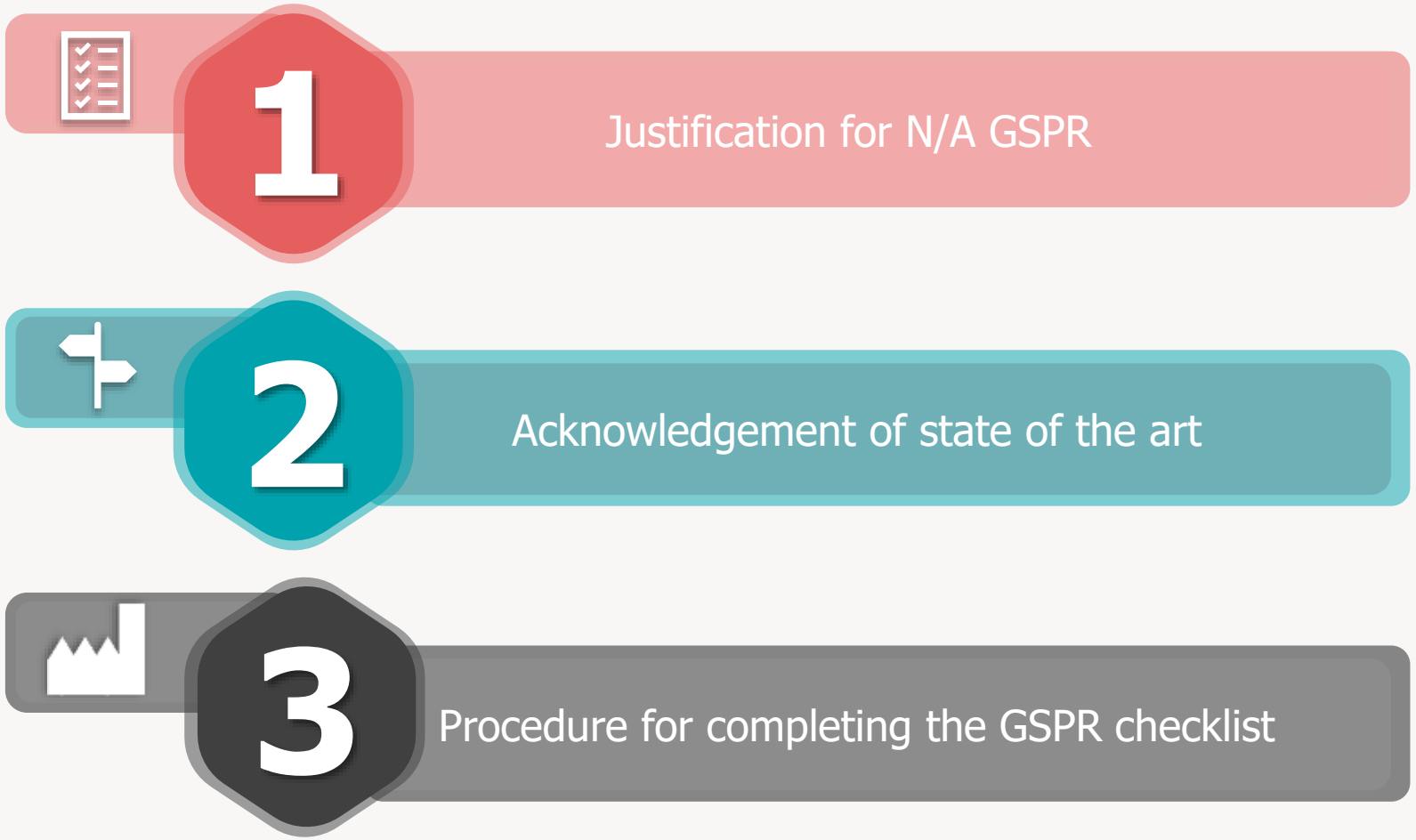
Have applied standards, Common Specifications, and guidances been identified, along with extent of compliance and version / year claimed?

Have all other applicable Directives & Regulations been identified)?

If cited standards are in a reference list and not directly in the GSPR Checklist, is the list of claimed standards traceable?

Are the cited standards versions consistent with those listed in the test reports or has a gap analysis bee presented?

Annex I / GSPR Compliance



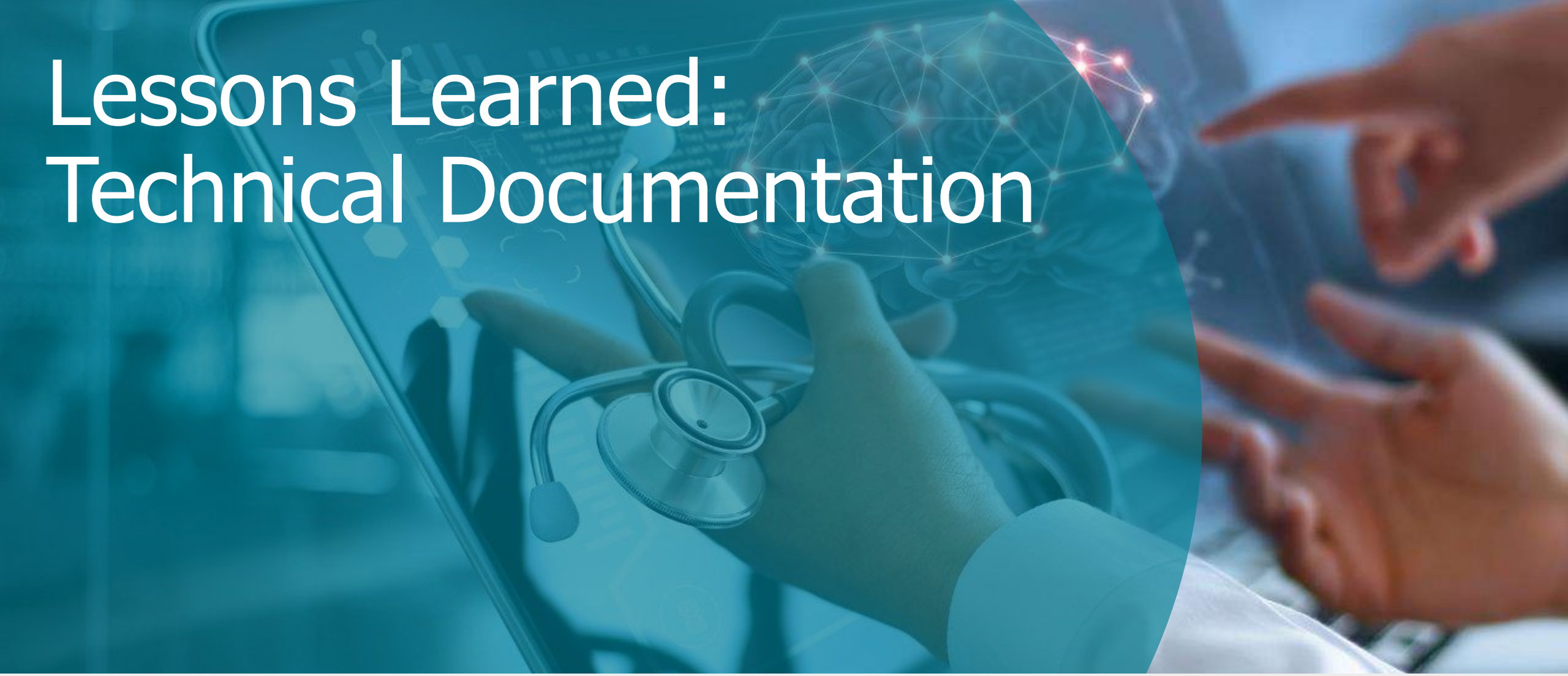
Next: Lessons learned - Technical Documentation assessments

Agenda – **Our lessons learned**

- Introduction & achieving certification
- QMS audits
- Technical Documentation assessments

--- 10 min break ---

- Performance Evaluation & Clinical Evidence
- NB updates & conclusions
- Panel Q&A



Lessons Learned: Technical Documentation

Dr Heike Moehlig-Zuttermeister
Technical Team Manager – IVD Medical Devices

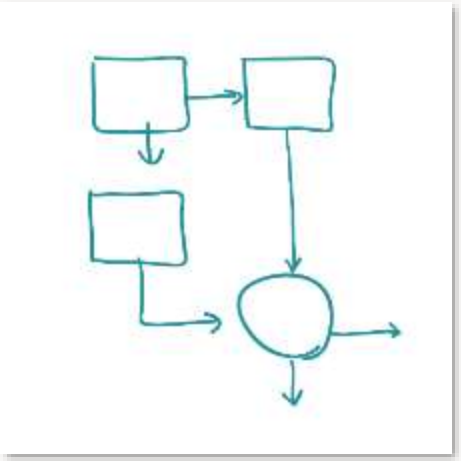
May 2021

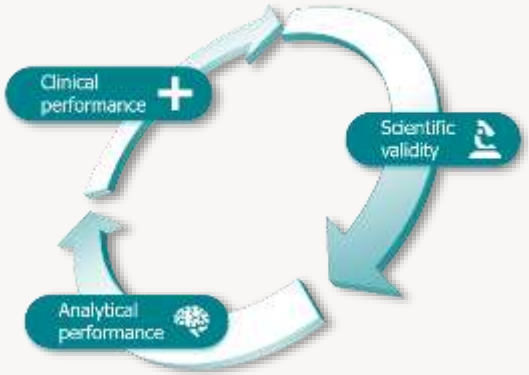
By Royal Charter

bsi.

Agenda

- Summary of our Questions
- Technical Documentation
  1. General Aspects
  2. Details of Annex II & III
  3. Summary
  4. Lessons learnt

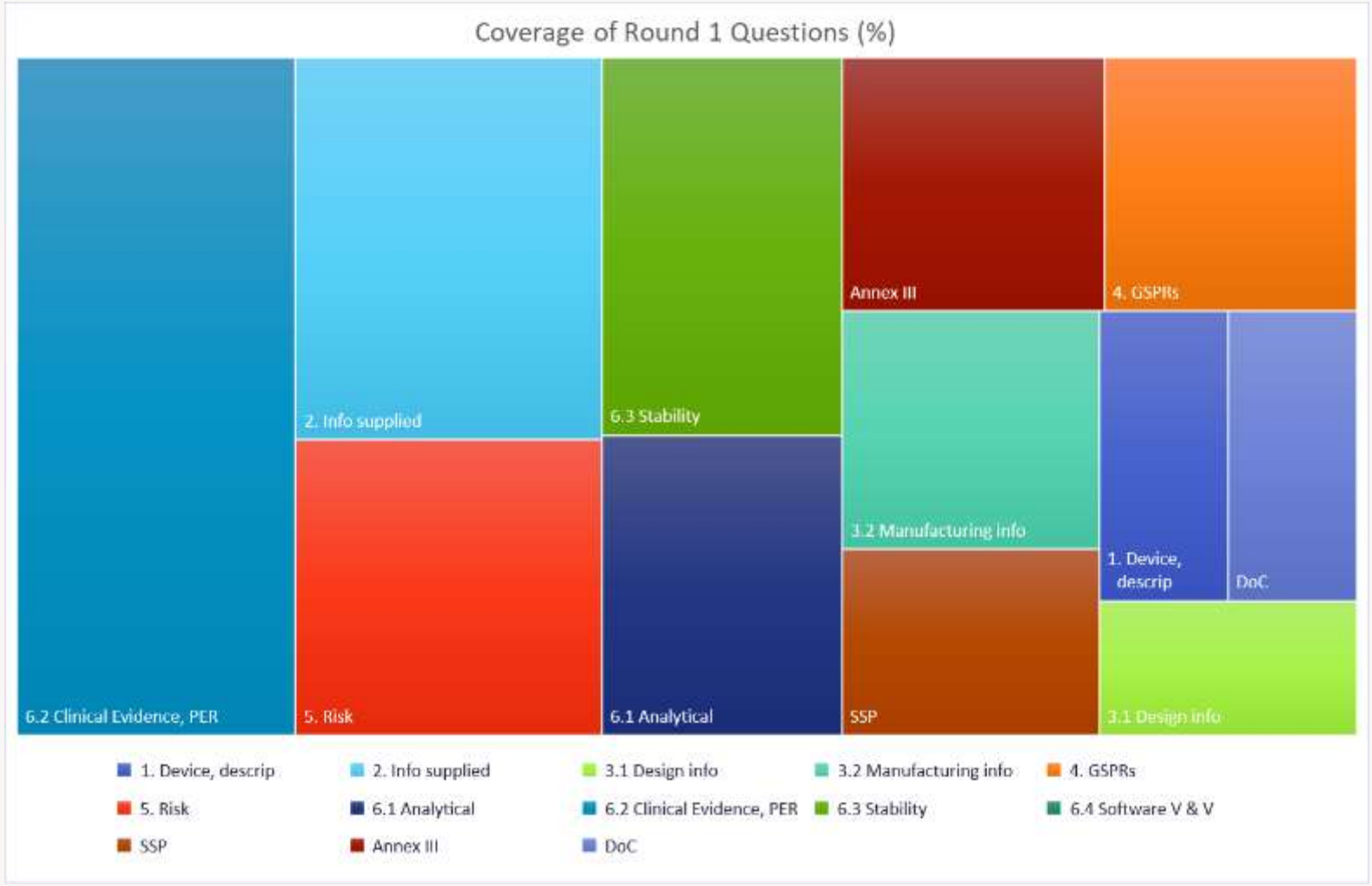




Summary of Round 1 Questions raised

- Questions cover all aspects of Annex II, III, XIII

- Majority Clinical Evidence
  - *Covered next*
- Information supplied
- Followed by Risk, analytical and stability
- DoC and SSP (if required) common



1. General aspects

- Process
- General experience

Technical Documentation – General Requirements

Article 10 – General obligations of manufacturer

4. Manufacturers shall draw up and keep up to date the technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

Depth and extent of assessment is the **same** for Class B, C and D
MDCG 2019-13 (Sampling)

- "quality management system…… **proportionate** to the risk class and the type of device" *(Article 10 sec 8)*
- "Its depth and extent shall be **proportionate** and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose" *(Annex XIII sec 1)*

Overview of experiences with Technical Documentation

- Variable in quality / completeness
  - ✓ *Searchable, easy to navigate, clear, organised*
- Consistency of device name
  - ✓ Across the technical file
- Use IVDR terminology
  - ✓ *There is no clinical utility, efficacy*
- Provide justifications for non-applicability
  - ✓ NB should not assume

Overview of experiences with Technical Documentation

- Provide Justifications for non-applicability
  - ✓NB should not assume
- To be compliant with IVDR Requirements
  - ✓Take into account MDCG guidance
  - ✓Consider international & European Standards

https://ec.europa.eu/health/md_sector/new_regulations/guidance

Guidance - MDCG endorsed documents and other guidance

~~Deutsch~~ **English**

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

The documents on this page are not legally binding. They present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.

