MDR – What we currently know

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BSI Medical Devices

April 2020

By Royal Charter

bsi.

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

Agenda

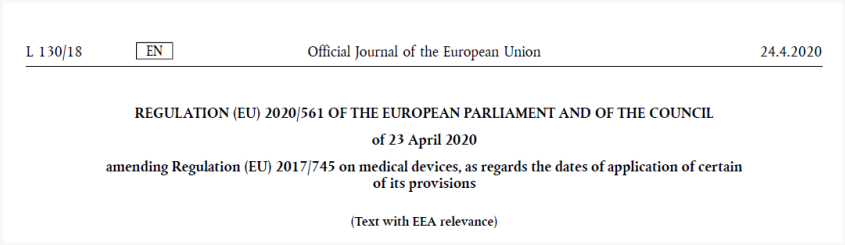
December 2019

… supposed to be what was due 26 May 2020

1. What we currently understand about the MDR DoA
2. The latest on the rolling plan of the Commission and implementation priorities including what happens in the absence of EUDAMED
3. BSI learnings from initial MDR assessments

1. MDR Date of Application

What we currently understand about the MDR DoA



L 130/18 EN Official Journal of the European Union 24.4.2020

REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 April 2020

amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions

(Text with EEA relevance)

Council of the European Union

Brussels, 7 April 2020
(OR. en)

7180/20

Interinstitutional File:
2020/0060 (COD)

PHARM 8
SAN 122
MI 102
COMPET 142
CODEC 245

EUROPEAN COMMISSION

Brussels, 3.4.2020
COM(2020) 144 final

2020/0060 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions

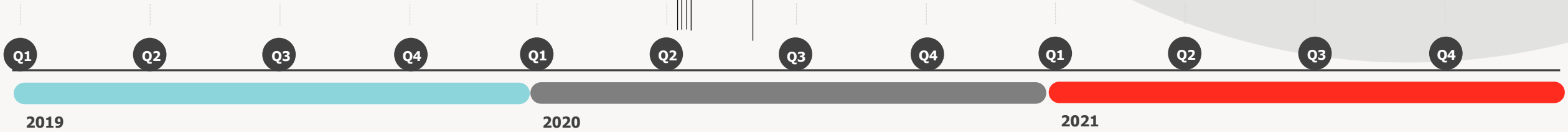
EU 2020/561 Publication & Enter into Force
24 Apr 2020

Parliament Vote
17 Apr 2020

Council Review
07 Apr 2020

Commission Proposal
03 Apr 2020

Original DoA
26 May 2020



Amending Regulation EU 2020/561

- Whereas …

- The COVID-19 outbreak and the associated public health crisis presents an unprecedented challenge to Member States and constitutes an immense burden for national authorities, health institutions, Union citizens, and economic operators.
- The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/745.
- Those extraordinary circumstances have a significant impact on various areas covered by Regulation (EU) 2017/745, such as the designation and work of notified bodies and the placing on the market and making available on the market of medical devices in the Union.

- Medical devices, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, play a crucial role in the context of the COVID-19 outbreak and the associated public health crisis to ensure the health and safety of Union citizens and to enable Member States to give necessary medical treatment to patients who are urgently in need of such treatment.
- Given the unprecedented magnitude of the current challenges, and taking into account the complexity of Regulation (EU) 2017/745, it is very likely that Member States, health institutions, economic operators and other relevant parties will not be in a position to ensure the proper implementation and application of that Regulation from 26 May 2020 as laid down therein.

