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Sitem MDR Support Panel Tech Doc reviewability

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Question: what is N°1 / N°2 / N°3 ?

N°1: Trad. 510(k) ToC

(1) Medical Device User Fee Cover Sheet (Form FDA 3601)

(2) Center for Devices and Radiological Health (CDRH) Premarket Review Submission Cover Sheet (Form FDA 3514)

(3) 510(k) Cover Letter

(4) Indications for Use Statement (Form FDA 3881)

(5) 510(k) Summary or 510(k) Statement

(6) Truthful and Accuracy Statement

(7) Class III Summary and Certification

(8) Financial Certification or Disclosure Statement

(9) Declarations of Conformity and Summary Reports

(10) Device Description

(11) Executive Summary/Predicate Comparison

(12) Substantial Equivalence Discussion

(13) Proposed Labeling

(14) Sterilization and Shelf Life

(15) Biocompatibility

(16) Software

(17) Electromagnetic Compatibility and Electrical Safety

(18) Performance Testing – Bench

(19) Performance Testing – Animal

(20) Performance Testing – Clinical

N°2: MDR ToC

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

1.2. Reference to previous and similar generations of the device

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

3. DESIGN AND MANUFACTURING INFORMATION

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

6. PRODUCT VERIFICATION AND VALIDATION

6.1. Pre-clinical and clinical data

6.2. Additional information required in specific cases

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7. The post-market surveillance plan drawn up in accordance with Article 84.

8. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85

N°3: IMDRF ToC

CHAPTER 1 – REGIONAL ADMINISTRATIVE	
1.01	Cover Letter
1.02	Submission Table of Contents
1.03	List of Terms/Acronyms
1.04	Application Form/Administrative Information
1.05	Listing of Device(s)
1.06	Quality Management System, Full Quality System of Other Regulatory Certificates
1.07	Free Sale Certificate/ Certificate of Marketing authorization
1.08	Expedited Review Documentation
1.09	User Fees
1.10	Pre-Submission Correspondence and Previous Regulator Interactions
1.11	Acceptance for Review Checklist
1.12	Statements/Certifications/Declarations of Conformity
1.12.01	Performance and Voluntary Standard
1.12.02	Environmental Assessment
1.12.03	Clinical Trial Certifications
1.12.04	Indications for Use Statement with Rx and/or OTC designation Enclosure
1.12.05	Truthful and Accurate Statement
1.12.06	USFDA Class III Summary and Certification
1.12.07	Declaration of Conformity
1.13	Letters of Reference for Master Files
1.14	Letter of Authorization
1.15	Other Regional Administrative Information
CHAPTER 2 – SUBMISSION CONTEXT	
2.01	Chapter Table of Contents
2.02	General Summary of Submission
2.03	Summary and Certifications for Premarket Submissions
2.04	Device Description
2.04.01	Comprehensive Device Description and Principle of Operation
2.04.02	Description of Device Packaging
2.04.03	History of Development
2.04.04	Reference and Comparison to Similar and/or Previous Generations of the Device
2.04.05	Substantial Equivalence Discussion
2.05	Indications for Use and/or Intended Use and Contraindications
2.05.01	Intended Use; Intended Purpose; Intended User; Indications for Use
2.05.02	Intended Environment/Setting for use
2.05.03	Pediatric Use
2.05.04	Contraindications For Use
2.06	Global Market History
2.06.01	Global Market History
2.06.02	Global Incident Reports and Recalls
2.06.03	Sales, Incident and Recall Rates
2.06.04	Evaluation/Inspection Reports
2.07	Other Submission Context Information
CHAPTER 3 – NON-CLINICAL EVIDENCE	
3.01	Chapter Table of Contents
3.02	Risk Management
3.03	Essential Principles (EP) Checklist
3.04	Standards
3.04.01	List of Standards
3.04.02	Declaration and/or Certification of Conformity
3.05	Non-clinical Studies

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Do you really want to be creative when submitting a 510(k) to the FDA ?

Why do you then try to be creative with the tech.doc you submit to NB?

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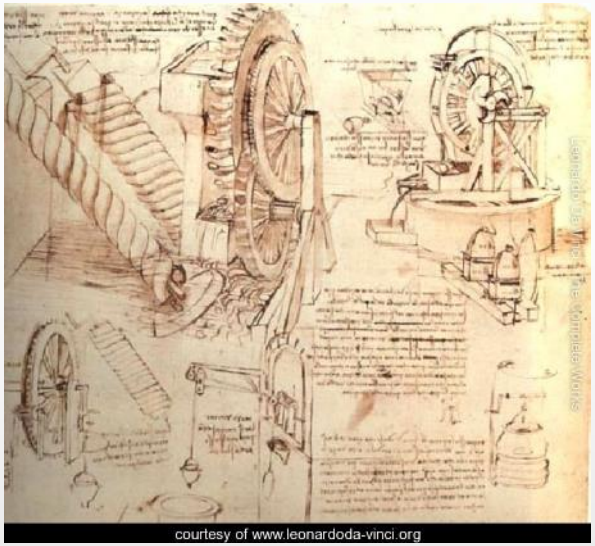
Conformity assessment – basics – general principles



Technical Documentation :
contains evidence for fulfilling GSPR = evidence for conformity & state of the art

level of scrutiny & sampling rate

Low risk **High risk**

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GSPR (ER) – Risk Management – V&V – clinical evaluation -> technical documentation

GSPR

GENERAL REQUIREMENTS

REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

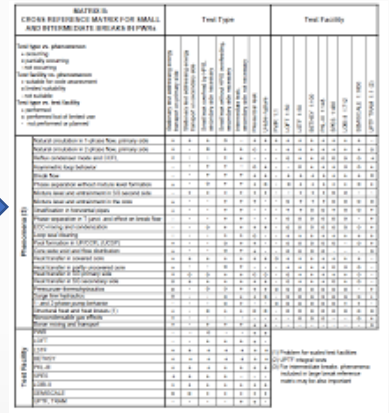
REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

?!

Risk Management

Impact of Risk (Consequence)		Probability of Risk (Likelihood)		
		Unlikely (0-33%)	Moderately Likely (33%-66%)	Highly Likely (66%-100%)
Major		Medium	High	Extreme
Moderate		Medium	Medium	High
Minor		Low	Medium	Medium
Seriousness of Risk = Probability x Impact				

?!



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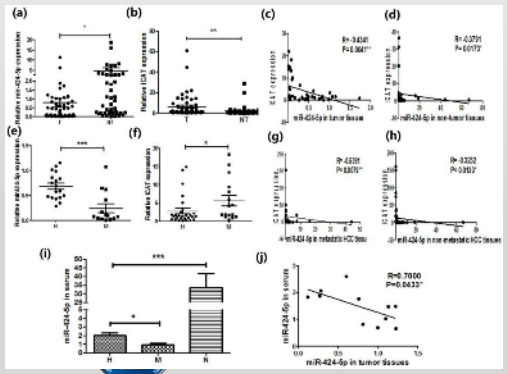

Post Market Surveillance + PMCF

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General Safety and Performance Requirements (GSPR)

Example (Regulations MDR* / IVDR)

Requirement	Description	Applicable (yes/no)	Applied Standards (Annex Z)	Fulfilment of the requirements
	CHAPTER I. General Requirements			
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Yes	EN ISO 14971 EN ISO 14155 ISO 14708-1 ISO 14708-3 EN 60601-1 EN 60601-1-2 EN 62304 EN ISO 13485	Hazard Analysis Report Risk Management Report System Verification Report Clinical Evaluation Report EN 60601-1 Test Report EN 60601-1-2 Test Report
2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.	Yes	EN ISO 14971	Risk Management Report
…	…			
11.3 ….	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	Yes	EN 556-1 EN ISO 11607-1 EN ISO 11607-2	Product label design Sterilisation validation plan Sterilisation validation report
23.4	Information in the instructions for use.	Yes	EN 15223-1 EN 1041:2008	IFU