MDCG work in progress

Ongoing guidance documents

Overview of experiences with Technical Documentation

- Final Technical Documentation should include all required amendments
  - ✓No change in structure

- Technical Documentation proportionate to risk class & intended purpose
  - ✓What is needed for a Control, Calibrator?
  - ✓What is needed for Software?
  - ✓What is needed for a test/assay – NGS assay vs ELISA?
  - ✓What is needed for different user *> professional , CDx– near-patient – self test <*

Standalone file!

Documentation Submissions for IVDR

- ✓A complete and well-organized file decreases time (and therefore cost!) of review
- ✓Annex II & III
  - ➢ *"to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex"*
  - ➢Annex II 4. d) *"precise identity"*
- ✓See BSI's Documentation Submissions Best Practices Guideline

Remember – Searchable, bookmarked pdf

https://www.bsigroup.com/globalassets/localfiles/en-za/iso-13485/ivdr-best-practice-documentation-submissions-sa.pdf

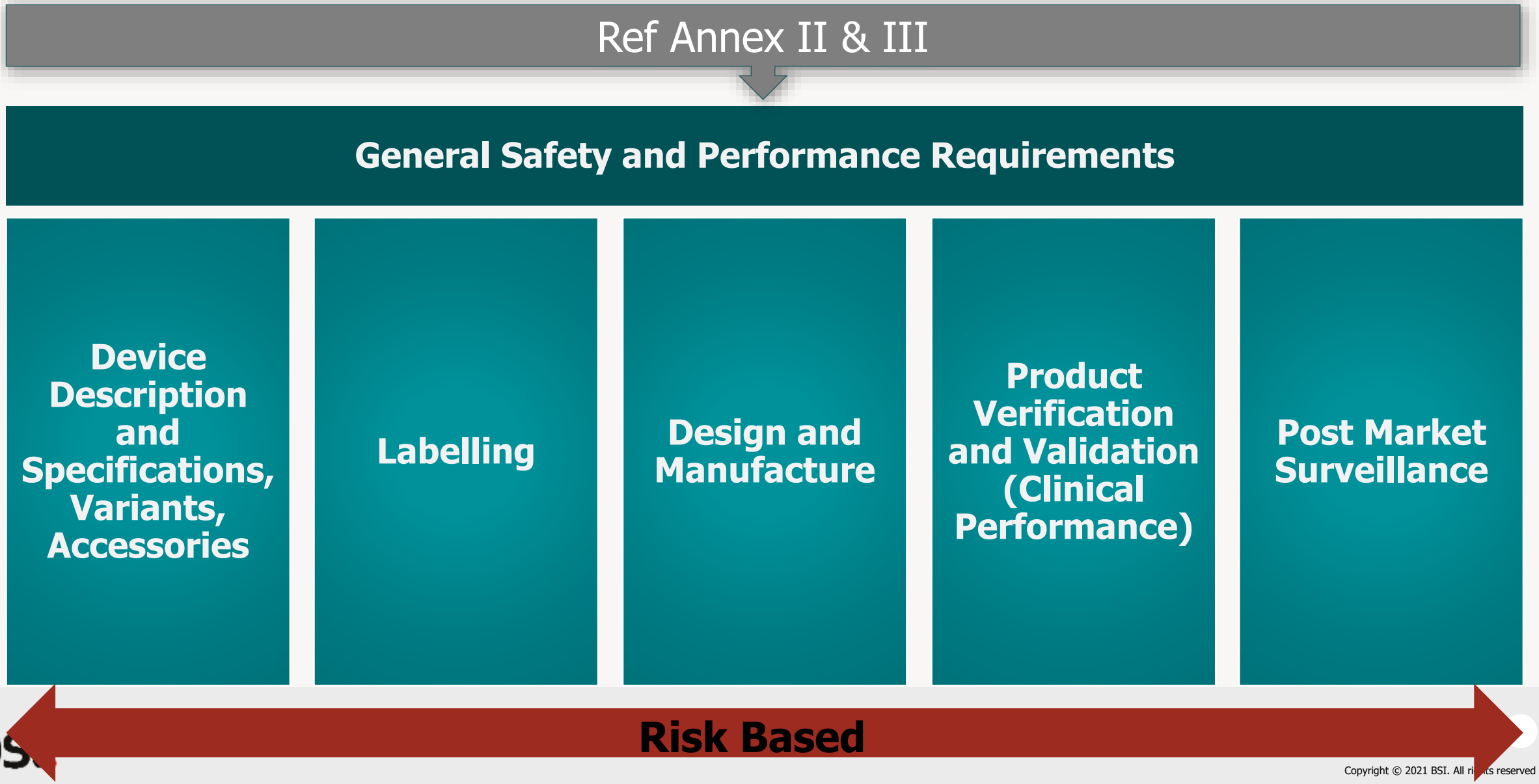
Overview of experiences with Technical Documentation

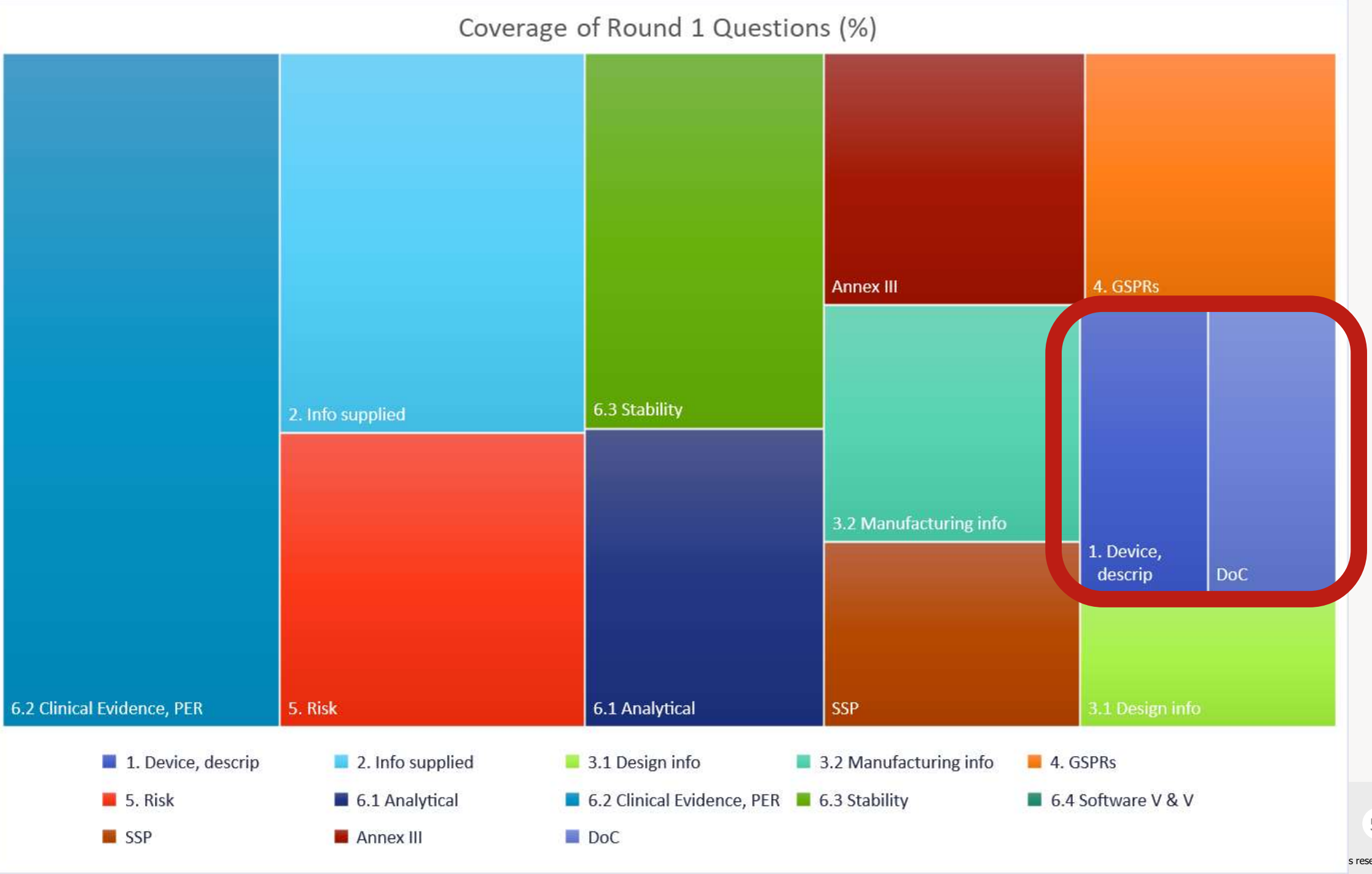
- Intended Use = Intended Purpose
  - ✓Consistent throughout the Technical Documentation
  - ✓Claims are supported by Clinical Evidence in the Performance Evaluation Report (analytical performance, scientific validity, clinical performance)
  - ✓GSPR 20.4.1 (c) i, ii, iii to be covered – clear medical purpose
  - ✓Link to State of the Art
  - ✓Claims, contraindications, limitations captured in RM & PMS
  - ➢**Redline throughout the Technical Documentation**

2. Technical Documentation

- Detailed look into Annex II & III

Technical Documentation




Coverage of Round 1 Questions (%)
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3.2 Manufacturing info
4. GSPRs
5. Risk
6.1 Analytical
6.2 Clinical Evidence, PER
6.3 Stability
6.4 Software V & V
SSP
Annex III
DoC

Majority of identified deficiencies

1.1 Device description and specification - Covers (a) to (m)

(a) product or trade name and a general description of the device

- ✓ *consistency*

(b) Basic-UDI-DI

- ✓ *BUDI-DI approach is the responsibility of the manufacturer*
- ✓ *Multiple MDCG guidance available, https://ec.europa.eu/health/md_sector/new_regulations/guidance*

(c) intended purpose and intended users

- ✓ *conistency*

Majority of identified deficiencies

1.1 Device description and specification - Covers (a) to (m)

(f) Classification

- ✓ *Incorrect rules or not all applicable rules*
- ✓ *Provide decision tree*

(g) description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers

- ✓ *Links to Annex II 3.1 "critical ingredients"*
- ✓ *Spell out your reactive/critical ingredients*

Majority of identified deficiencies

1.2 Reference to previous and similar generations of the device

(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

✓ *Previous generations – provide overview of changes*

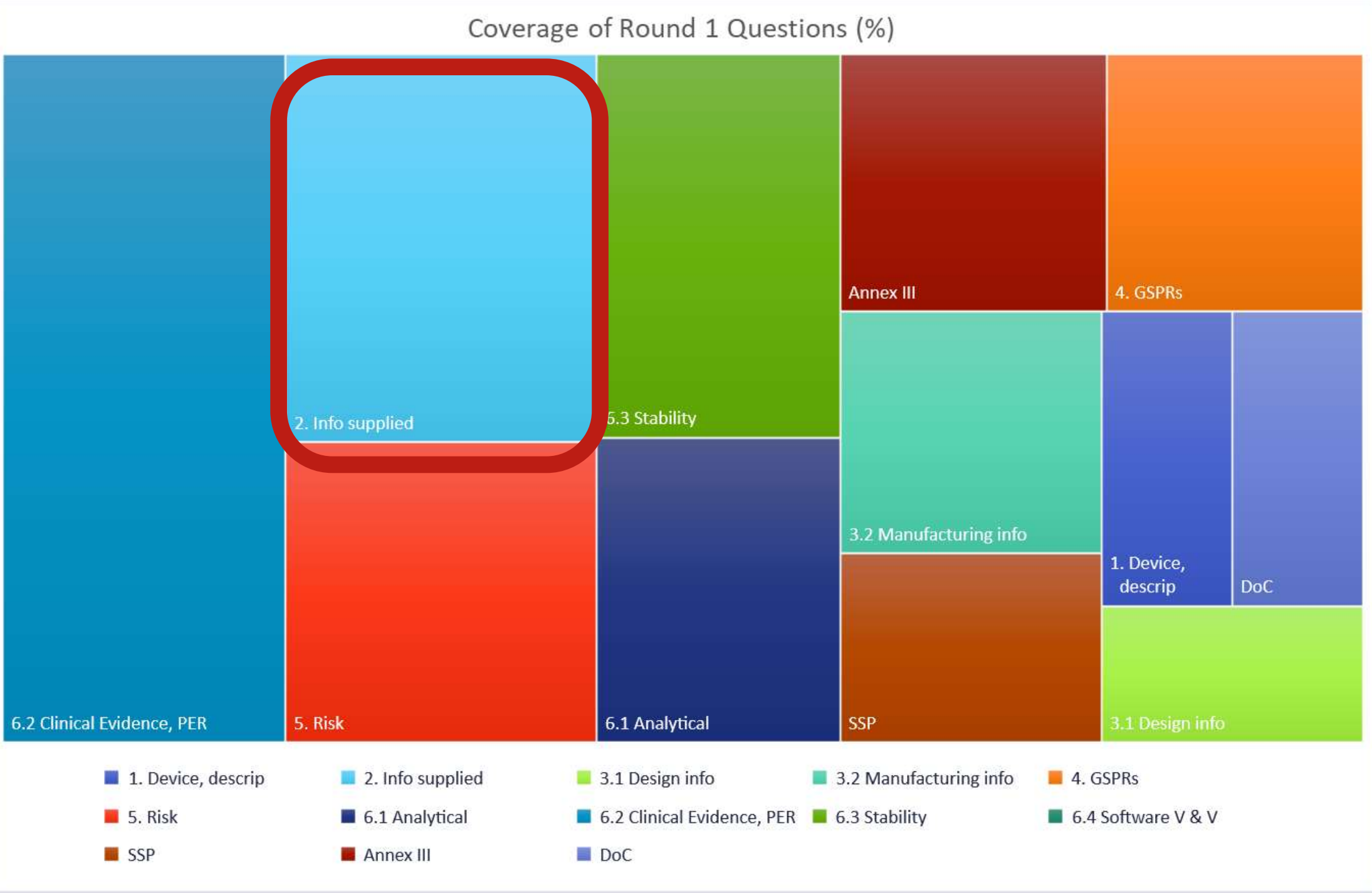
Declaration of Conformity Annex IV

- Sec 4: Intended purpose
- Sec 8: Name of NB
  - ✓ *Refer to Nando*

    https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main
- Sec 10: Place and...indication for, and on behalf of whom, that person signed