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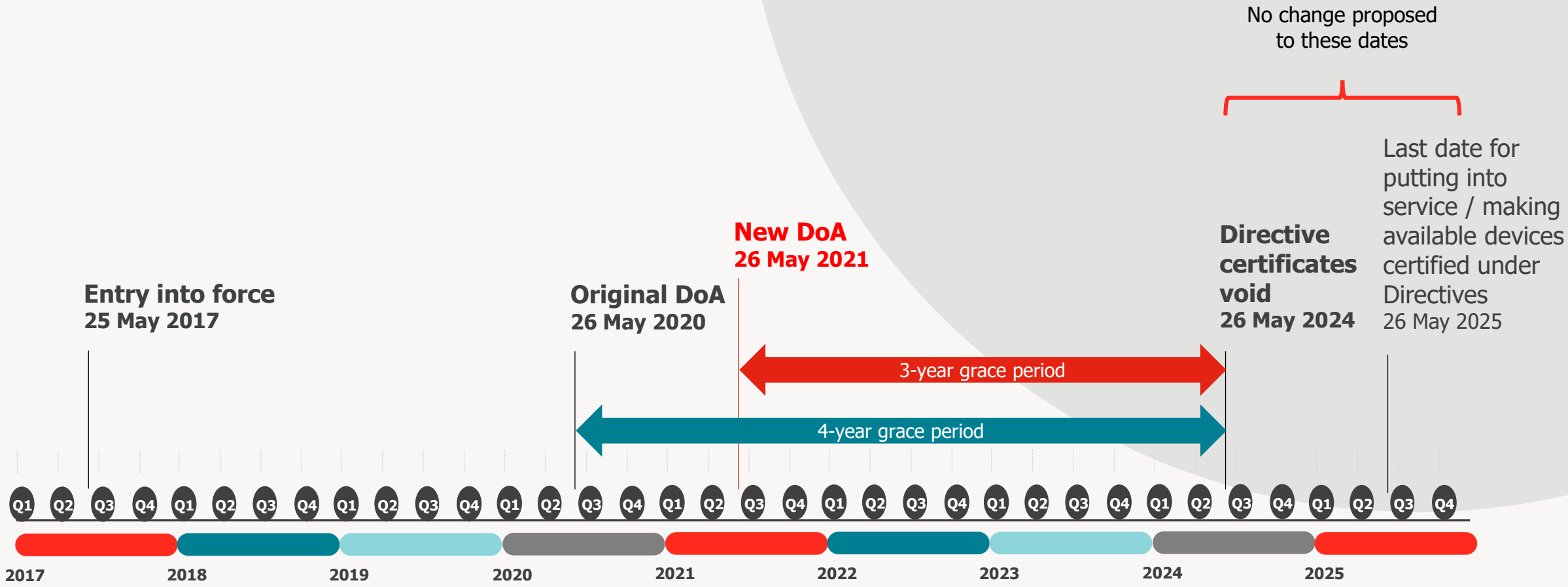
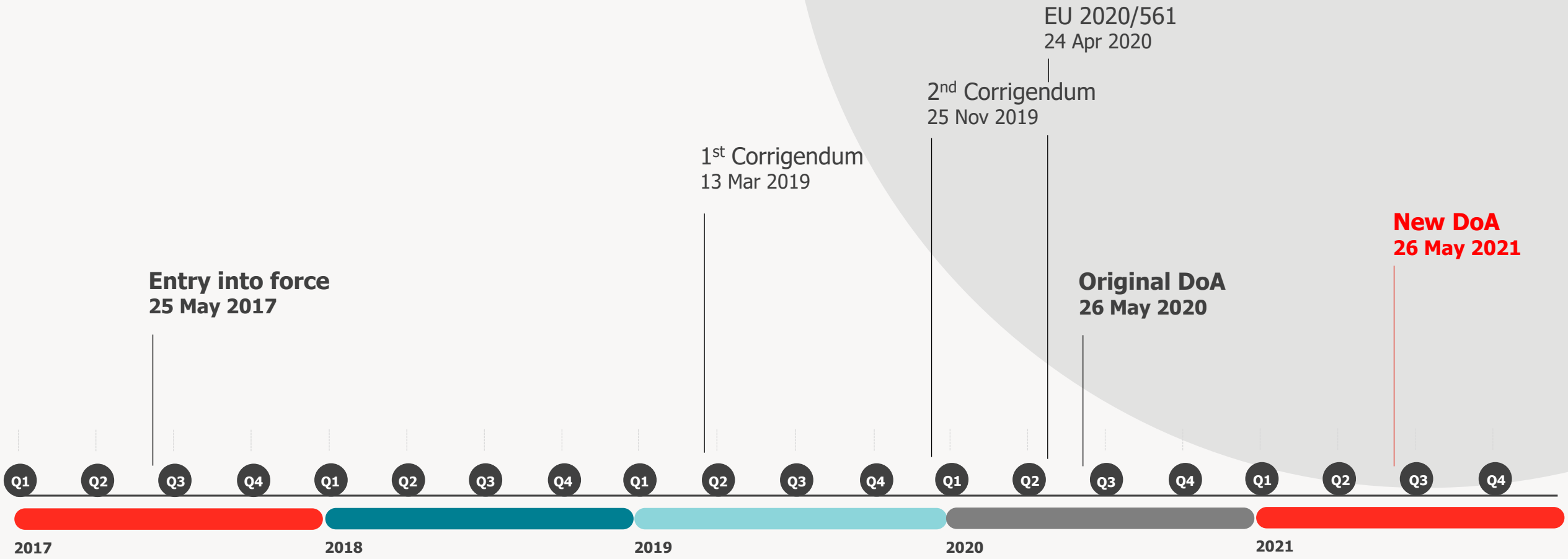
Amending Regulation EU 2020/561