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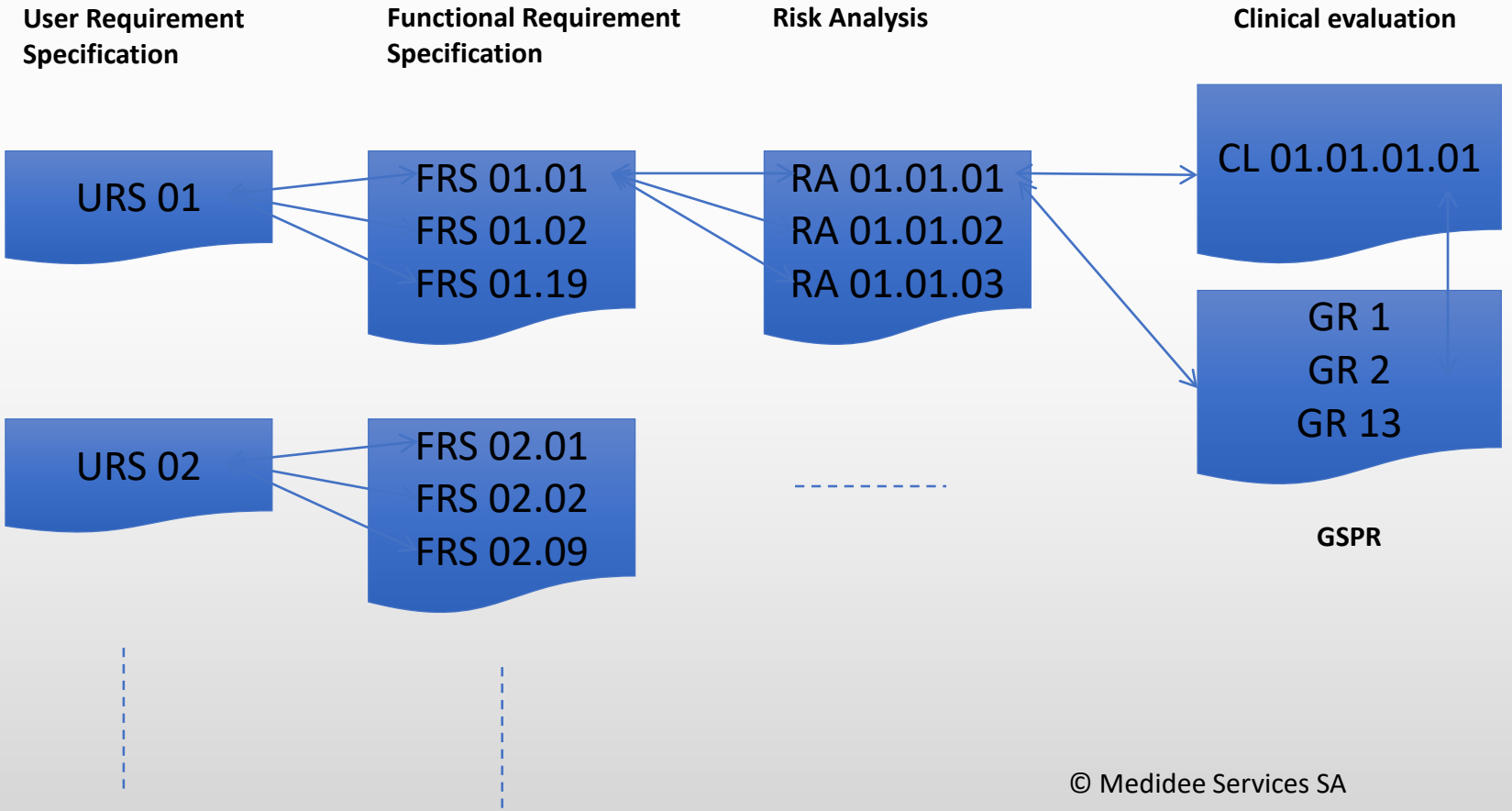
Process & logical links - CE technical documentation



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- 010_Audit Report
- 011
- 012
- 013
- 014
- 015_Product Workflow_Class 100000
- 016_Product Workflow_Class 10000
- 017
- 018
- 019

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Some examples of NB questions related to technical documentation

The “grand classic”: Information xyz could not be located in the documentation submitted.

The “it’s your job to match it”: The MFG claims conformity to ISO xyz:2016. The referenced test reports demonstrate conformity with ISO xyz:2007. No rationale is given why and how the results obtained may be leveraged to fulfil the requirements of the 2016 version of the standard.

The “naïve 1”: There could no substantiation be located in the submitted documentation for the sample size chosen for validation of xyz.

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Some examples of NB questions related to technical documentation

The “Chinese connection”: Test report xyz referenced in section xyz of the GSPR does not relate to the device submitted.

The “naïve 2”: The biological risk assessment and supportive reports cover the raw material but not the final medical device.

The “clinical evaluation classic”: The indications do not exclude patients younger than x years – no clinical data is present substantiating safety and performance in patients younger than x.

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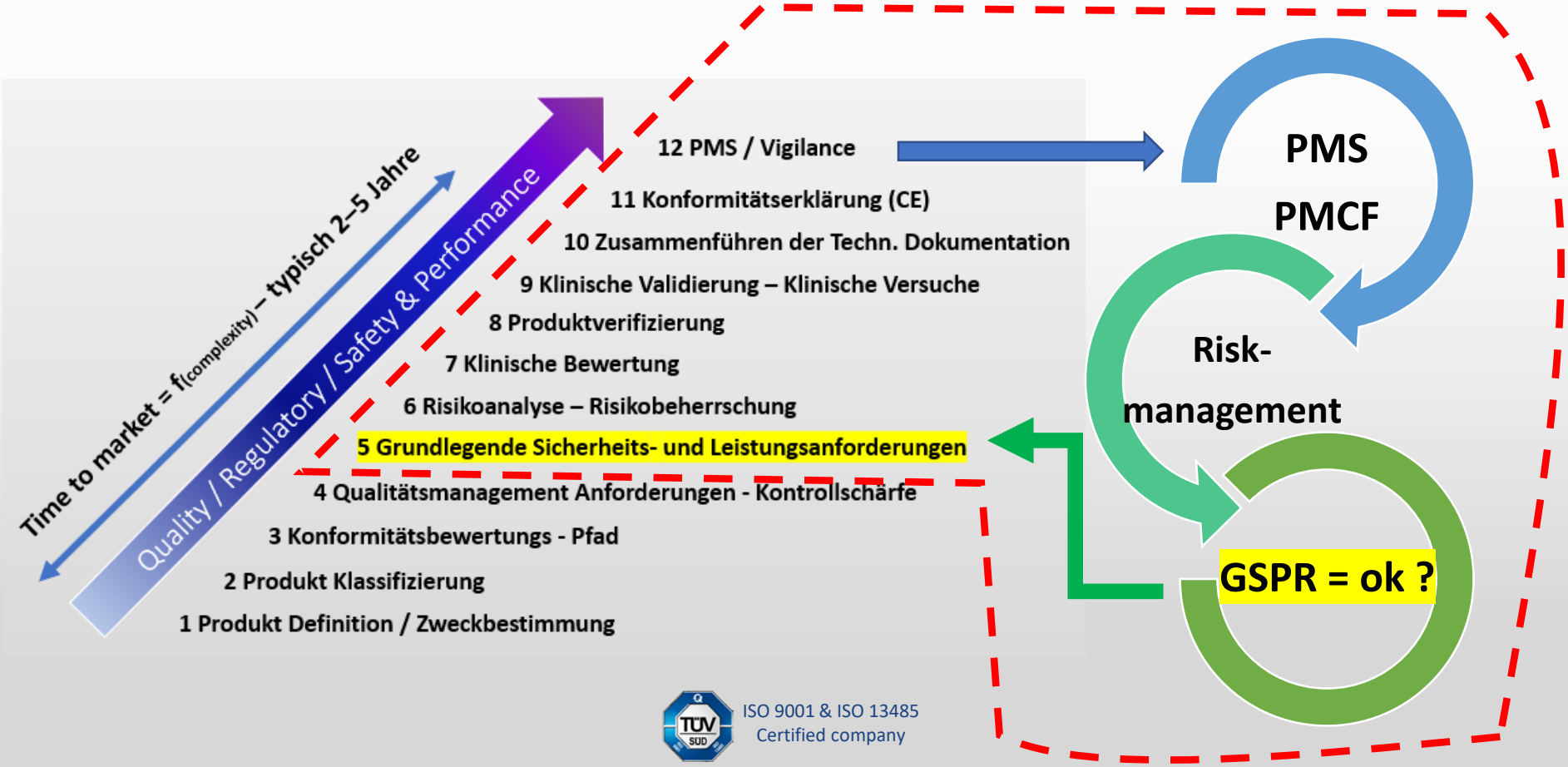
Conformity assessment

–> continuous process – you will have to update



ISO 9001 & ISO 13485
Certified company

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Summary: Ensure Reviewability of tech.doc

- **Put yourself in the position of the reviewers and take into account the review process at your NB !**
- **Indicate clearly where to find the evidence (not “Risk Management Report” but “RM Report, section 3.2 – page 8)**
- **Ensure traceability between Specs, Risk Analysis, CER, GSPR -> the V&V matrix is key**
- **Use hyperlinks, make native searchable pdf, use consistent wording**
- **Make meaningful summaries for each section – with links to the further evidence**
- **Provide Tech.Doc structure according Annex II and III if EU only (check first with NB if you want to use IMDRF ToC)**