The EU declaration of conformity shall contain the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN referred to in Article 28 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The Basic UDI-DI as referred to in Part C of Annex VI;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;
5. Risk class of the device in accordance with the rules set out in Annex VIII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
7. References to any CS used and in relation to which conformity is declared;
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. Where applicable, additional information;
10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.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4. GSPRs
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DoC
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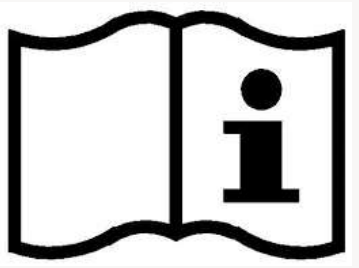
2. Info supplied
3.1 Design info
3.2 Manufacturing info
4. GSPRs
5. Risk
6.1 Analytical
6.2 Clinical Evidence, PER
6.3 Stability
6.4 Software V & V
SSP
Annex III
DoC

Information to be supplied by the manufacturer
Annex II.2



A complete set of

(a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;

(b) the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

Link to GSPR 20

Majority of identified deficiencies

GSPR 20

- 20.4.1. (c) – intended purpose
  - ✓ *Consistency*
  - ✓ *Missing medical application*
  - ✓ *Testing population*
- 20.4.1 (e) – intended user
- 20.4.1 (l) – storage & stability

Controls, Calibrators

Majority of identified deficiencies

GSPR 20

- 20.4.1 (n) – hazardous symbols & compliance to (EC) 1272/2008
- Reference to SSP – to include Eudamed website – Article 29.1

Some specifics for NPT

20.1 (d) Abbreviated IFU

✓ *instrument manuals need to be referenced (clear identity) and provided for review*

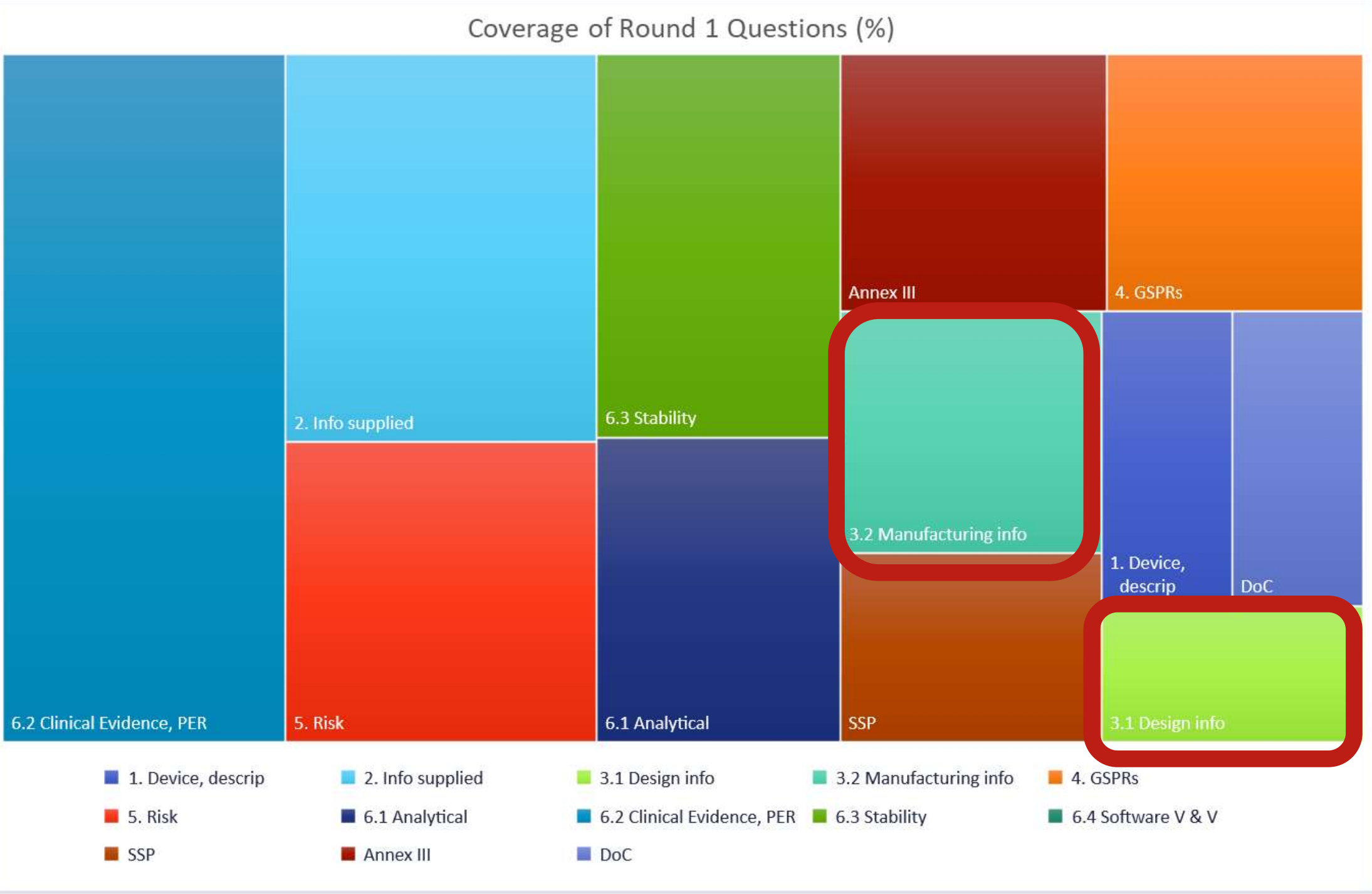
Majority of identified deficiencies

GSPR 20

- 204.1 (w) – analytical performance characteristics
  - ✓ *Consistency*
  - ✓ *Missing characteristics e.g., interference, specimen types*

- 20.4.1 (x) – clinical performance characteristics
  - ✓ *Consistency*
  - ✓ *Missing characteristics*

Controls, Calibrators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Annex III
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4. GSPRs
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6.1 Analytical
6.2 Clinical Evidence, PER
6.3 Stability
6.4 Software V & V
SSP
Annex III
DoC

Majority of identified deficiencies

3.1 Design information

(a) a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;

✓ *Provide clear information on critical ingredients*

(e) for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self- testing or near-patient testing

✓ *Provide specific Design inputs related to user environment & usability*

Majority of identified deficiencies

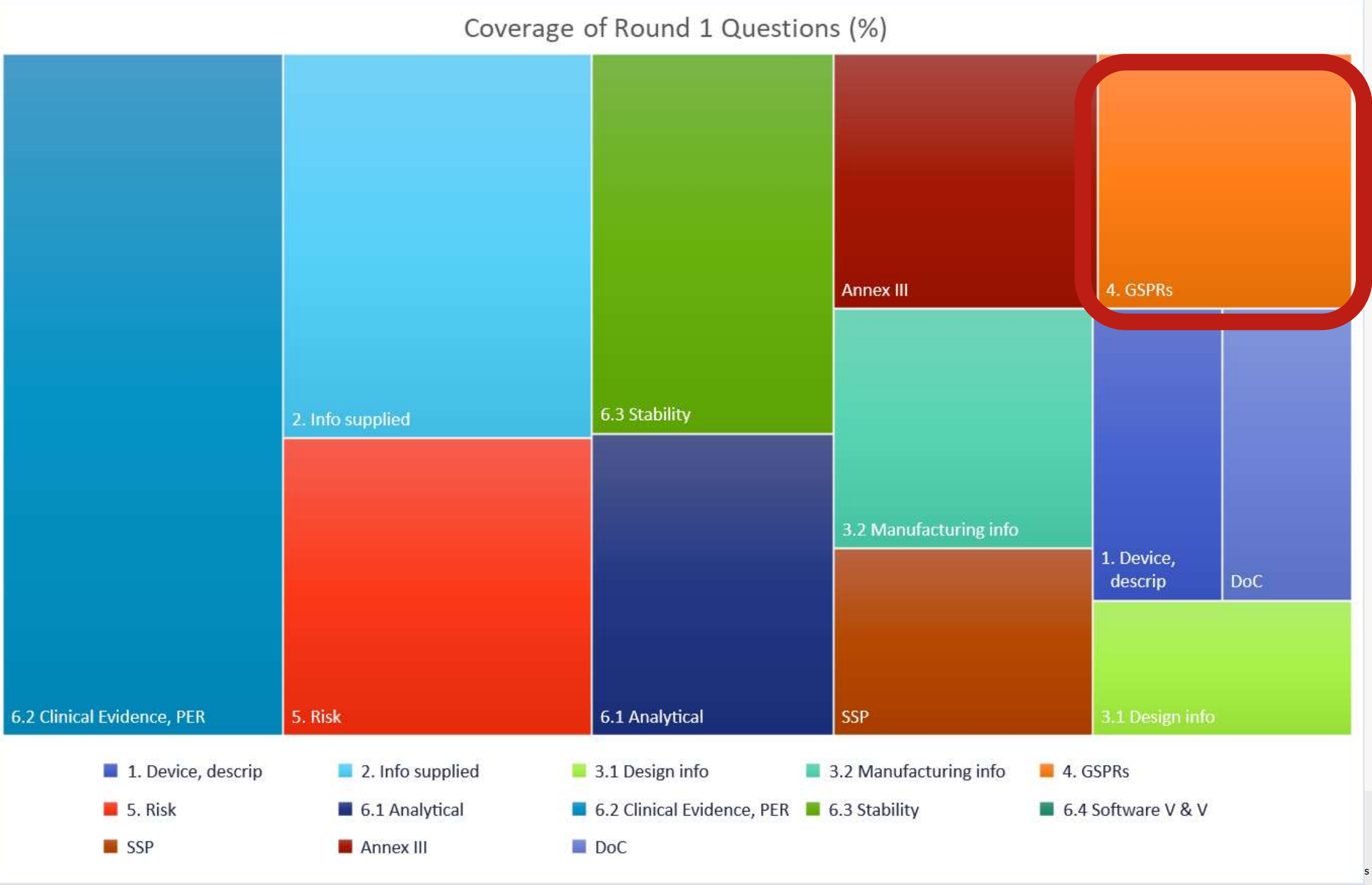
3.2 Manufacturing information

(a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;

✓ *Provide relevant QC documents including an example batch record*

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

✓ *Be clear regards your organisational setup*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SSP
4. GSPRs
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DoC
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5. Risk
6.1 Analytical
6.2 Clinical Evidence, PER
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SSP
Annex III
DoC

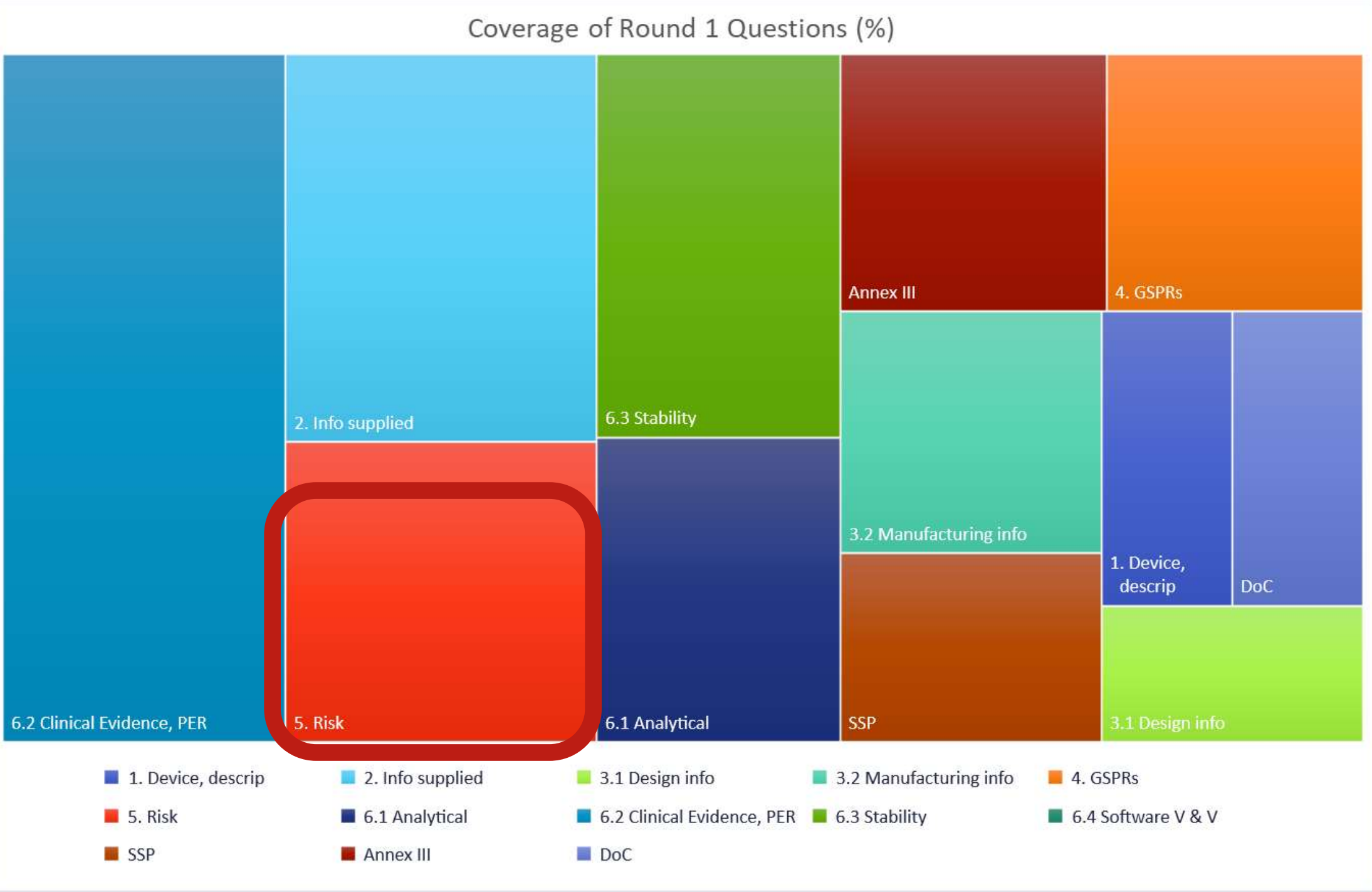
Majority of identified deficiencies

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

- ✓ *Provide justifications for any non-applicable*
- ✓ *Be clear which devices/system are covered by your Checklist – indicate dedicated applicabilities*