Corrigenda & Amendments

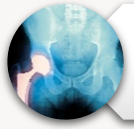


Impact on Priorities

The following devices/products need MDR certificates by 26 May 2021 (instead of 26 May 2020) for continued market viability:


Devices utilising Human tissue derivatives


Article 117 Drug/Device combinations


Custom-made Class III implants


Devices without a medical purpose – Annex XVI

Transition timeline is 6 months from date of CS publication or 26 May 2021, whichever is latest

NBs cannot accept applications until the CS is published


Class I re-usable surgical instruments


Software that was Class I under MDD and now up-classified

2nd Corrigendum extended transition to 26 May 2024

Amending Regulation EU 2020/561 → MDR Article 120 (3)

After 26 May 2021 (instead of 26 May 2020), devices with a NB certificate under MDD/AIMDD, Class I devices that are up-classified under MDR can only be placed on market if:

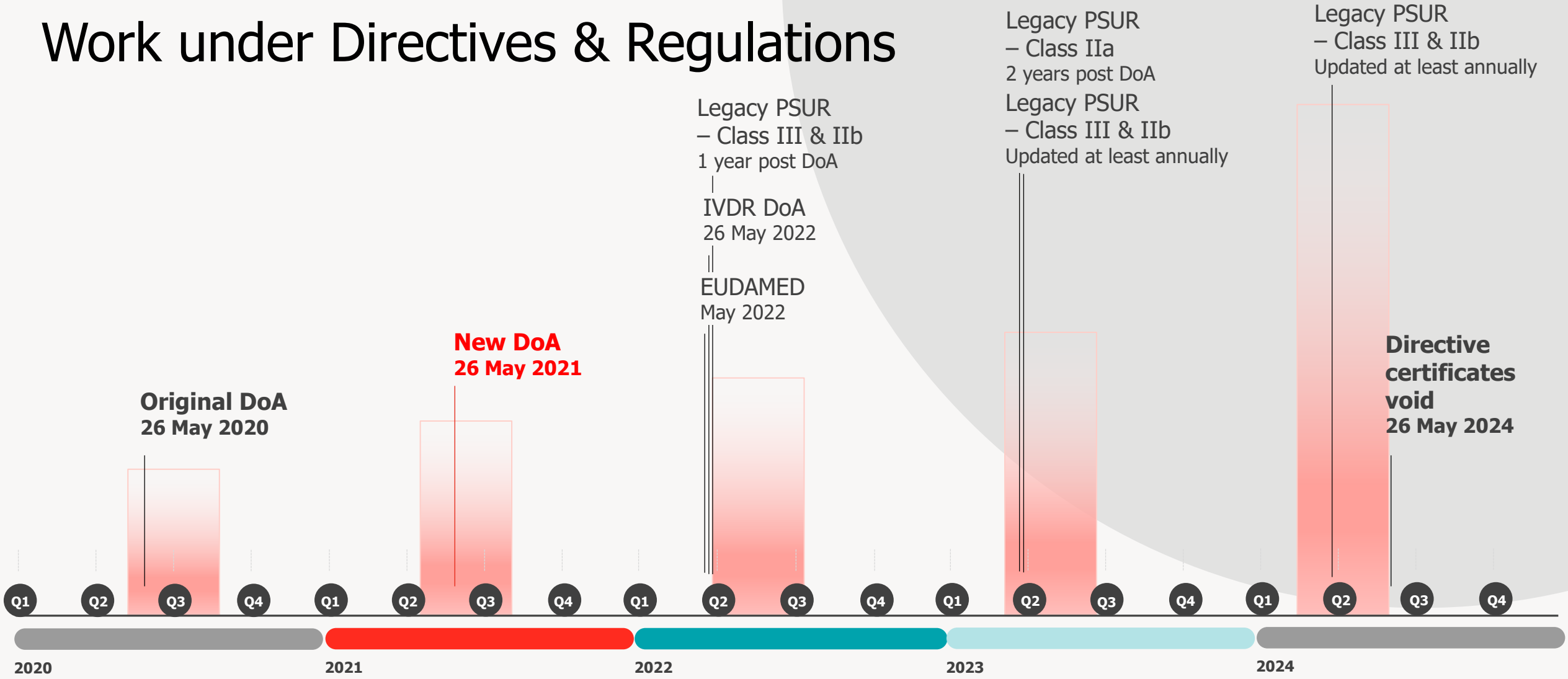
- They continue to comply with applicable Directives
- There are no significant changes in the design or intended purpose