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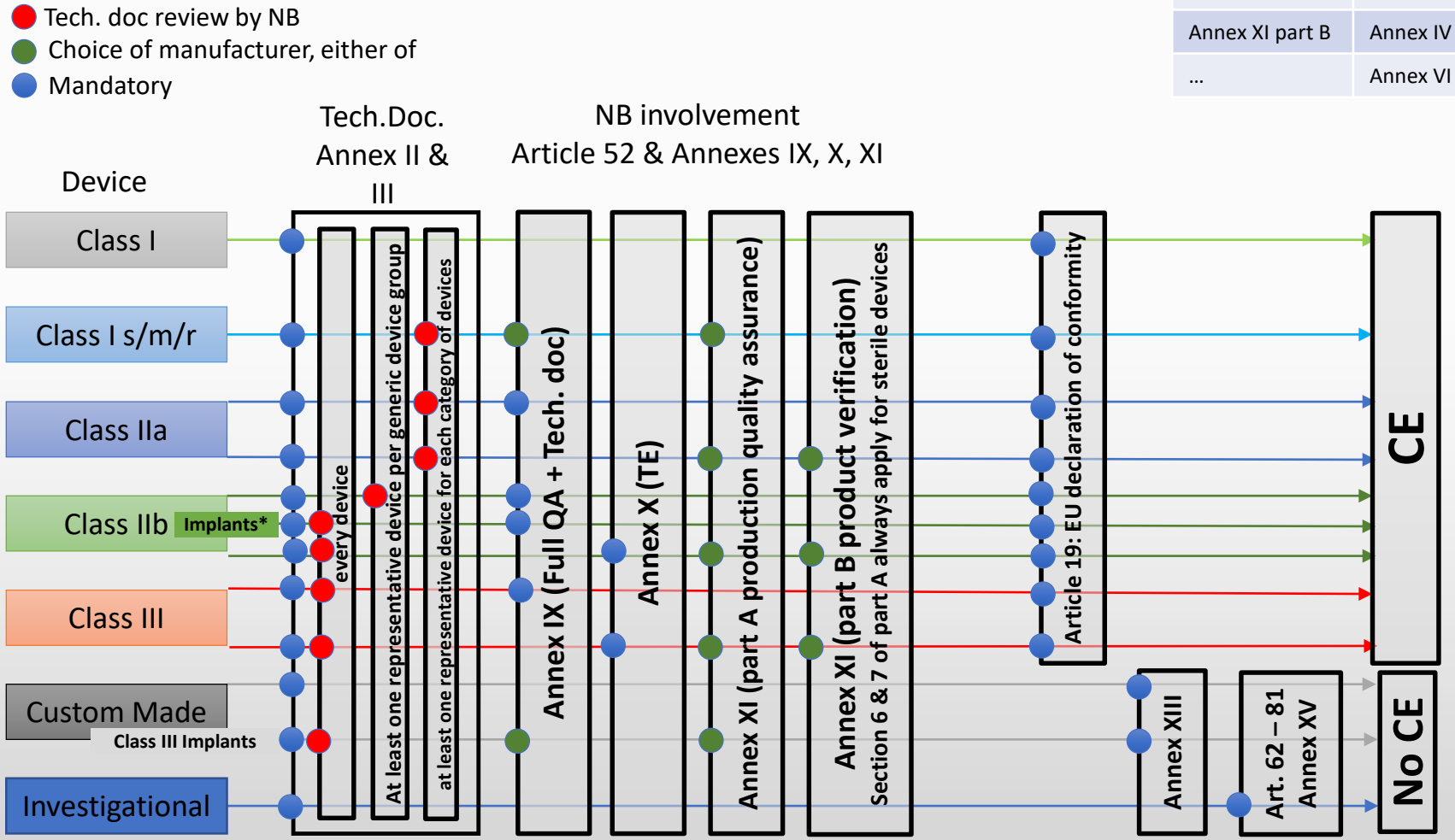
Tech Doc Requirements & NB review

MDR	MDD
Annex IX	Annex II
Annex X	Annex III
Annex II	Annex VII
Annex XI Part A	Annex V
Annex XI part B	Annex IV
…	Annex VI



*except: except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

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Guidance Technical Documentation MDR

https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/downloads/

Technical Documentation and Medical Device Regulation

A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745

Dr Julianne Bobela, Project Associate; Dr Benjamin Frisch, Senior Associate; Kim Rochat, Senior Partner; and Michael Maier, Senior Partner; all at Medidee Services SA

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Guidance

https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

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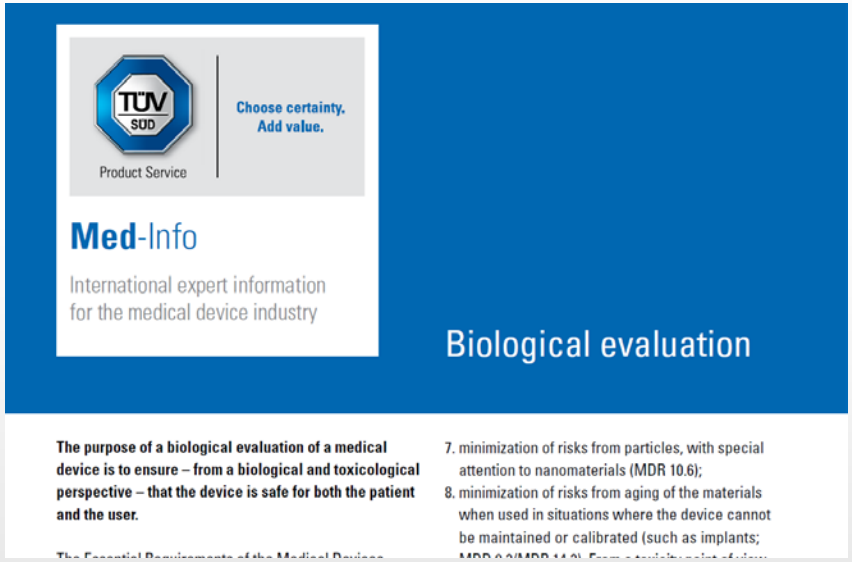
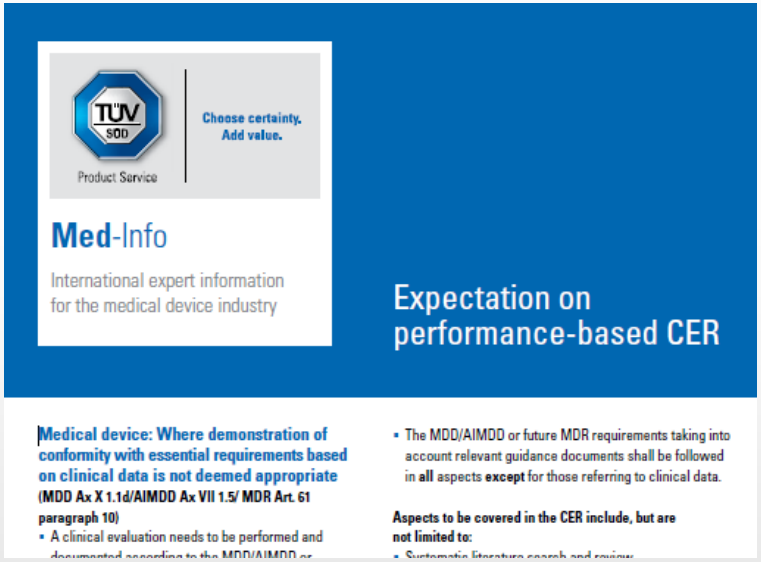
Guidance





https://www.tuv-sud.com/industries/medical-devices-healthcare/med-info-download-center#tab_1397654997088748131160

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Guidance

IMDRF/RPS WG/N9(Edition 3) FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-nivd-dma-toc-n9.pdf