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

- ✓ *precise identity!*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Annex III
DoC

Majority of identified deficiencies

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

Links to GSPR 1-8

Majority of identified deficiencies

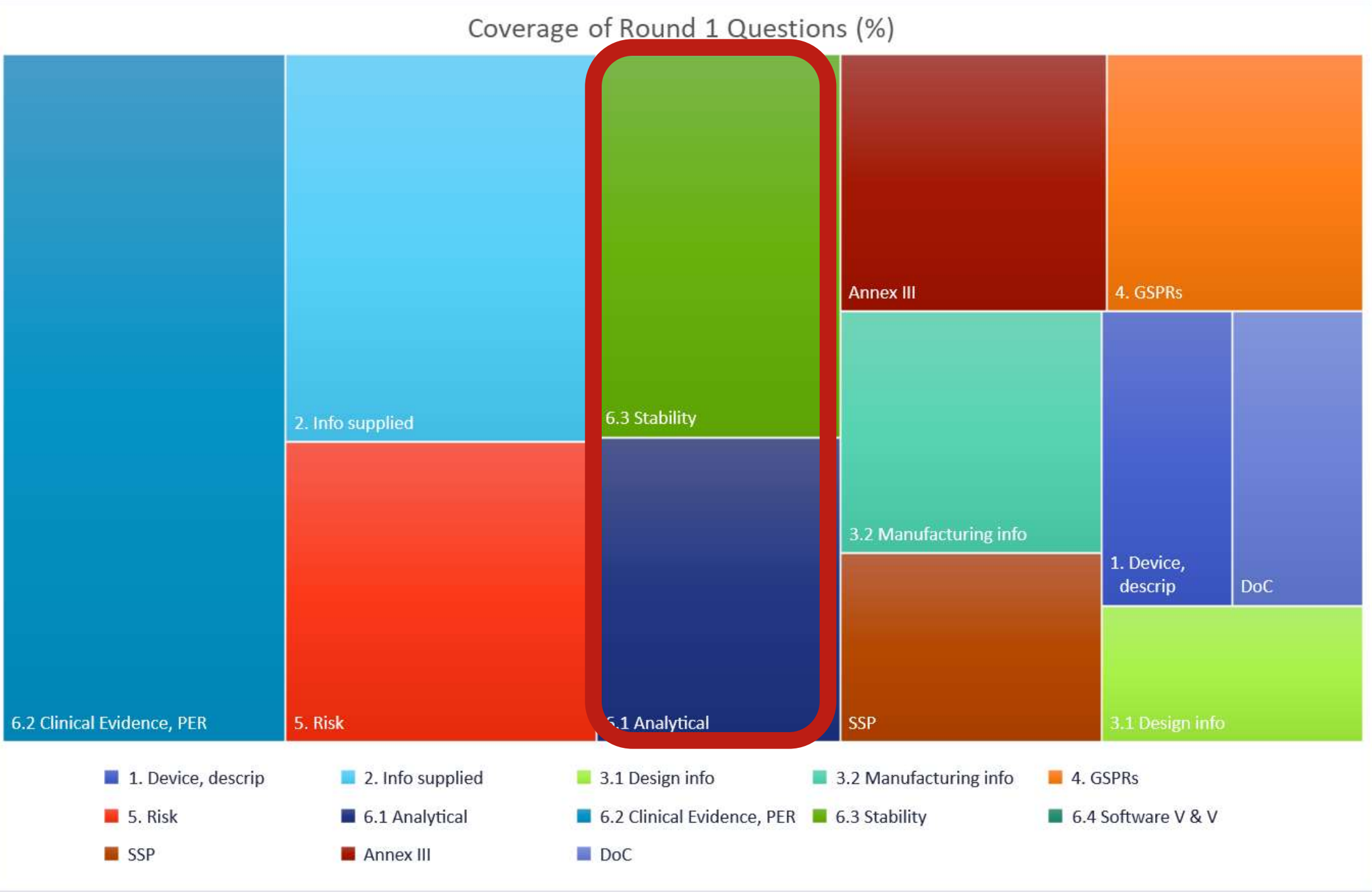
- Missing documents!
- Compliance to EN ISO 14971:2012 or ISO 14971:2019?
- RM process & methods differ among organisations
  - Can be complex – regarding the "system"
    - *Covering test/assay, calibrator/control, SW, instrument?*
  - Think about the auditor!
    - *Tell a story to have an understanding about your applied methods!*

Majority of identified deficiencies

- State of the art considerations – GSPR 1
- Residual & foreseen risks – GSPR 3 & 4

8. All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.

Links to IFU claims
Links to Performance Evaluation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SSP
Annex III
DoC

Majority of identified deficiencies

Annex II.6.1 Information on analytical performance on the device

- ✓Consistency to IFU
- ✓Justify non-applicability
- ✓Missing studies and/or partial studies to support IFU claims
  - ➢Interference
  - ➢Specimen claims

Links to Annex XIII 1.2.2

Majority of identified deficiencies

Annex II.6.1 Information on analytical performance on the device

✓Indications which instruments have been used

- ➢Closed platform
- ➢Open platform

✓Comparison Study

- ➢Should be CE-marked
- ➢No CE-marked device available – think about “state of the art”

Links to Annex XIII 1.2.2

Annex XIII 1.2.2

No CE marked assay and/or no reference measurement procedure available

Watch out for other well documented methods of the composite reference standard

Clinical Performance Study is required!

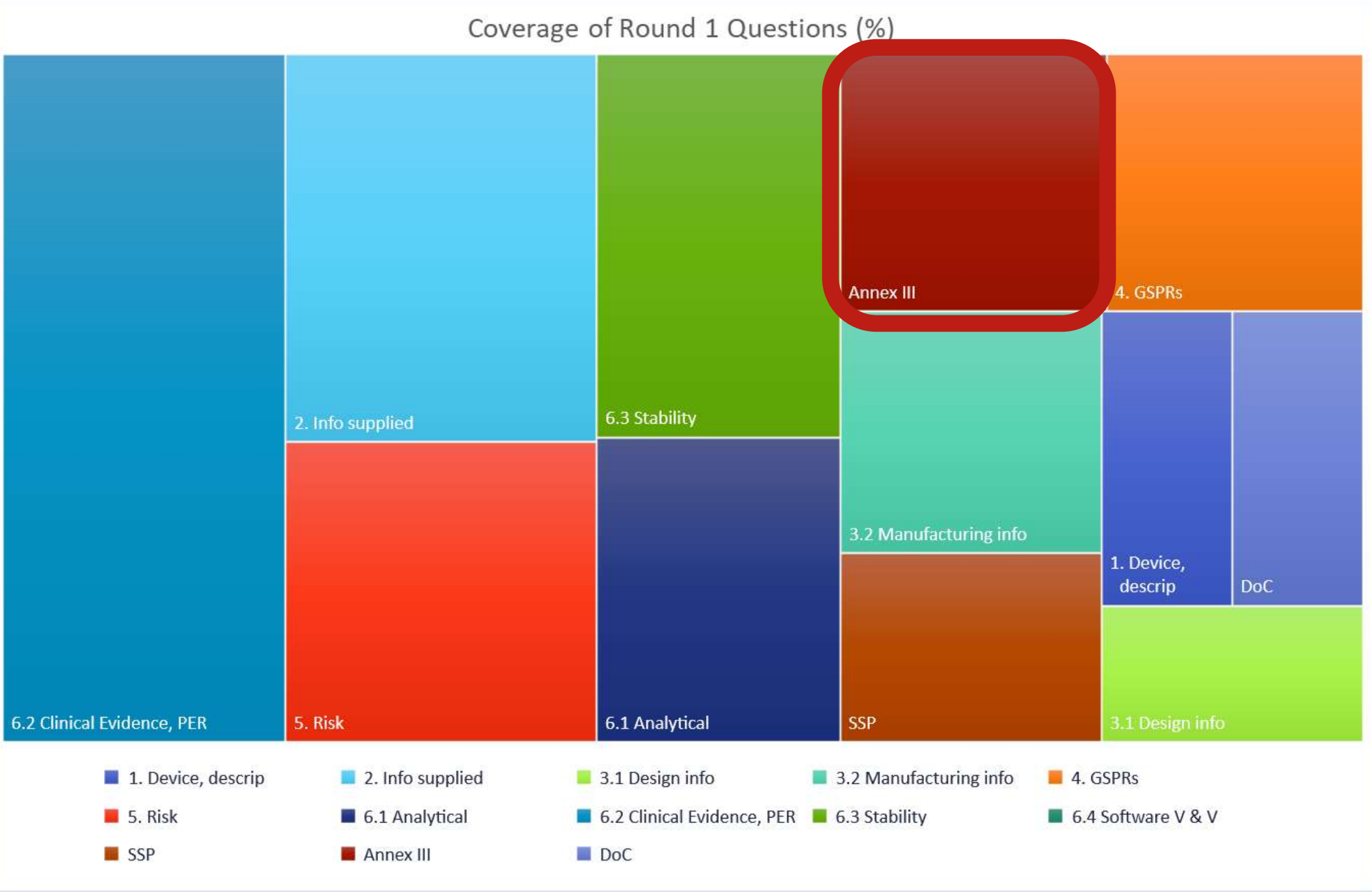
1.2.2. Demonstration of the analytical performance

The manufacturer shall demonstrate the analytical performance of the device in relation to all the parameters described in point (a) of Section 9.1 of Annex I, unless any omission can be justified as not applicable.

As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

For novel markers or other markers without available certified reference materials or reference measurement procedures, it may not be possible to demonstrate trueness. If there are no comparative methods, different approaches may be used if demonstrated to be appropriate, such as comparison to some other well-documented methods or the composite reference standard. In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Analytical performance shall be demonstrated and documented in the analytical performance report.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SSP
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Annex III
DoC

Technical Documentation on PMS Annex III

Initial certification

Surveillance

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 78 to 81 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1. The post-market surveillance plan drawn up in accordance with Article 79.

   The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 78.

2. The PSUR referred to in Article 81 and the post-market surveillance report referred to in Article 80.

Links to PMS – Article 78, 79, 80, 81

Majority of identified deficiencies

- PMS Plan does not cover all elements of Annex III a) and b)
  - ✓IVDR is very prescriptive!
- Scope of PMS Plan is not clear
  - ✓Which devices/groups are covered?
  - ✓IVDR does not spell out to have ONE plan for individual devices
  - ✓Be proportionate!
  - ✓All risk class specifics need to be covered?