However, the following MDR requirements will apply from

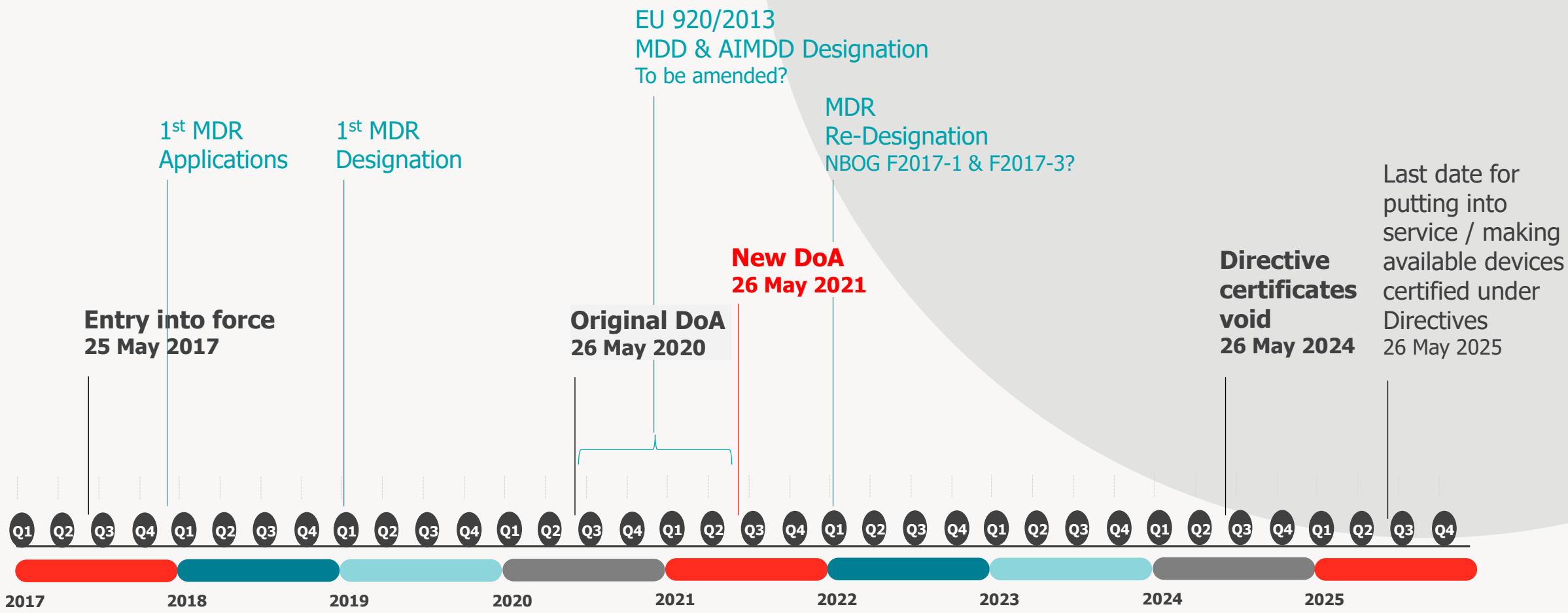
26 May 2021

- post-market surveillance
- market surveillance
- vigilance
- registration of economic operators
- registration of devices