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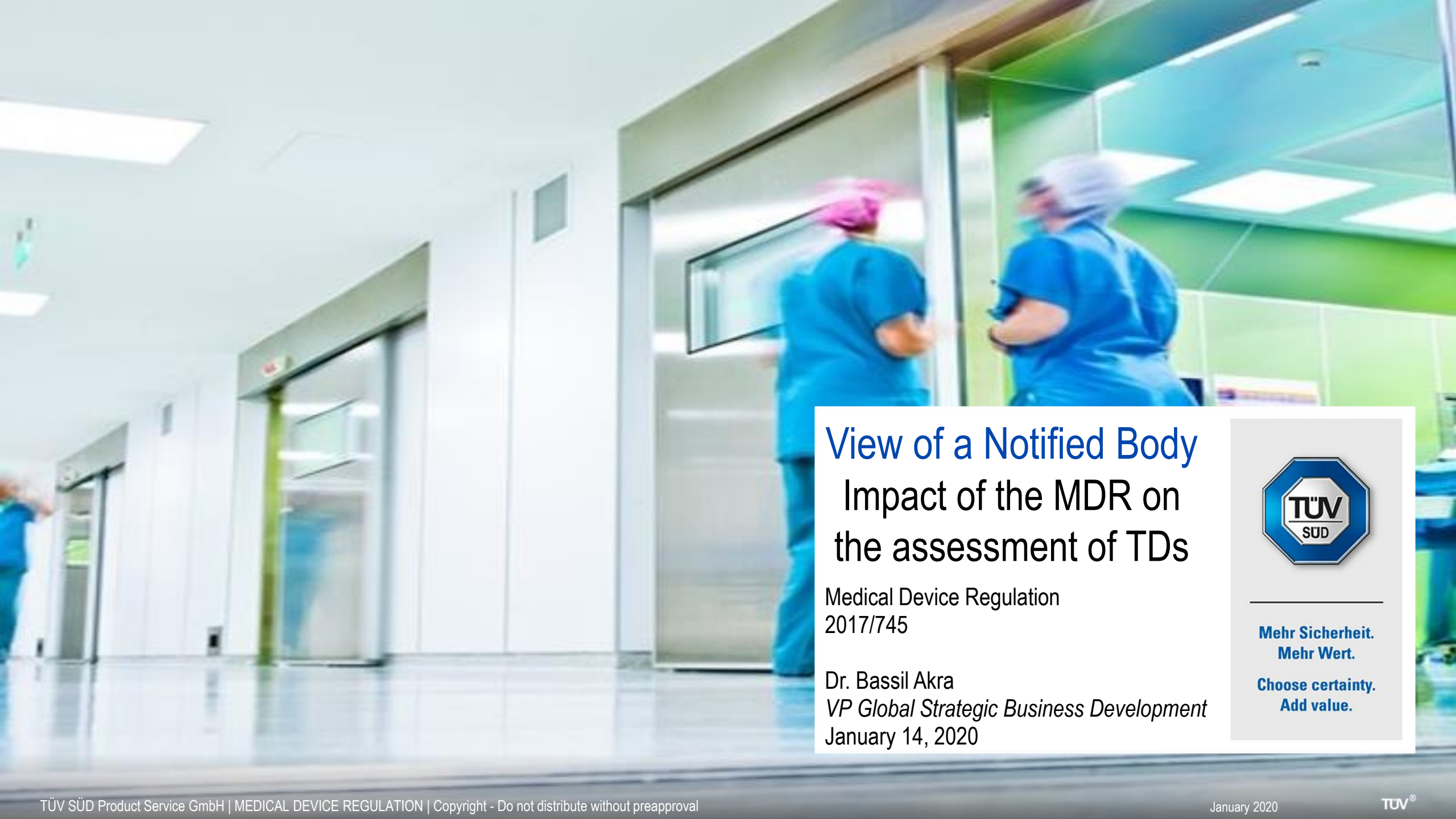
Thank you for your attention!



View of a Notified Body

Impact of the MDR on the assessment of TDs

Medical Device Regulation
2017/745

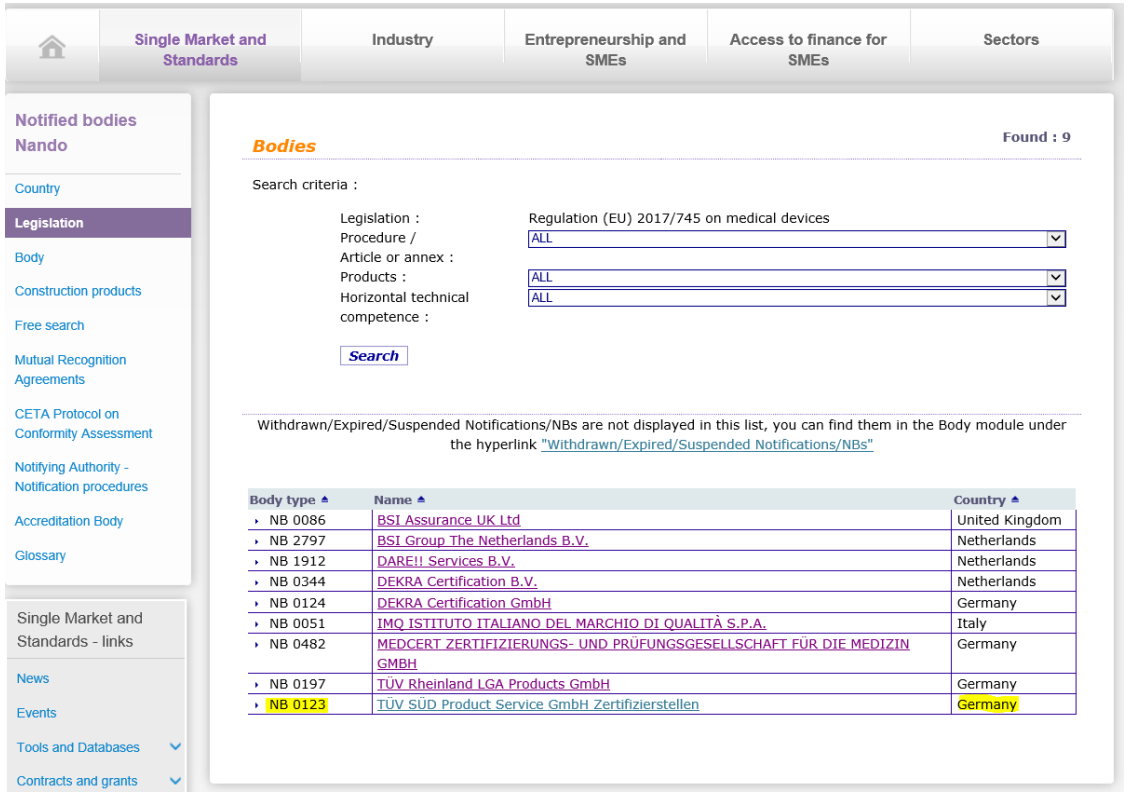
Dr. Bassil Akra
VP Global Strategic Business Development
January 14, 2020

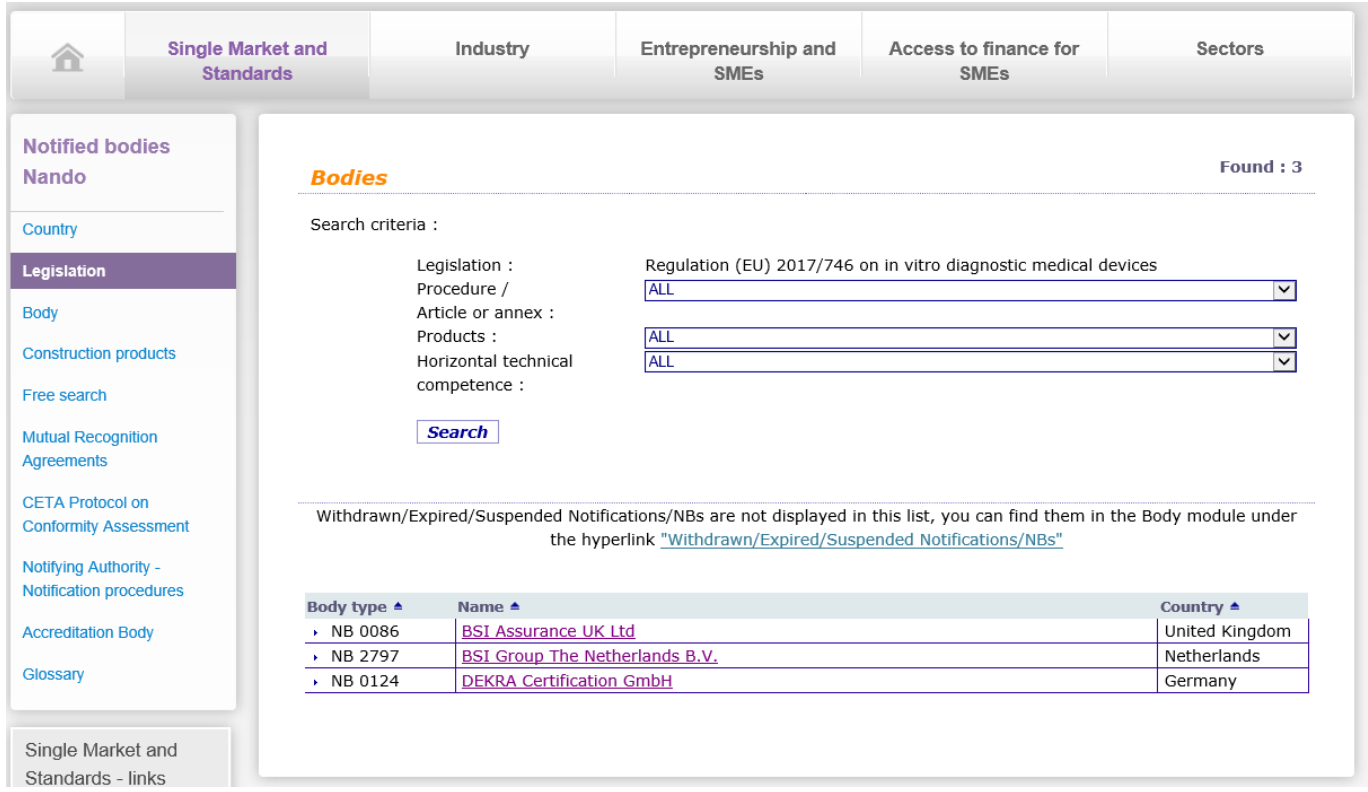
Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.