1. For each device manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(8).

Majority of identified deficiencies

- Justification not doing a PMPF

  ✓Triggers & indicators for doing PMPF need to be spelled out

4. PMPF shall be understood to be a continuous process that updates the performance evaluation referred to in Article 56 and Part A of this Annex and shall be specifically addressed in the manufacturer's post-market surveillance plan. When conducting PMPF, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of er
ratio and of detecti

Links to SSP Article 29 2(f)
Links to PEP & PER Annex XIII 1.1 & 1.3.2

PEP: Performance Evaluation Plan
PER: Performance Evaluation Report

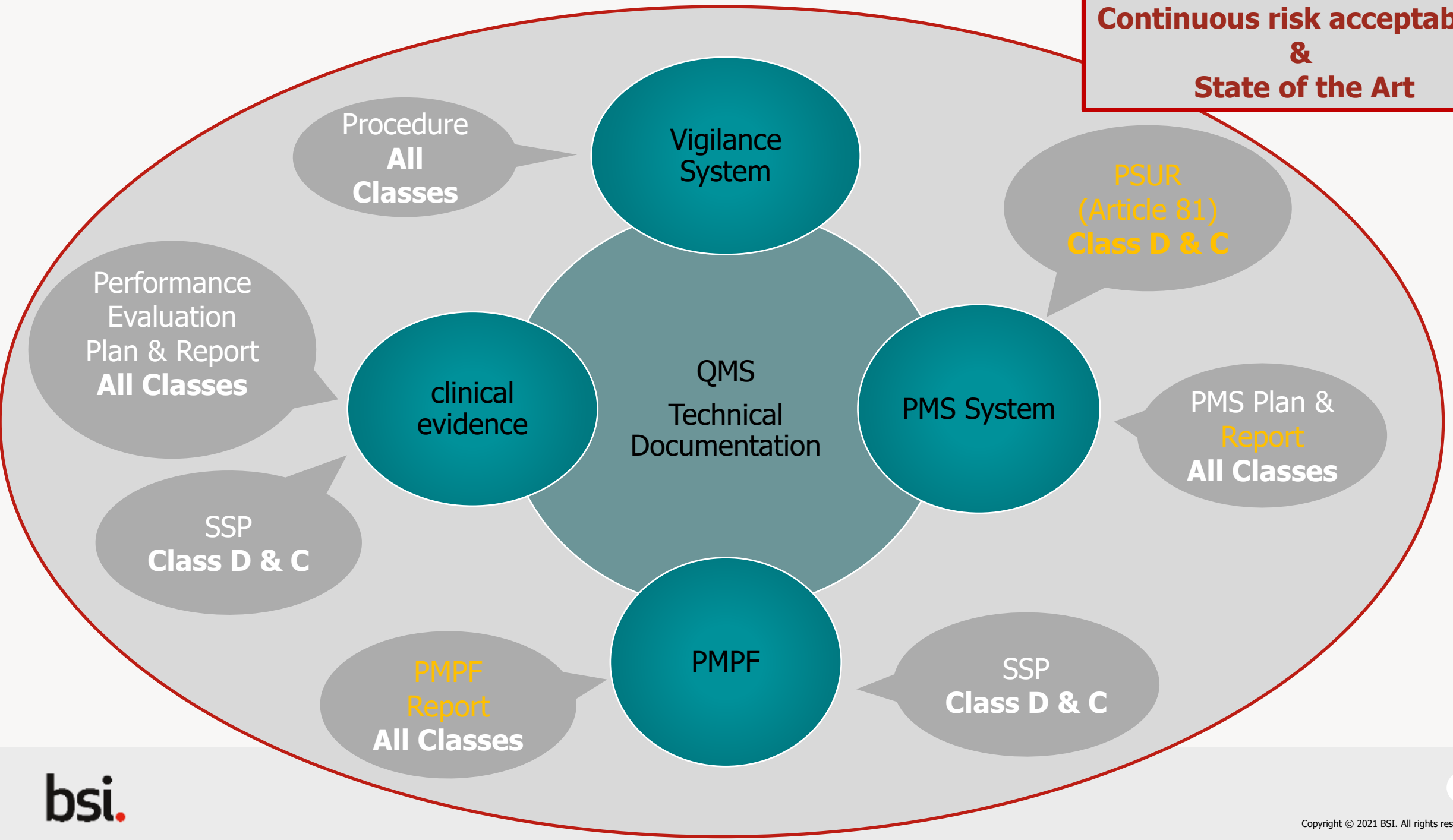
2. Technical Documentation

- Summary

TD is not a separate document

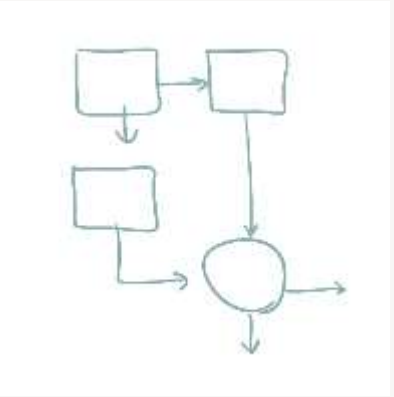
It is more a story covering lifetime of the device

Continuous risk acceptability
&
State of the Art



Learning Points…

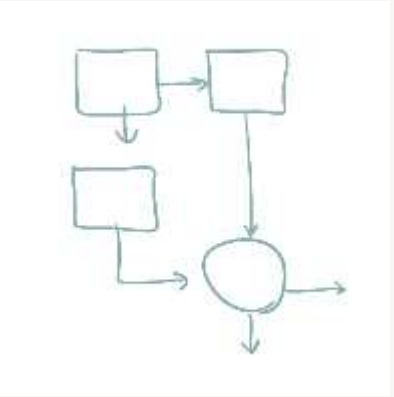
- IVDR is very prescriptive
  - ✓Gap analysis to cover all elements
  - ✓Provide justifications for non-applicability
  - ✓Use international standards & guidelines for your implementation



- Use IVDR terminology!
- Verify Consistency across your file

Learning Points…

- Clear intended purpose – redline across the TD
  - ✓Performance claims traceable
  - ✓Performance claims can be supported?



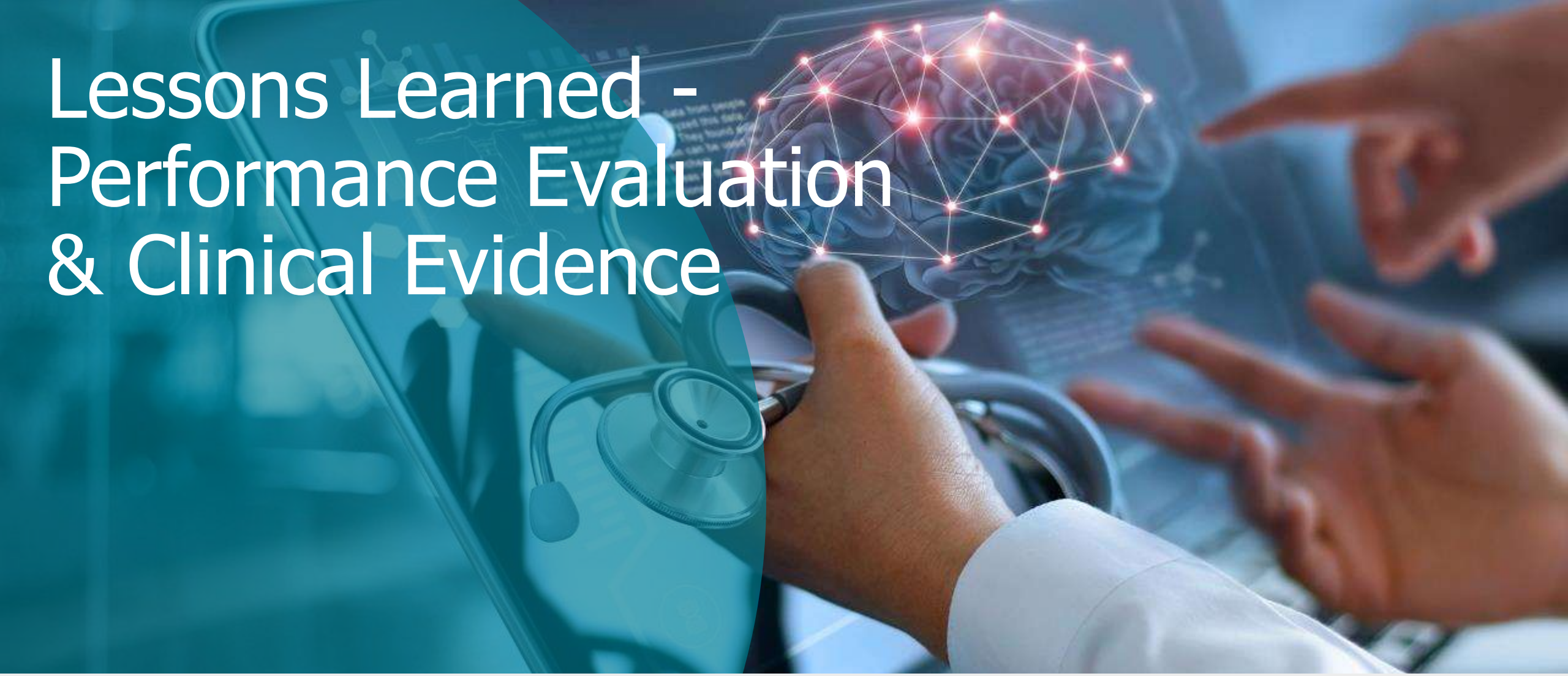
- Tell a story – understandable for your auditor
  - ✓Consider your device type
    - ➢ Risk classification
    - ➢ System vs assay/test vs controls/calibrators vs Software

- **Scrutinise age of documents – any changes?**

Next: BREAK!

- Followed by Lessons Learned on Performance Evaluation & Clinical Evidence

Lessons Learned - Performance Evaluation & Clinical Evidence



Dr Elizabeth Harrison
Technical Team Manager - IVD

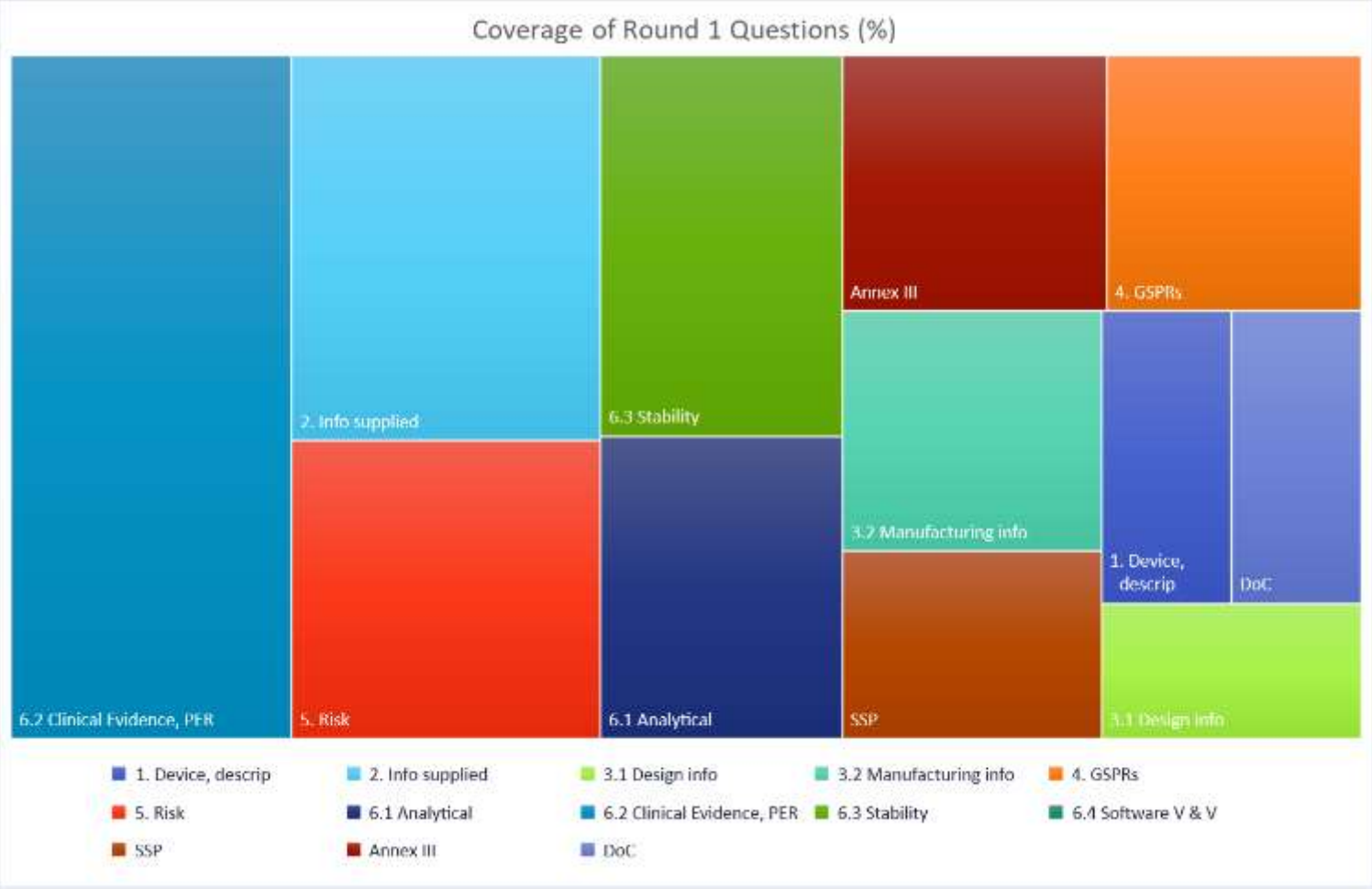
12 May 2021

By Royal Charter

bsi.

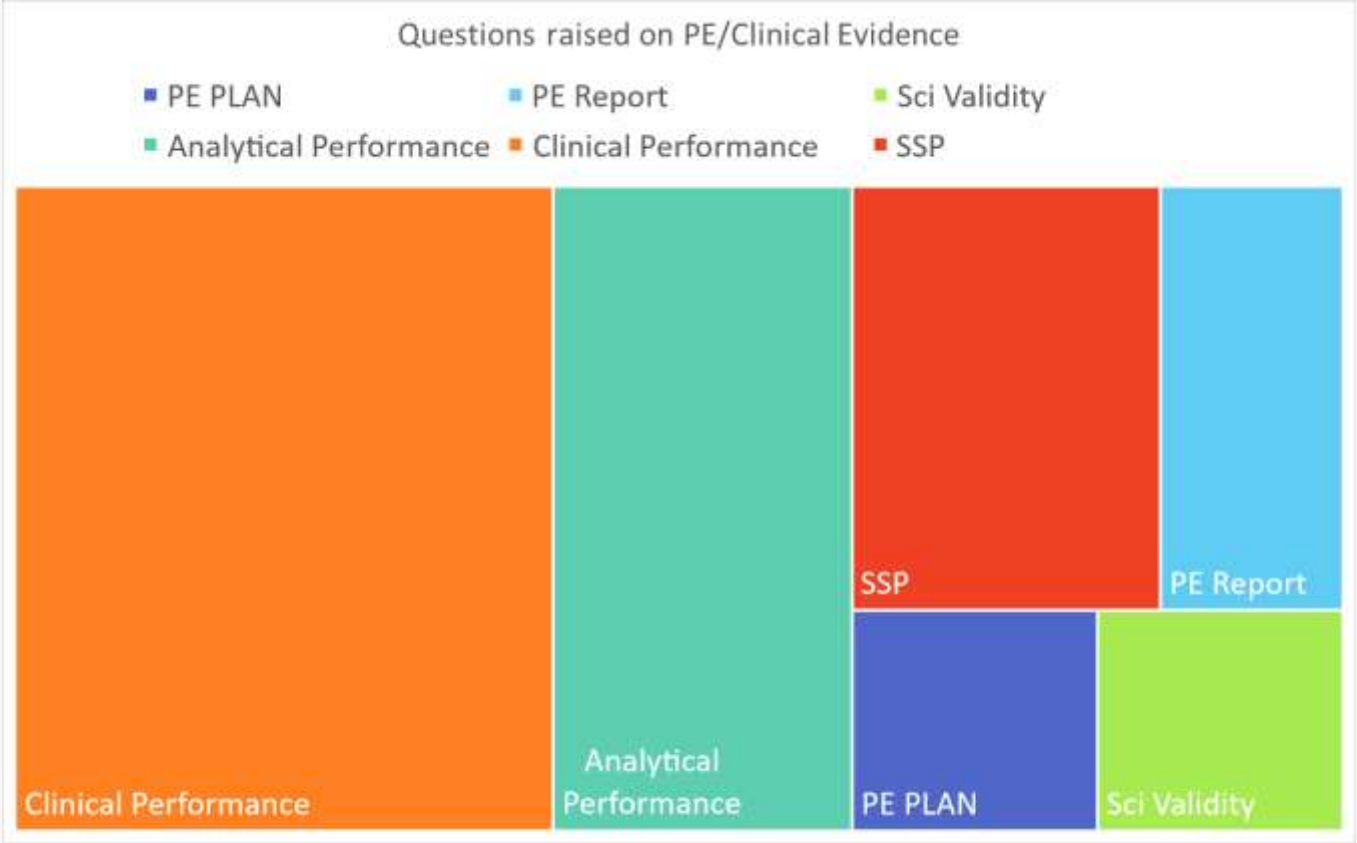
Agenda

- Performance Evaluation Plan
- Clinical Evidence
  - (Analytical covered under TD)
  - Scientific Validity
  - Clinical Performance
- Performance Evaluation Report