Work under Directives & Regulations



Work under Directives and Regulations



Work under Directives and Regulations

(EU) 2020/403

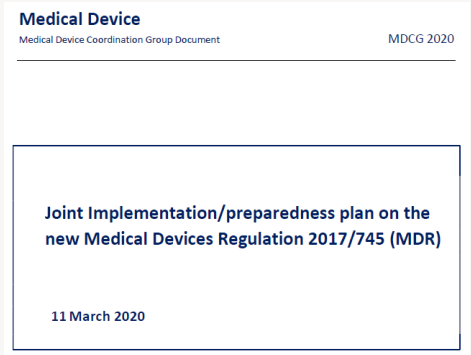
"… notified bodies and market surveillance authorities to deploy all the measures at their disposal to support the efforts aimed at ensuring that the supply of PPE and medical devices throughout the EU market will match the continuously increasing demand …"

- Changes, renewals, scope extensions, supplier verification …
- "… case-by-case basis where devices are considered relevant to ensure medical care, especially if clinically necessary during the period of COVID-19 restrictions …"

MDCG 2020 4

2. Rolling Plan

Implementation of MDR


Medical Device
Medical Device Coordination Group Document
MDCG 2020

Joint Implementation/preparedness plan on the new Medical Devices Regulation 2017/745 (MDR)

11 March 2020

CoVid-19 Pandemic
11 Mar 2020

Joint Implementation / Preparedness Plan
11 Mar 2020

Rolling Plan
Dec 2019

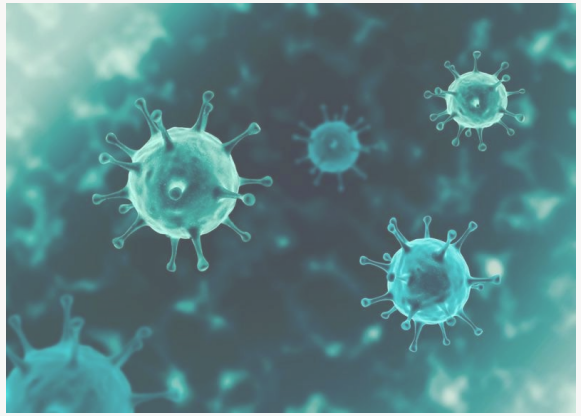
Original DoA
26 May 2020

New DoA
26 May 2021

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

2019 2020 2021

BSI Strategy for Extraordinary Events



Audits postponed in North America
Mar 2020

Audits postponed in Europe
Feb 2020

Audits postponed in China
Jan 2020

Original DoA
26 May 2020

New DoA
26 May 2021

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

2019 2020 2021

MDCG 2020 4 – Extraordinary Measures

- … COVID-19 global outbreak as well as the rapid spread of the virus across various regions of the globe, the resulting travel and quarantine restrictions have significantly affected the ability of notified bodies to conduct mandatory on-site audits under the medical devices legislation.
- … in the interest of public health, this document outlines temporary extraordinary measures for notified bodies to follow in order to allow continued availability of safe medical devices to the market and assist in the prevention of the risk of medical device shortages.
- It is considered that alternative solutions to carrying out on-site audits by notified bodies under the Medical Devices Directives should be allowed under specific circumstances, including the possibility to perform remote audits under certain conditions.
- This guidance takes immediate effect and is valid for the whole period of duration of the pandemic COVID-19 as declared by the World Health Organisation.

MDCG 2020 4 – Extraordinary Measures

- Scope:

☑ Surveillance audits
☑ Re-certification audits
☑ On-site verification audits for substantial changes
☑ Transfer audits

☒ Unannounced audits (unless there are immediate safety concerns)
☒ Audits that need on-site assessments e.g. some manufacturing related NC close-outs (unless there are immediate safety concerns)

MDCG 2020 4 – Extraordinary Measures

- Although this guidance applies to the Medical Device Directives only, for Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR) in the event that the availability of devices is **affected by COVID-19** restrictions the principles in this guidance may apply.