NANDO

http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34





Common understanding documents “Guidance Documents”

Current Status

Various Task Forces of the EU Commission are working on:

- Guidance on sampling of medical devices – **Published**
- Explanatory note on MDR codes – **Published**
- Guidance and templates for PSURs
- Guidance and template for SSCPs – **Published**
- Guidance on classification of Software as a Medical Device – **Published**
- Guidance and templates for PMCFs
- Guidance for sufficient clinical data
- Guidance for equivalence approach – Gap Document to MEDDEV 2.7.1 Rev. 4
- Common specifications, Clinical Evaluation Guidance for Software, etc.
- Implementing act for reprocessing single use medical devices

32 documents endorsed as of December 2019

- 9 documents on UDI
- 2 documents on EUDAMED
- 16 documents on Notified Bodies
- 1 document on Clinical investigation and evaluation
- 2 documents on new technologies
- 4 documents on other topics

Scheer guidelines

MDR – Article 120 Transitional Provisions

Article 120

Transitional provisions

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

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

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which 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.

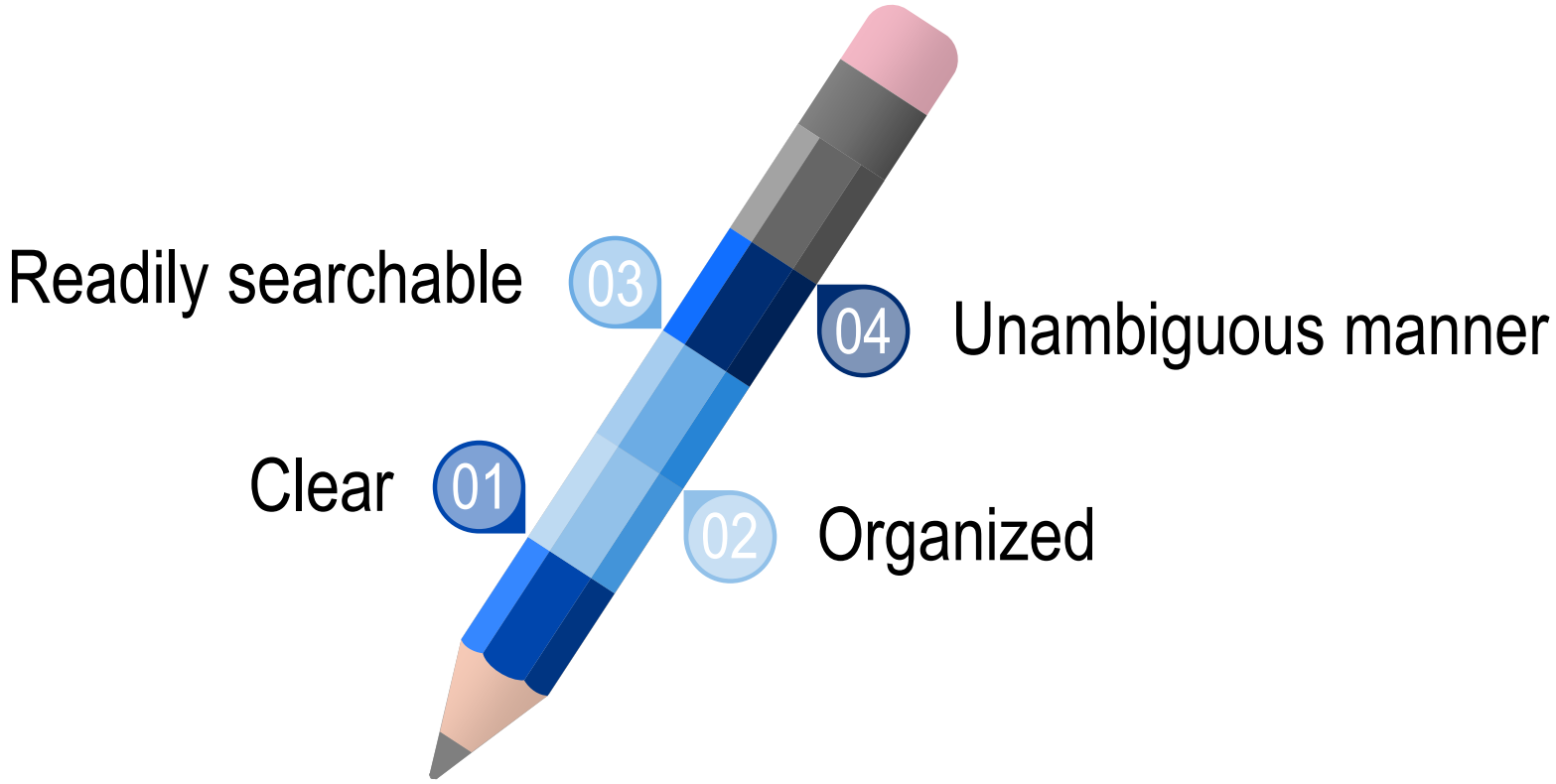
Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article may continue to be made available on the market or put into service until 27 May 2025.

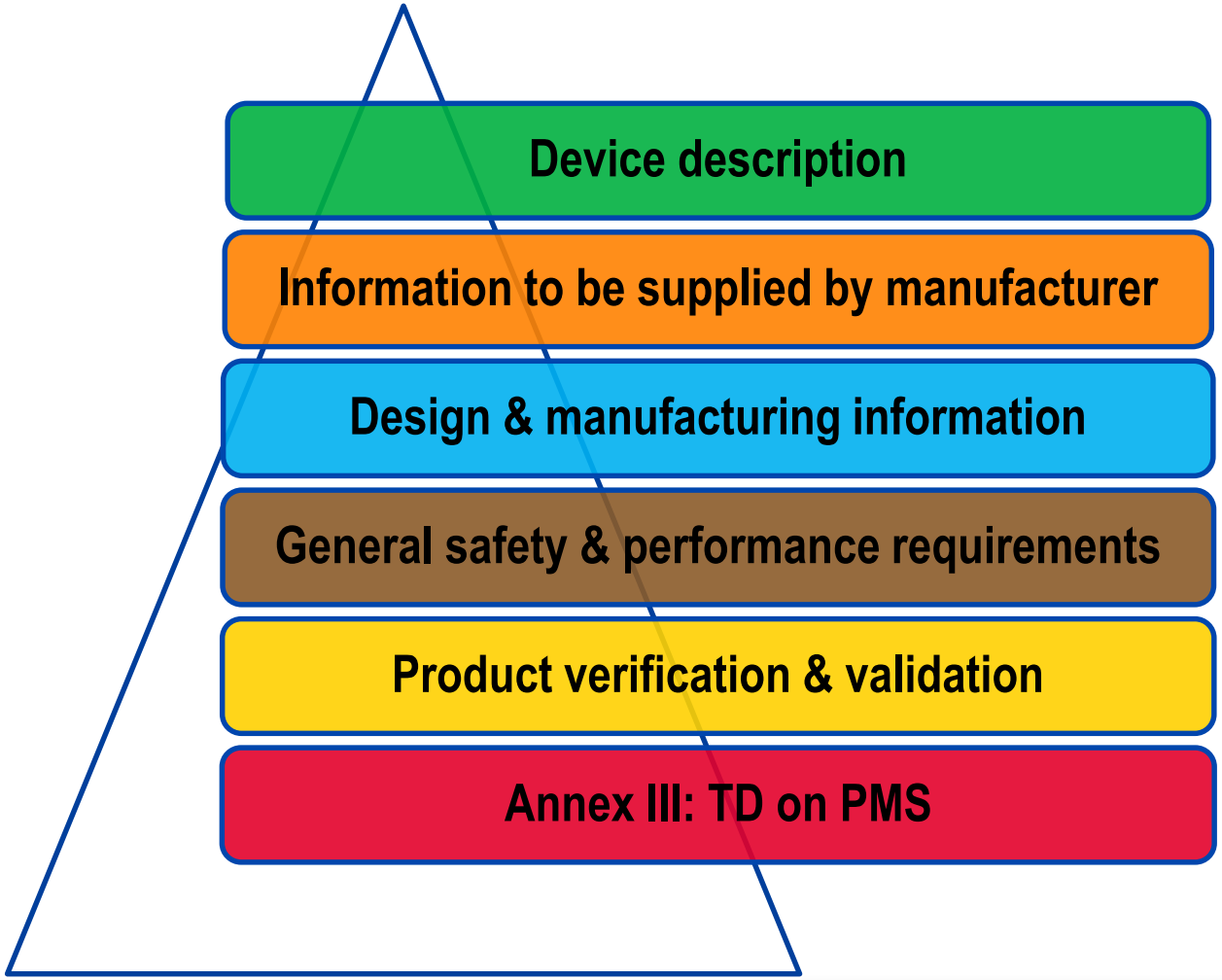
5. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.