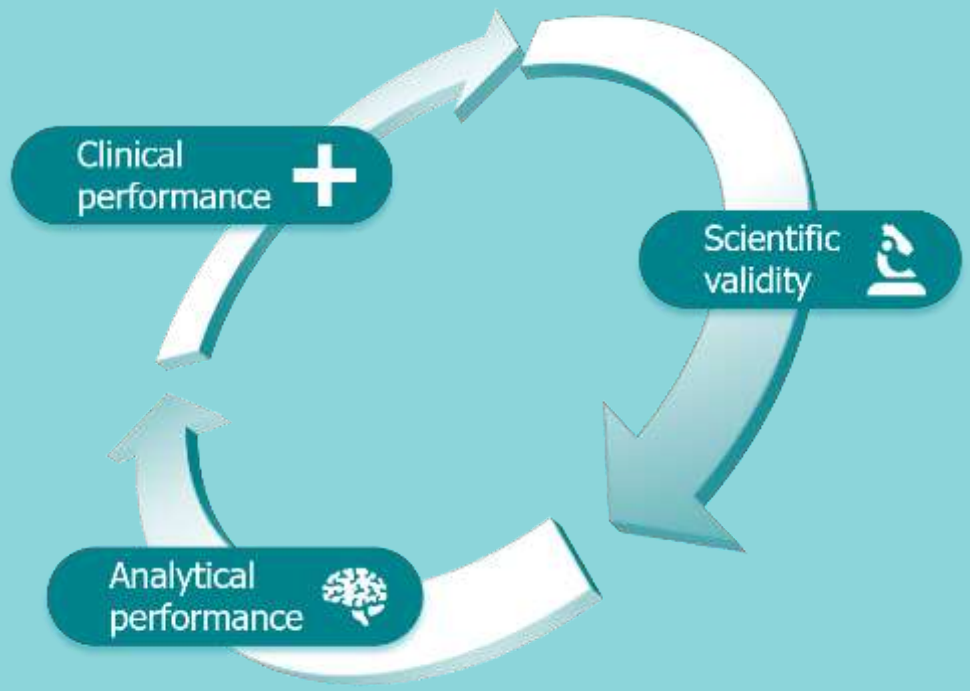


Further analysis of Questions on PE/Clinical Evidence

- Majority of questions centre around information provided for Clinical Performance (>40%)
- Analytical performance was the next biggest area for questions
  - Reference TD presentation
- Where an SSP is required (class C), understandable that questions raised whilst lack of guidance



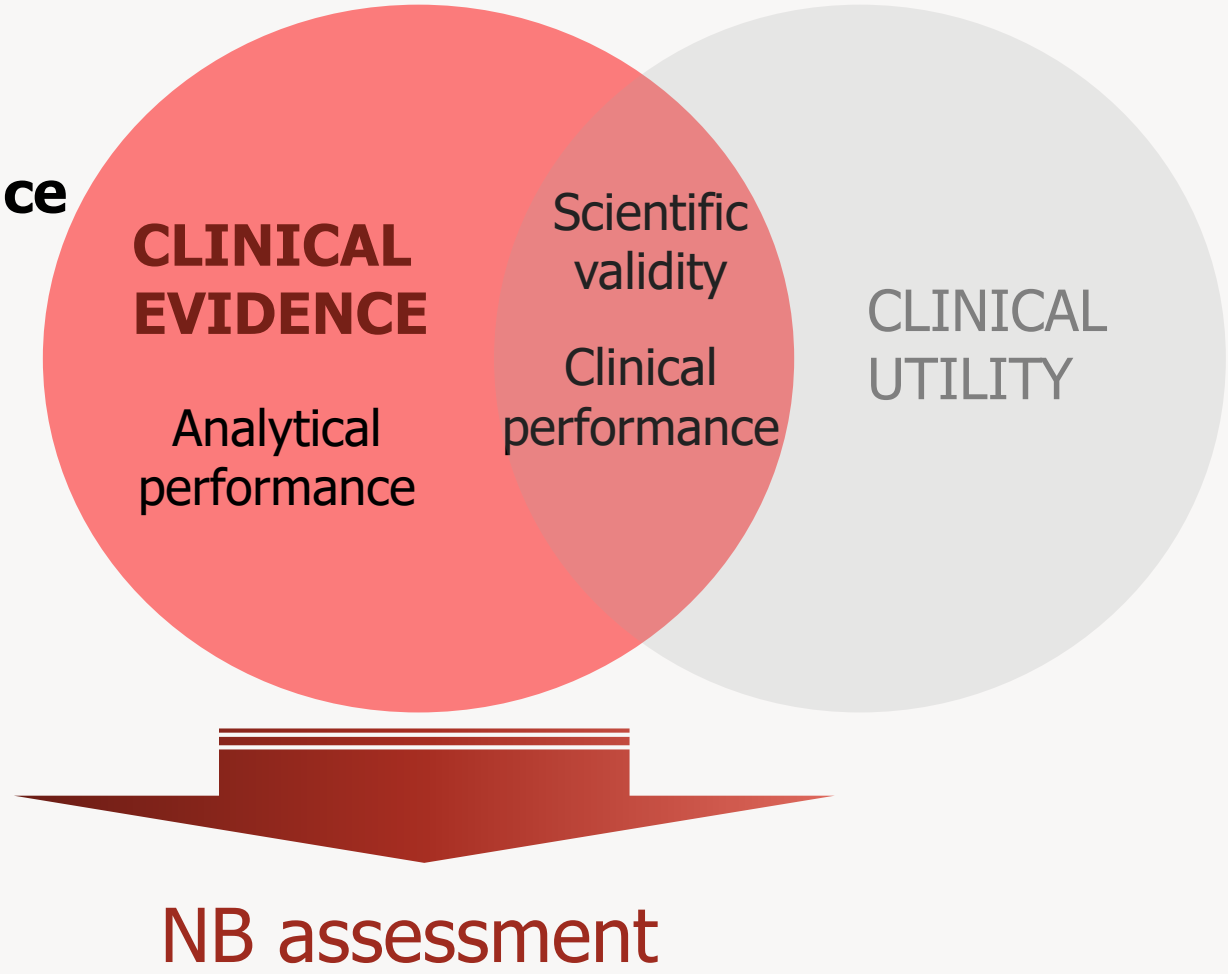
- Performance Evaluation under the IVDR



Clinical Evidence

= Scientific Validity + Analytical Performance + Clinical Performance

= clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a **qualified assessment** of whether the device achieves the **intended clinical benefit and safety**, when used **as intended** by the manufacturer

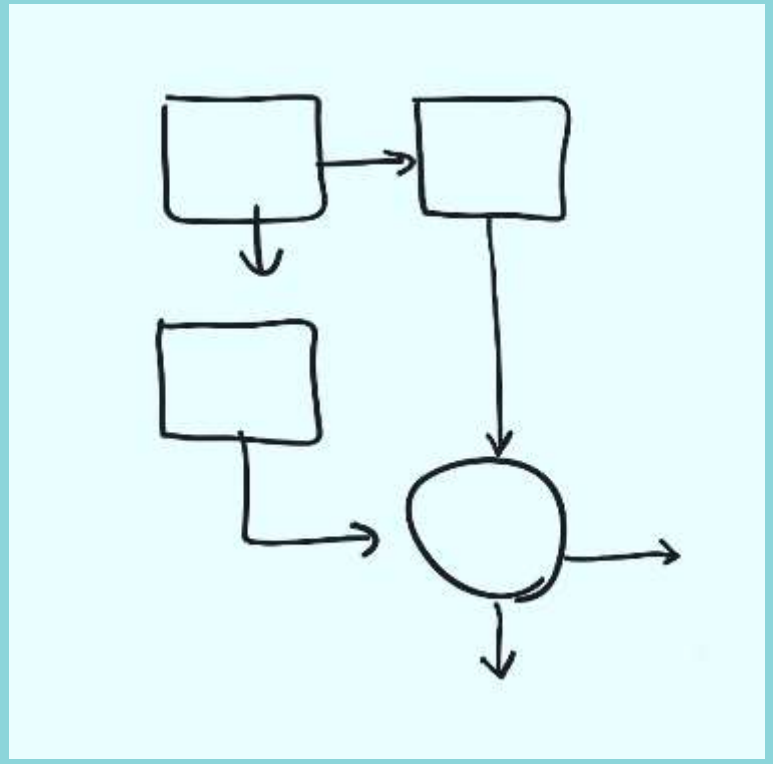


Performance Evaluation

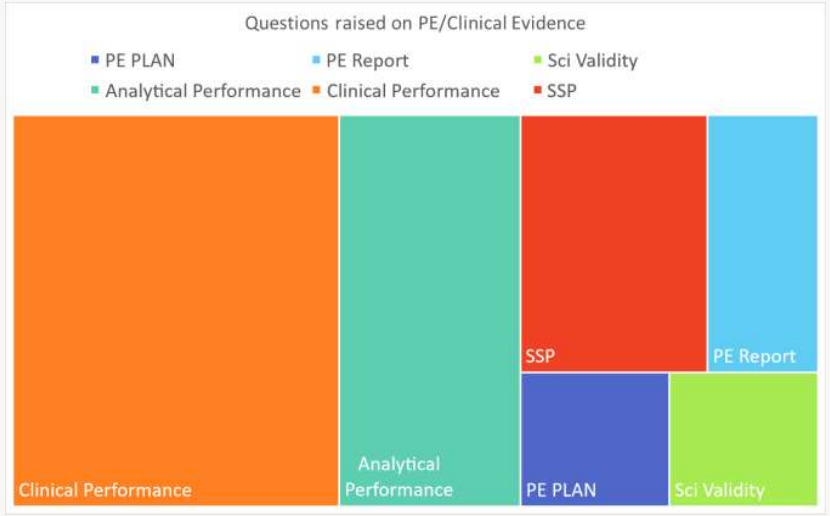
- **Performance Evaluation Plan**
- **Performance Evaluation Report**
  - - Scientific Validity Report
  - - Analytical Performance Report
  - - Clinical Performance Report
  - - & *Conclusion (see An XIII, 1.3.2)*

Performance Evaluation **Plan**

- Reference: **IVDR Annex XIII sec 1.1**

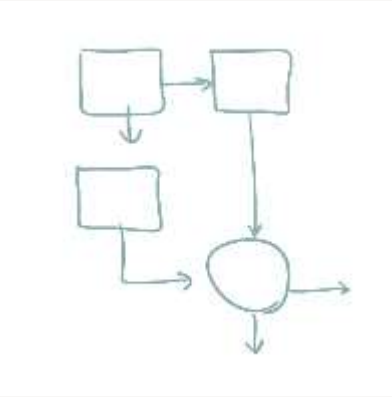


Questions on PE Plan



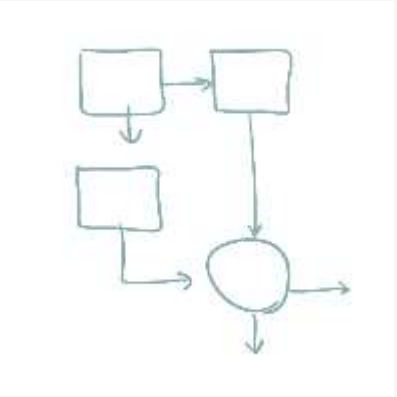
- Majority of questions relate to:
  - Meeting requirements of Annex XIII section 1.1
    - Indent 9: — a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;
    - Indent 10: — an indication and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device;
    - Indent 12: — an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;

Performance Evaluation Plan



- The aim is to outline the strategy to prove the performance **claimed intended purpose**
  - *Poor intended purpose is difficult to prove!*
  - *If state of the art is not defined, then a PE strategy cannot be planned to meet it*
  - *Devices with broad intended purpose still need to meet PE requirements*
    - *E.g. microbiology culture media, Class A sterile specimen receptacles, software, accessories*
    - *Thing carefully about intended purpose then plan a strategy to prove it*

Performance Evaluation Plan



- PE Plan *shall include at least…(13 indents)*

✓Where any of the above mentioned elements are *not deemed appropriate* in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.

➢ Typical BSI questions regarding PE Plan are due to not all of the elements being clear or justified as not applicable.