- In general, initial certification audits or audits to extend the scope of certification under the Directives should not be performed using these temporary extraordinary measures. However, notified bodies may apply these extraordinary measures on a case-by-case basis for such audits in cases where devices are considered relevant to ensure medical care, especially if **clinically necessary** during the period of **COVID-19** restrictions.

What is ‘clinically necessary’?

World Health Organization

- Infrared thermometer
- Pulse oximeter + cables & sensors
- Oxygen concentrator
- Medical gas cylinders + pressure & flow regulator
- Laryngoscope + blades
- Ventilators
- Breathing circuits
- CPAP + accessories
- BPAP + accessories
- Nasal cannula + accessories
- Infusion pumps
- Blood gas analysers
- ECG + accessories
- Suction pumps
- Autoclaves + accessories
- Humidifier + tubing
- Oxygen masks
- Compressible ventilator bags
- Nasopharyngeal airway sets
- Endotracheal tube introducer sets
- Arterial blood sample kits
- Central venous catheter kits
- Gastro-enteral feeding syringes, tubing + accessories
- Urethral catheters
- Airway management forceps
- Kidney basins
- Antiseptic wipes
- Tape
- Drapes
- Gloves
- Surgical masks
- Face shields
- Goggles
- Gowns
- Aprons

- Lab Screening test kits
- Lab Confirmation test kits
- RT-PCR kits
- Extraction Kits
- RT-PCR cartridges
- Swabs
- Viral transport medium
- CoVid-19 antigen & antibody tests

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Priority Medical Devices in the context of COVID-19 – WHO/2020-nCoV/MedDev/TS/O2T.V1 – 09/04/2020

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items

MDCG 2020 4 – Extraordinary Measures

- Extraordinary Measures:

- Postponement of on-site surveillance audits under the Directives in line with documented procedures of the notified body for force majeure.
- On-site audits may be replaced by remote audits using the most advanced available Information and Communication Technologies as appropriate in accordance with legislation on information security and data protection.
- Assessment of all relevant and required documents/records off-site by the notified body.
- To take into account existing recent results from MDSAP audits (or other appropriate audits) in lieu of Directive audits, where available
- To consider published international guidance such as those issued by the International Accreditation Forum (IAF) e.g. on how to use information and communication technologies and for alternative auditing methods in extraordinary circumstances.

Joint Implementation / Preparedness Plan – 11 March 2020
+ EU Commission Communication – 24 April 2020