Technical documentation (TD) shall be presented in a…



TD Requirements: What does it include?



General requirements: Clauses 1-9

SPR 1: Performance & safety

SPR 2: Reduction of risks

SPR 3: Risk management system

SPR 4: Risk control measures & residual risks

SPR 5: Risks related to use

SPR 6: Device lifetime

SPR 7: Packaging, transport, storage

SPR 8: Risk-benefit ratio

SPR 9: Devices w/o medical purpose

Requirements regarding design & manufacture: Clauses 10-22

SPR 10: Chemical, physical & biological properties

SPR 11: Infection & microbial contamination

SPR 12: Devices incorporating a medicinal product; substances absorbed or locally dispersed

SPR 13: Devices incorporating materials of biological origin

SPR 14: Construction of devices & interaction with their environment

SPR 15: Devices with a diagnostic or measuring function

SPR 16: Protection against radiation

SPR 17: Electronic programmable systems & software

SPR 18: Active devices & devices connected to them

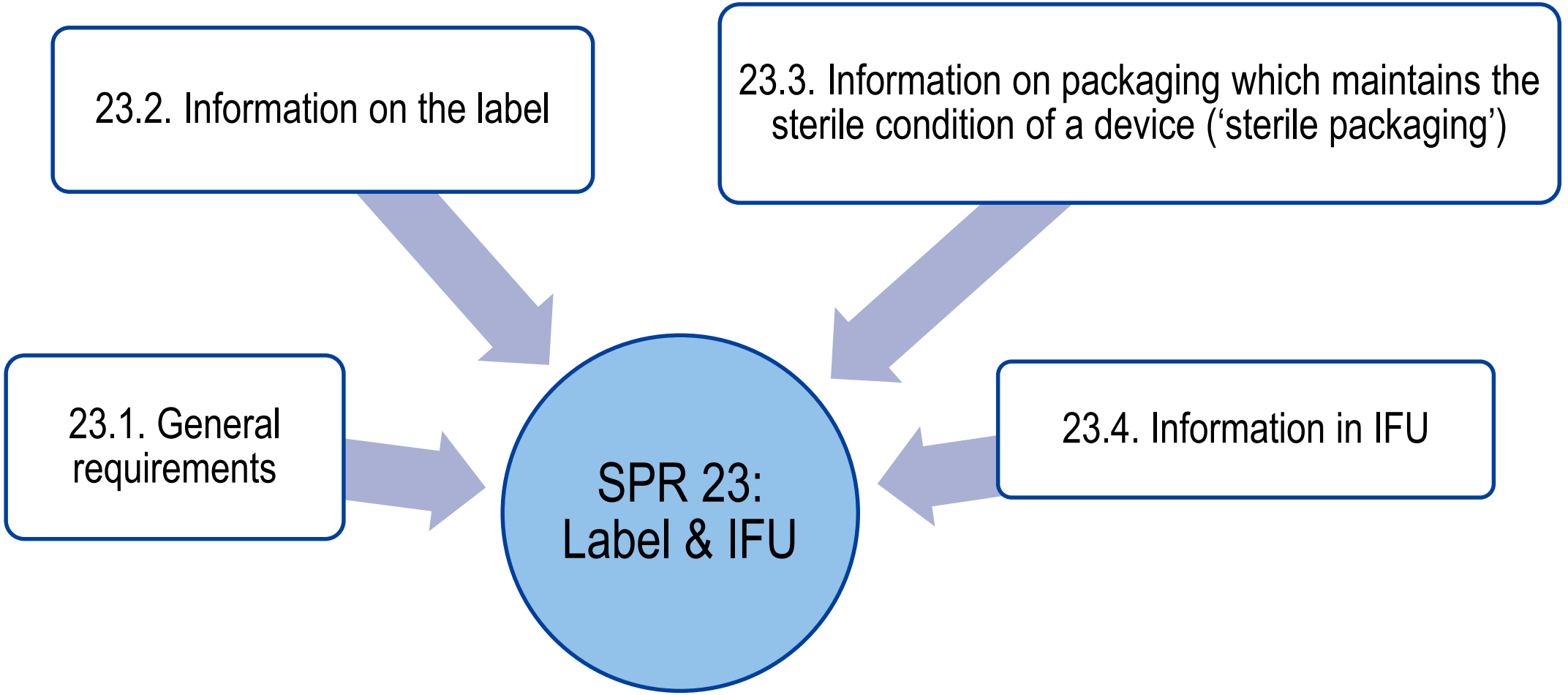
SPR 19: Particular requirements for active implantable devices

SPR 20: Protection against mechanical & thermal risks

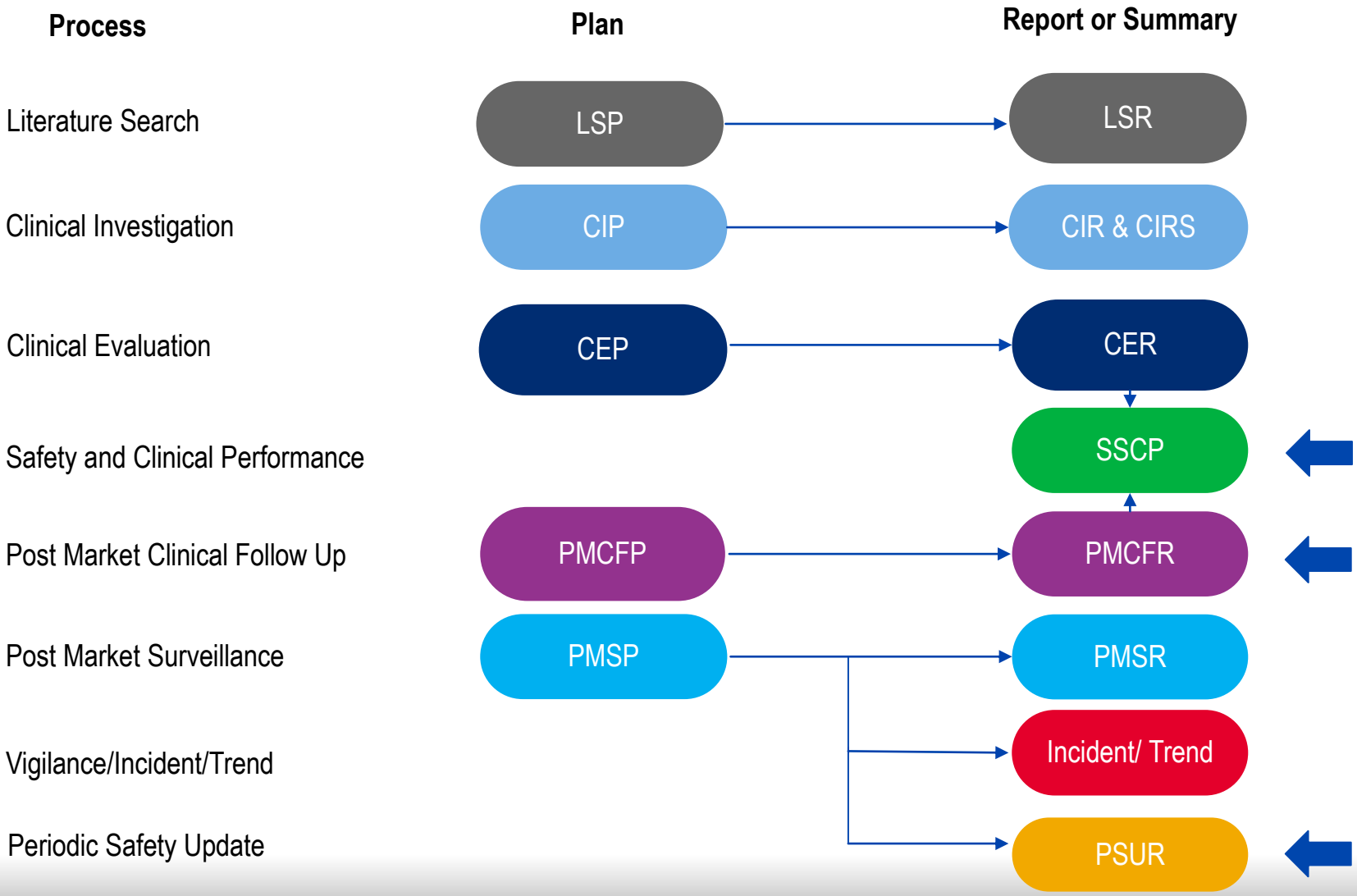
SPR 21: Protection against the risks posed to the patient or user by devices supplying energy or substances