Our IVDR review experience so far…

- *Should all devices have a Performance Evaluation Plan?*
- *Can a Performance Evaluation Plan cover multiple devices?*

Yes

But:

- The assessor of the technical documentation
  - ✓needs to make a conclusion of conformity for *the device being reviewed*
    - ✓this may be for a product specific certificate;
    - ✓or be a device sampled as part of a group of devices to be certified

- Does the plan make sense for a specific device?
  - Calibrators and controls if sold separately and organised in their own file?
  - Large families of products with similar intended purpose?

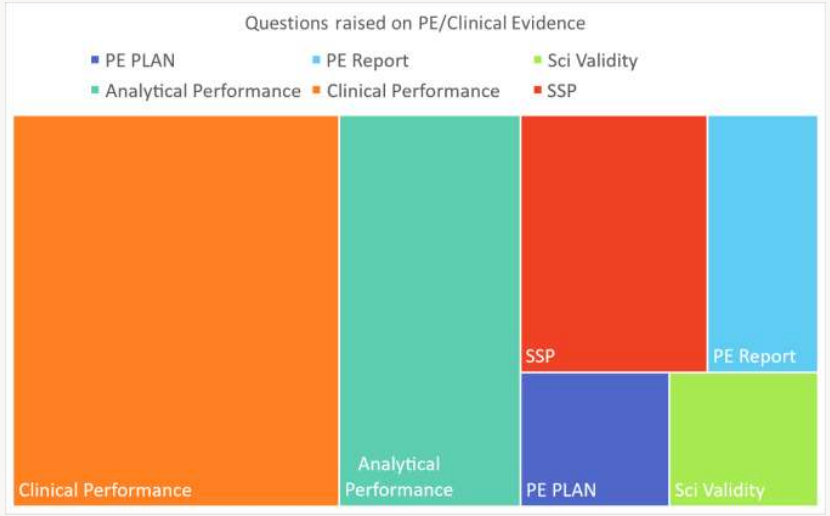
Where a device is 'legacy', *what is the "Plan"?*

- The PE Plan is how you are approaching evaluation of performance today
  - It is not an old study protocol!
- What is the intended use today? (i.e. what claims are you making?)
- What is '*state of the art*' today?
- How are you going to draw upon all performance information available to you today?

Scientific Validity

- Reference: **IVDR Annex XIII sec. 1.2**

Questions on Scientific Validity



- Majority of questions relate to:
  - ❖ Meeting requirements of Annex XIII section 1.2.1
  - ❖ & requirements under Annex XIII section 1.3.2 (PER)
  - ➢ Compliance with Annex XIII in general (documentation provided)
  - ➢ Literature search methodology
    - ➢ Including all aspects of intended use of the device

Scientific validity - consider

- Separation of performance claims from the scientific validity 'claims'
  - Link to Intended Use in the IFU
  - Claims being made in Marketing materials

- Should consider '<u>current</u> state of the art in medicine' *(links to description in the PE Plan!)*

- Should be valid for <u>current European clinical practise</u>

Scientific validity - consider

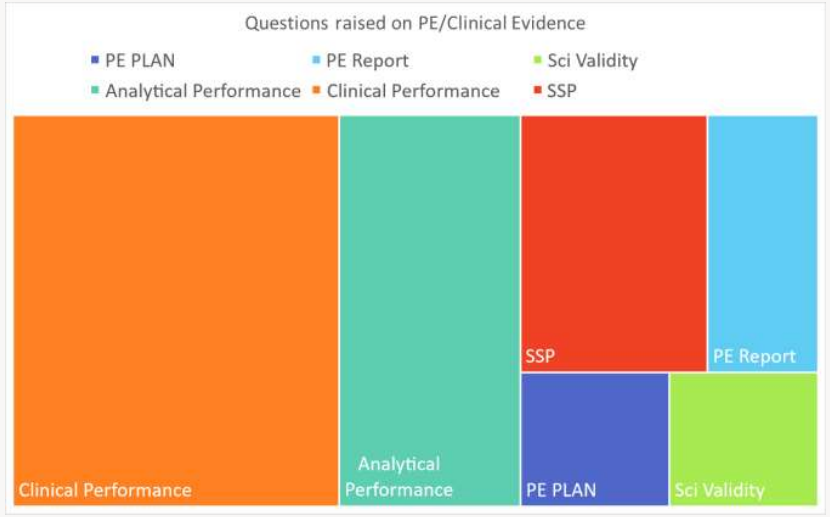
- Annex VII states that the NB shall review the methodology for Literature searching
- The literature review must be 'systematic'

- GHTF guidance available: GHTF/SG5/N7:2012
- No IVDR Performance Evaluation guidance *yet*

Clinical Performance

- Reference: **IVDR Annex XIII sec 1.2.3**

Questions on Clinical Performance



- Majority of questions relate to this part of clinical evidence:
  - ❖ Meeting requirements of Annex XIII section 1.2.3

    - ➢ Clinical performance claims (historic data) match the device under review today
    - ➢ Clinical performance data supporting different use setting (e.g. professional vs NPT)
    - ➢ Justification/s not being provided when certain studies have not been performed
    - ➢ Justification for sample types / study protocol compared to claimed use / IFU; data presented in the IFU not supported
    - ➢ If used, literature search methodology

Clinical Performance Elements

Demonstration of the clinical performance of a device **shall** be based on one or a combination of the following sources:

1. **Clinical performance studies**
2. **Scientific peer-reviewed literature**
3. **Published experience gained by routine diagnostic testing**

➢ **and Other sources of clinical data**

1. Clinical Performance Studies

- Annex XIII Part 2
  - 2.1 Purpose of clinical performance studies
  - 2.2 Ethical considerations
  - 2.3 Methods
    - Study design
    - Clinical Performance Study Plan
    - Clinical Performance Study Report
  - Other performance studies

Reference –
ISO 20916: 2019*

Clinical performance studies **shall** be performed unless due justification is provided for relying on other sources of clinical performance data.

* ISO 20916:2019 - In vitro diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice

1. Clinical Performance Studies

- Regular gap in Technical Documentation reviews at BSI
  - *"Clinical Performance Studies"* do not meet the requirements of Annex XIII 2.3
  - Studies were performed to meet requirements of IVDD **not IVDR**
  - These are '**other sources of clinical data'**

2. Scientific peer-reviewed literature

- The majority of legacy devices reviewed by BSI so far use this as the main pillar of clinical performance
  - Usually supported by IVDD performance data and/or PMS data as a source of "other sources of clinical data" data

- Performance Evaluation Report requirements (Annex XIII 1.3.2) link to this.
- This report **shall** include:
  - the justification for the approach taken to gather the clinical evidence;
  - the literature search methodology and the literature search protocol and literature search report of a literature review; …

3. Published experience gained by routine diagnostic testing

- "Published":
  - Made available to the public and with an identifiable source
- "Routine diagnostic testing":
  - The device being used according to its routine intended purpose on the EU population

➢ Examples

✓Data from proficiency testing or external quality assurance (EQA) schemes

✓Some legacy Class B devices have successfully used EQA / ring trial data

✓Demonstrated accurate measurements have been achieved with the device when used according to its intended purpose over many years

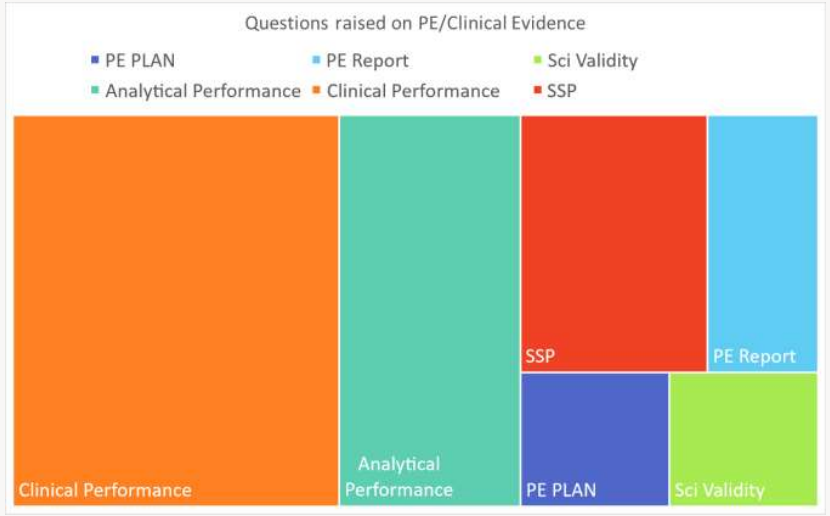
Performance Evaluation Report

- **Reference:** IVDR Annex XIII sec 1.3.2

Performance Evaluation Report

- **Performance Evaluation Plan**
- **Performance Evaluation Report**
  - -Scientific Validity Report
  - - Analytical Performance Report
  - - Clinical Performance Report
  - - & ***Conclusion*** *(see An XIII, 1.3.2)*

Questions on PER



- Questions all relate to:

  - ❖Compliance with Annex XIII section 1.3.2

  - ❖If there have been significant questions on
    - PE Plan
    - Scientific Validity
    - Analytical Performance
    - Clinical Performance
    - PMPF

The PE Report does not make sense

Performance Evaluation Report

- **Performance Evaluation Plan**
- **Performance Evaluation Report**

… linked to:

- **Post Market Performance Follow-up Plan**
  - - Annex XIII part B
  - - **Linked to conclusion of PER**
  - - PMPF evaluation report shall update the PER
  - - If deemed not appropriate, then justification to be given in the PER (An XIII, 8.)
- **Summary of Safety and Performance**

Summary of Safety and Performance (SSP)

- Class C devices (and Class D)
- No guidance issued other than IVDR Article 29
- BSI questions focus on
  - ➢Administration – need to show which version has been *validated by NB*
  - ➢Performance evaluation summary *too brief*
  - ➢Suggested profile and training for users not clear for *near-patient tests*

  MDR guidance for reference ***MDCG 2019-9***

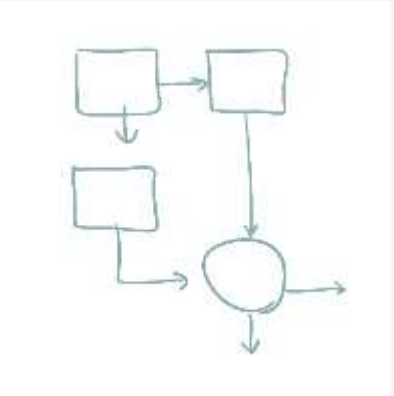
Guidance

- Guidance on Performance Evaluation expected in **Q2 2021** from the MDCG
- Guidance on SSP expected at the same time

- *Therefore, until this is issued, all requirements are still open to interpretation!*

Learning Points…

- Performance evaluation plan
  - All elements shall be included or justified as not applicable
  - Strategy for Performance Evaluation should be planned, even for legacy devices
  - Strategy for demonstrating PE for device families / calibrators / controls / accessories is key



- The stated Intended use/purpose is critical for setting the clinical evidence required
  - **Scientific Validity** should link to the clear claim/s being made today

Learning Points…

- Clinical Performance may be from multiple sources
  - ➢ Must be from at least one of 3 elements listed in Annex XIII

- 'Clinical Performance Studies' must meet requirements of XIII 2.3

- Link to the plan for Post-Market Performance Follow-up
  - Further studies may be needed if there are residual risks not addressed by the clinical evidence provided

Next: NB Updates & Conclusions

Agenda – **Our lessons learned**

- Introduction & achieving certification
- QMS audits
- Technical Documentation assessments

--- 10 min break ---

- Performance Evaluation & Clinical Evidence
- NB updates & conclusions
- Panel Q&A

NB Updates & conclusions

Dr Erica Conway
Global Head – IVD Medical Devices

12 May 2021

By Royal Charter

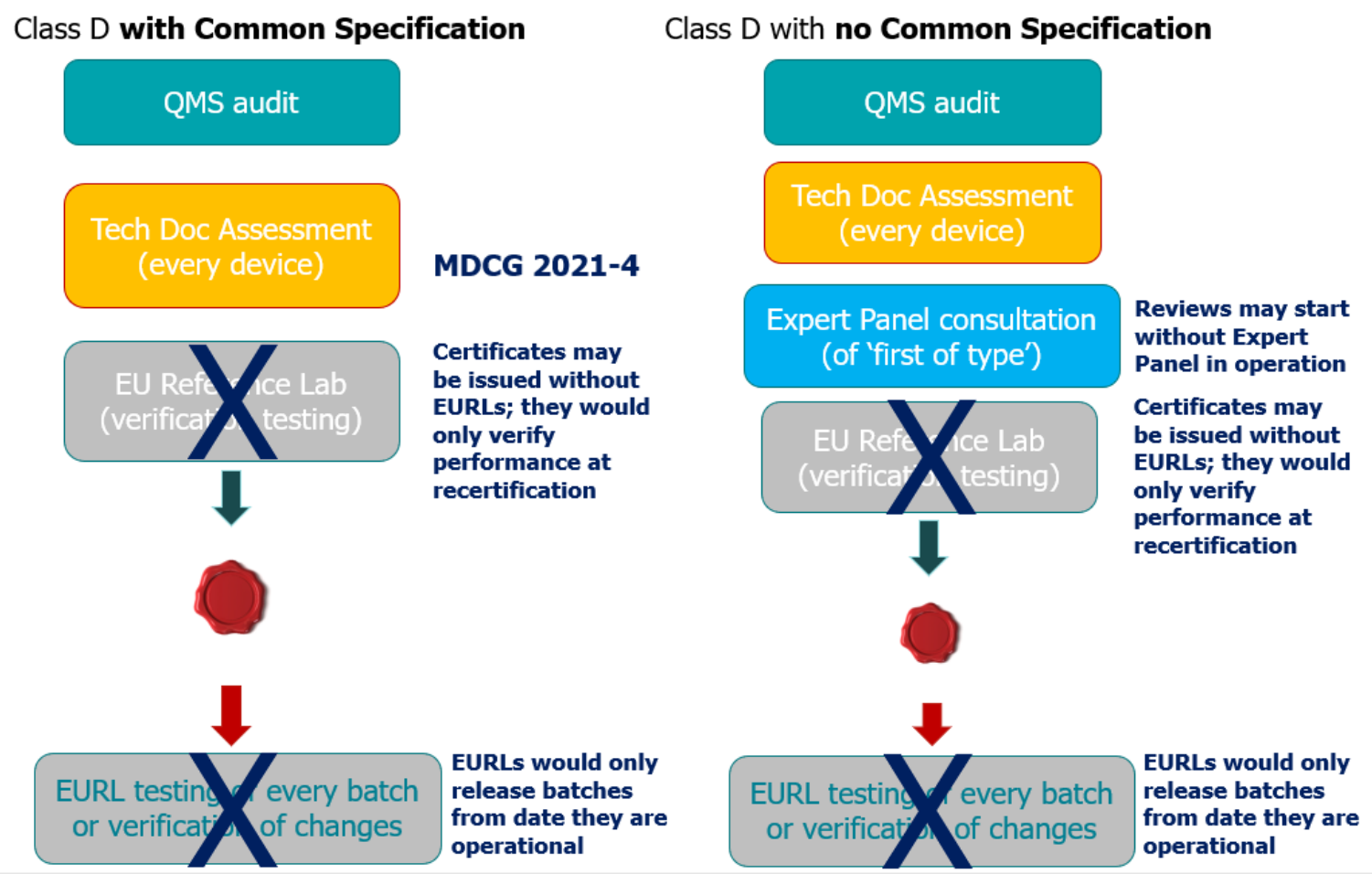
bsi.