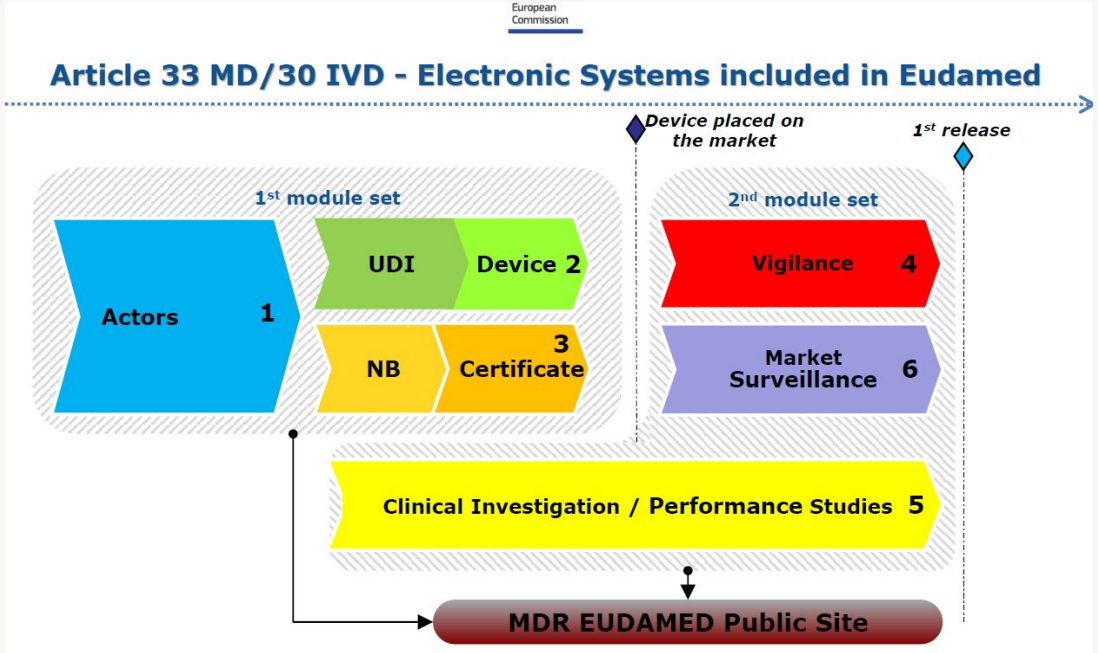
Rolling Plan

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

December 2019

1. EUDAMED
2. Switzerland / Turkey
3. MDCG Guidance
4. Expert Panels
5. Implementing Acts

1. EUDAMED



- Actor Module – ? 2020
- UDI / Devices Registration – May 2022
- NB / Certificates – May 2022

- Position Paper on Actor Registration + SRN – Q2 2020

- Guidance on Administration and Technical Solutions in the absence of EUDAMED – Q2 2020

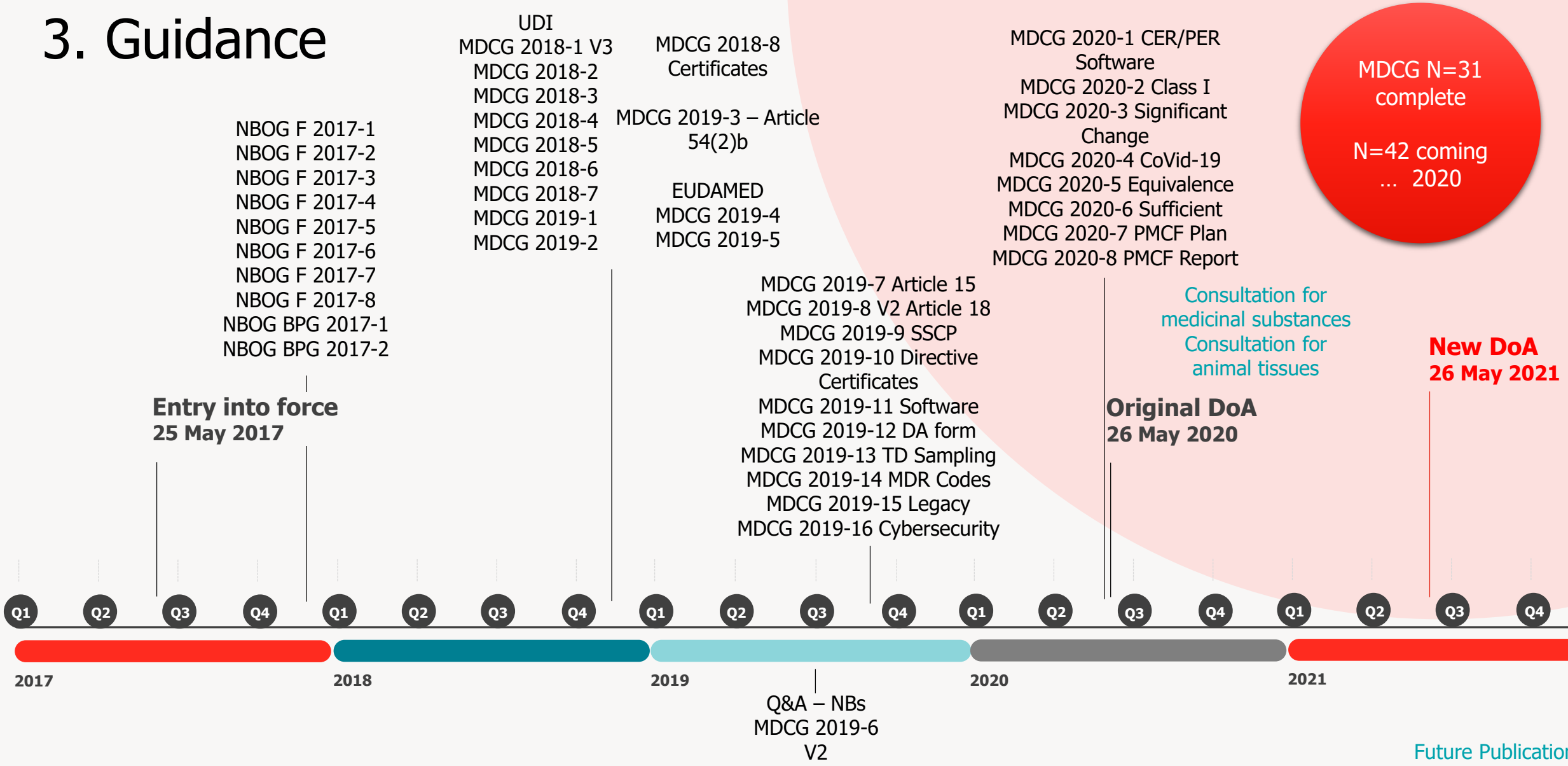
- Fact Sheet on information available to the public – Q2 2020