SPR 22: Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

Requirements regarding the information supplied with the device: Clause 23



Clinical Aspects – Processes, Plans (P), Reports (R), Summary (S)

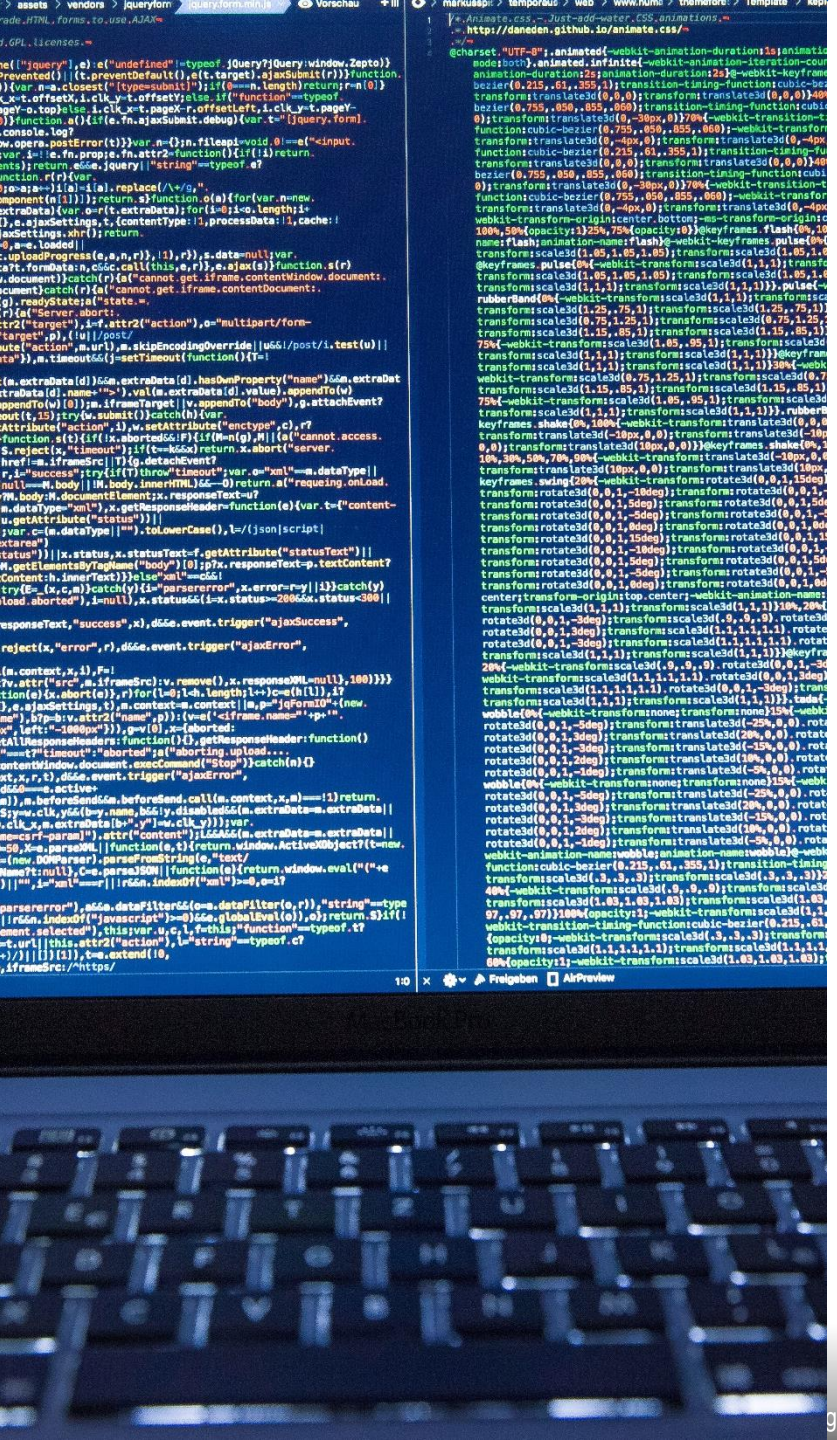


First experience with MDR

Auditing and Assessment Activities

Auditing

- Manufacturer's often lack procedures on specific MDR requirements
  - Technical documentation requirements often not defined:
    - create the TD
    - update the TD
    - control the TD
  - Language requirements
    - Manuals / Labels / Information provided with the device
    - Information provided through Software User Interfaces
    - Information provided on the device
  - CE marking of devices (Hardware / Software)
  - Selection of applicable risk class and conformity assessment procedure



Technical documentation assessment

- Consistency was expected to be a huge issue, and it truly is.
  - Wording and consistency throughout the TD of
    i. Intended purpose
    ii. Indications
    iii. Contraindications
    iv. Risks, Remaining Risks, Risk Benefit ratio
    v. Claims (marketing materials vs. clinical evaluation report vs. verification testing)

- Completeness of TD
  - Promotional materials missing
  - Scoping of documents missing, e.g. in the CER
  - Language requirements and translations incomplete
  - Process data not provided or incomplete (huge effort for manufacturers)
  - Verification / Validation methods unclear or not provided (GSPR and general)
  - Standards applied and documented evidence showing compliance missing
  - Information on design stages applied missing or incomplete, often refence to a procedure
  - Information on pre-clinical testing missing in TDs even though it had been performed
  - Post market activities not clearly planned

ght - Do not distribute without preapproval

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Efficient communication between Legal Manufacturer, Economic Operators & Notified Body