NB Updates

- Common Specifications expected Q2 2021 (adoption first round)
  - CS on the basis of the amended Decision 2002/364/EC + Chagas/syphilis, Kidd/Duffy and CMV/EBV, and possibly COVID-19
- MDCG Guidance expected in:
  - Performance Evaluation for IVDs
  - Guidance on interpretation of IVD notified body codes
  - Summary of Safety & Performance template (transposition of SSCP template)
- Consultation on-going: EMDN codes; work associated with EURLs
- NB and EMA working group on CDx – submission pilots underway
- Mirror MDCG IVD WGs formed on:
  - Class B & C devices additions or modifications post certification to the sampling plan
  - Develop a common position on significant changes for IVDs
  - Draft Common Specifications for stage 3 Common Specifications (mid 2022)

NB Updates

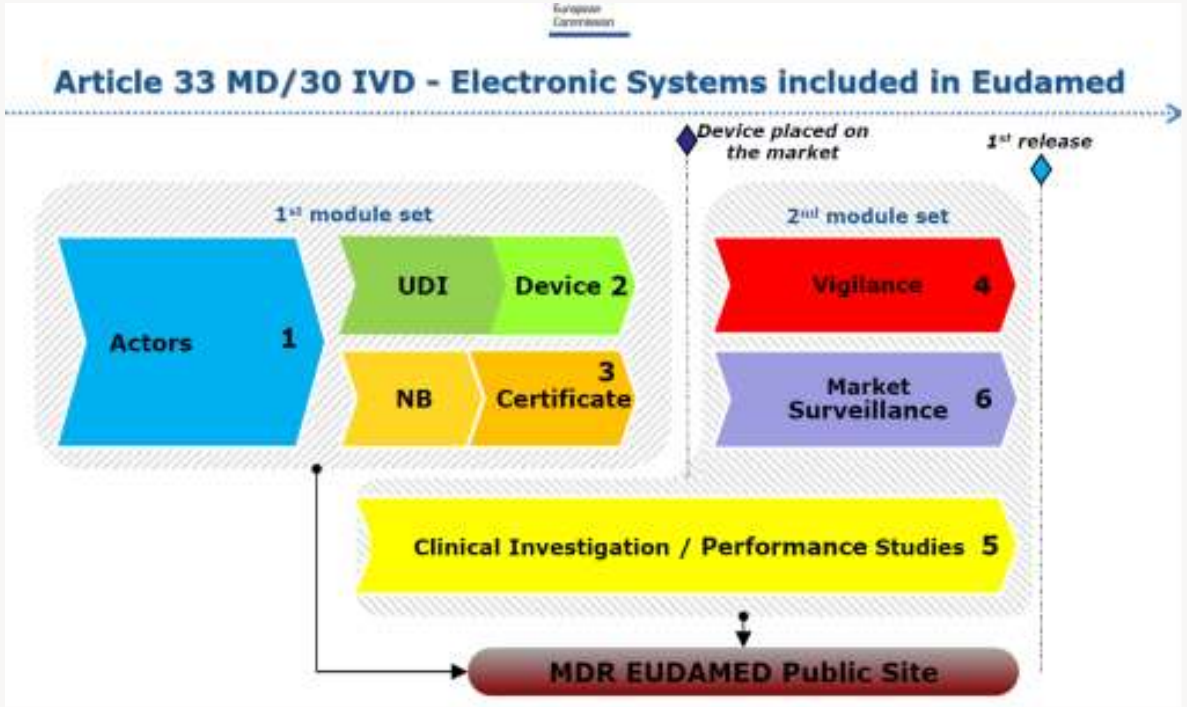
- MDCG 2021-04
  - Commission guidance on Class Ds
  - Team NB and IVD NB Working group – draft position paper



- Impact on conformity assessment process and risk being assessed by NBs

NB Updates

- **Eudamed** *playground*
- Providing insights to future certificate and documentation upload
  - ➢ It will be impossible for NBs to register their certificates without MFRs registered their operators (Actors module) and devices (Devices module)
  - ➢ Manufacturers outside EU can not register themselves until their EU AR is registered
  - ➢ Both manufacturers and EU ARs need PRRC identified in EUDAMED
  - ➢ Devices all need Basic UDI-DI regardless of classification
  - ➢ Annex IX Chapter II have Basic UDI-DI on certificate. All other devices, Basic UDI-DI is one way of associating certificates with devices
  - ➢ Impact on SSPs & IFUs
    - ➢ SSPs need a 'reference ID' and version control
    - ➢ Final IFU needed
      - ➢ Other languages will be uploaded when Eudamed operational

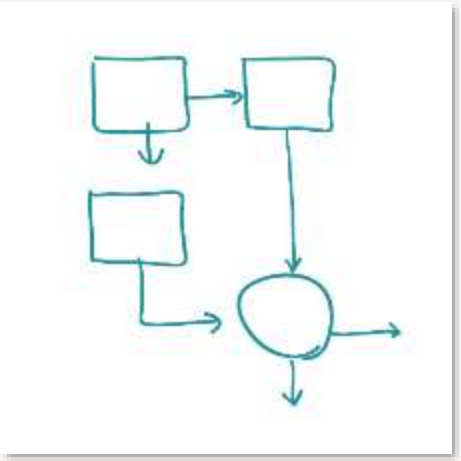


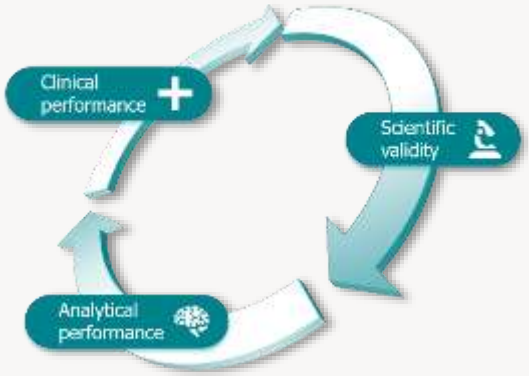
https://ec.europa.eu/tools/eudamed/#/screen/home

Conclusions…

…"*Are you ready?*"

- Making an Application
  - QMS readiness
  - Technical Documentation
  - Inc Performance Evaluation & clinical evidence
- Getting over the line….

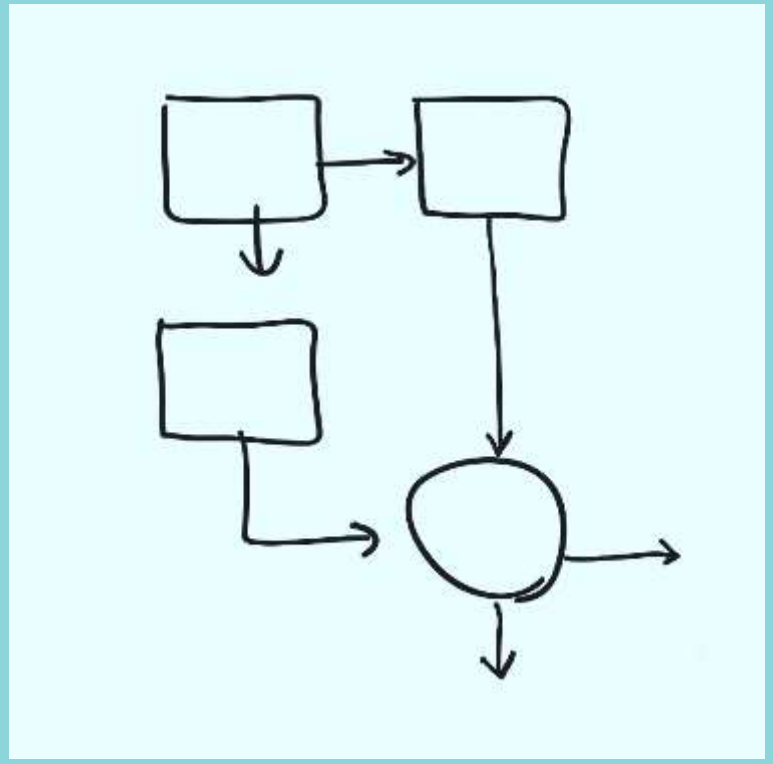




Making an Application…

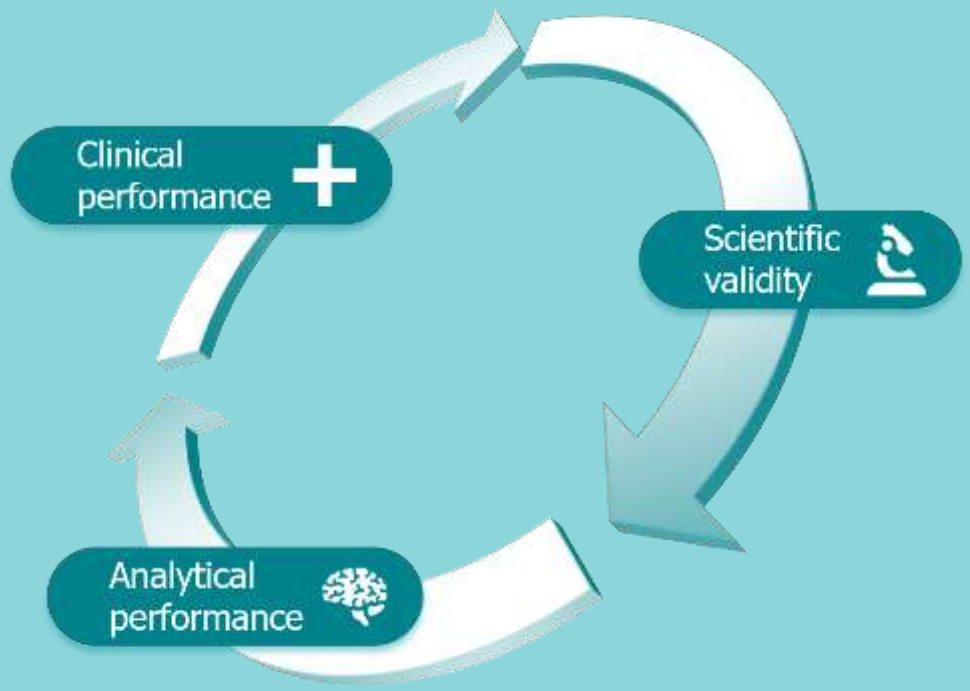
- Application information provided for your devices & QMS
  - Scope for QMS audit
  - Provisional transition timings
- Intended Uses
- Classification, Codes
- & Basic-UDI-DI
  - Eudamed

Lessons Learned – QMS Audits



Lessons Learned – Technical Documentation

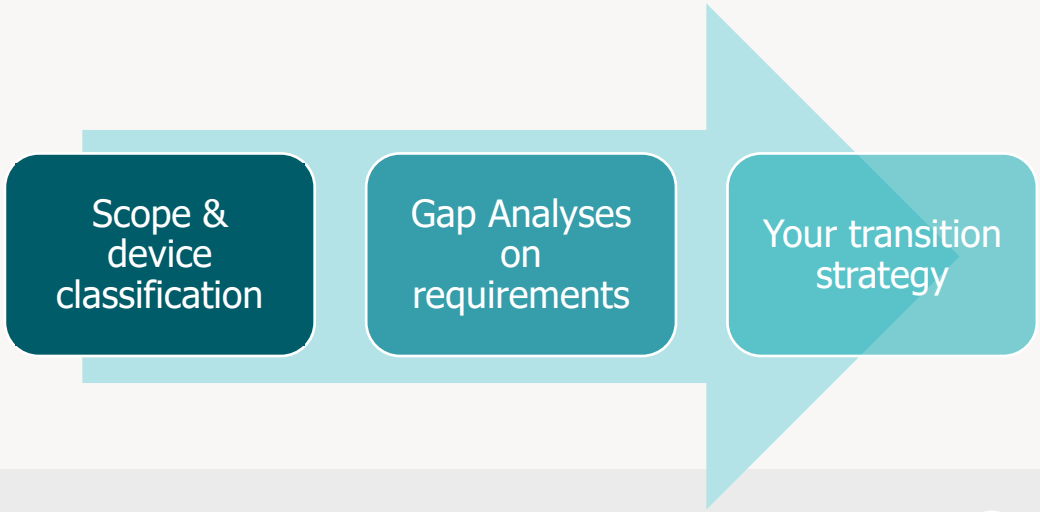
Lessons Learned – Performance Evaluation & clinical evidence



Getting over the line…

Make your application/s as soon as possible!

- Time until 26 May 2022 is running out!
  - For self-declared (IVDD) devices, certification is needed by this date
  - You need to allow time for the QMS Audit/s and Technical documentation review/s
    - ➢ At least 7, 8, 9.. 12 months or longer?
    - ❖ Timelines will extend as NBs get busier!
- Please, do not delay!



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