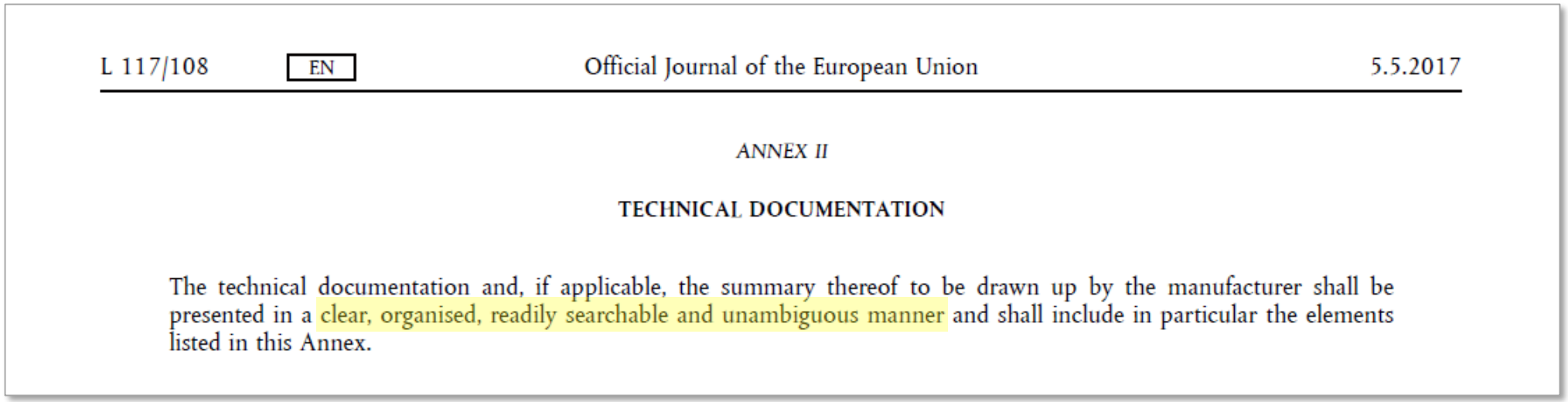
MDR Support Panel

sitem-insel

January 14th, 2020

Arik Zucker

MDR & NBs require a structured & readily searchable Technical Documentation



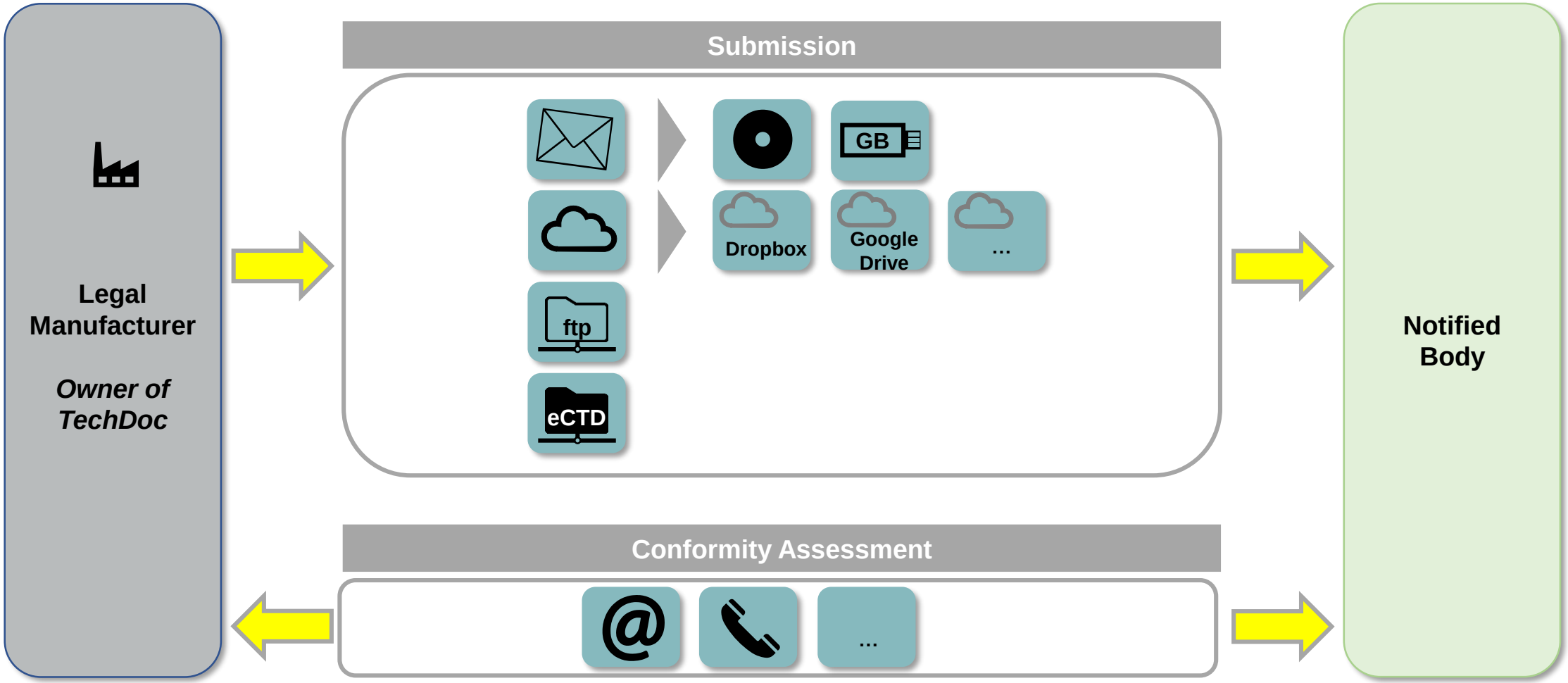
L 117/108 EN Official Journal of the European Union 5.5.2017

ANNEX II

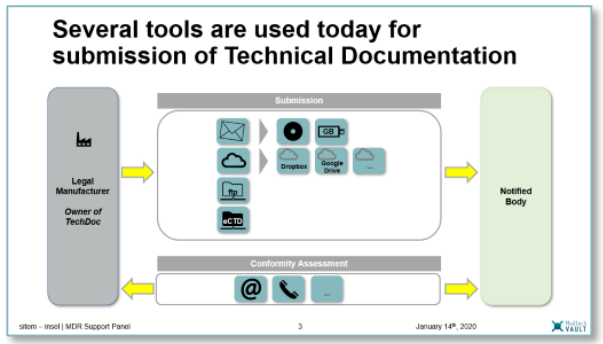
TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

Several tools are used today for submission of Technical Documentation



Are these tools really suitable for your future?



MDR challenges & future requirements of LM

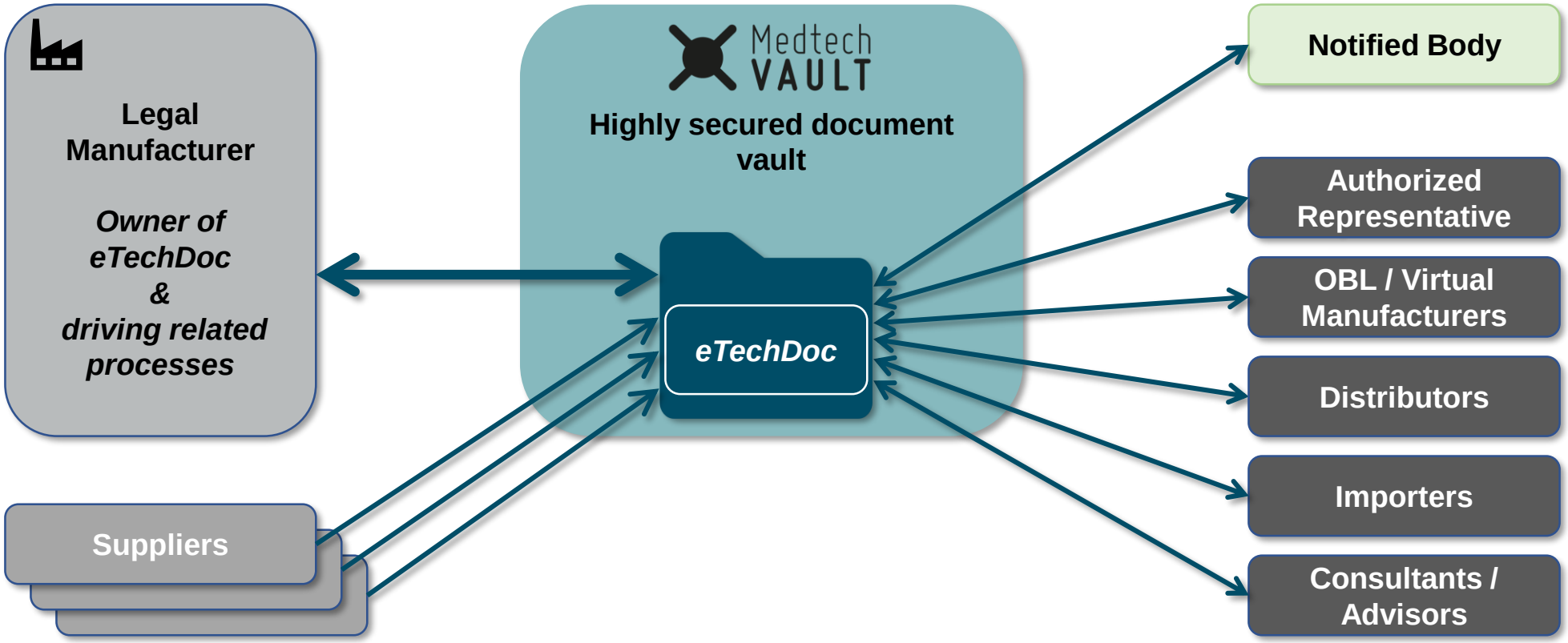
- Future business model
- Confidentiality requirements; in general & of supplier information
- Readily availability of TD upon request by CA / NB
- Trackability during conformity assessment & life cycle management / re-certifications
- Broader use of same TD content for multiple purposes such as other regulatory bodies, distributors, importers, etc.

In fact, the Legal Manufacturer has only 2 options

A. Maintain existing process by employing more regulatory staff
   - if you can get them in the first place
   - costly

B. Use an existing smarter tool that addresses the shortcomings of the current processes / tools, for example MedtechVault

MedtechVault is a solution to efficiently integrate all Economic Operators & the NB



MedtechVault is an add-on to your ERP system & QMS

MedtechVault can support your MDR readiness

Suitable for MDR challenges & future requirements of LM

- ✓ Future business model
- ✓ Confidentiality requirements; in general & of supplier information
- ✓ Readily availability of TD upon request by CA / NB
- ✓ Trackability during conformity assessment & life cycle management / re-certifications
- ✓ Broader use of same TD content for multiple purposes such as other regulatory bodies, distributors, importers, etc.

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