2. Switzerland / Turkey

- Switzerland – Mutual Recognition Agreement
- Needs to be re-negotiated prior to May 2021
- Under MDR / IVDR
  - Manufacturers need EU authorised representative

- Turkey – Customs Union
- Needs to be re-negotiated prior to May 2021

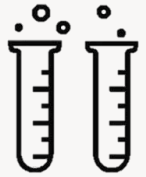
3. Guidance

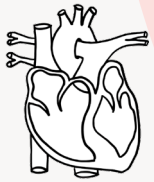
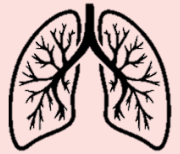
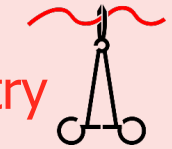
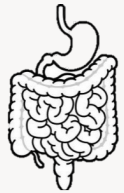
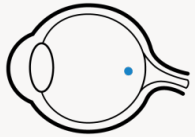


4. Expert Panels – Implementing Regulation (EU) 2019/1396

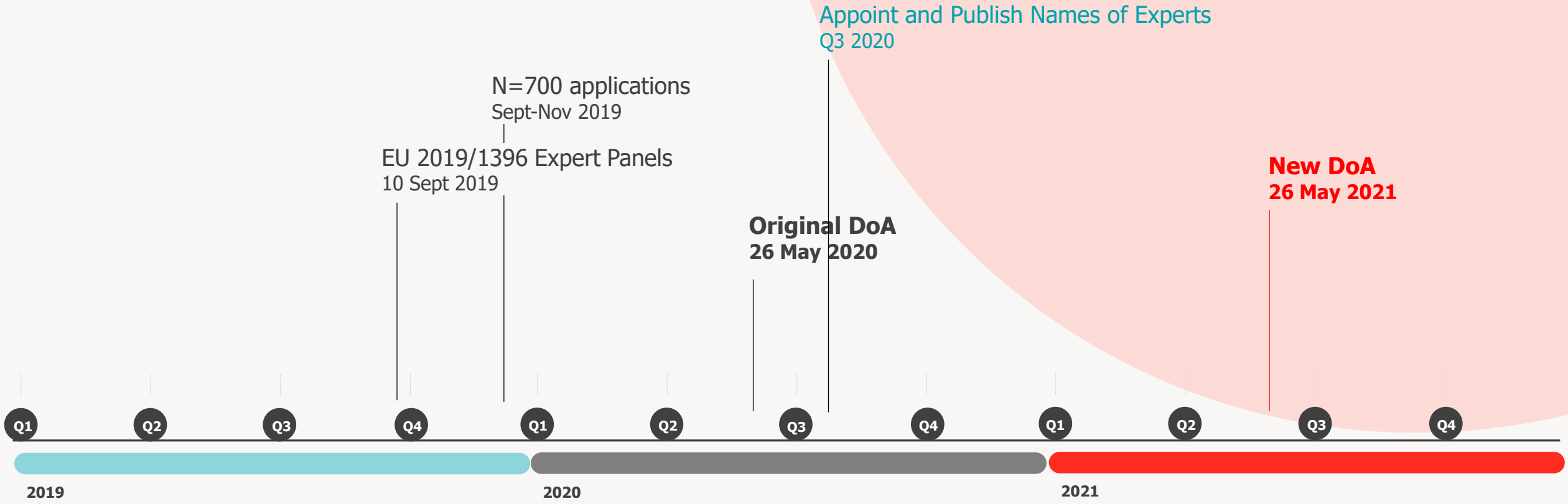




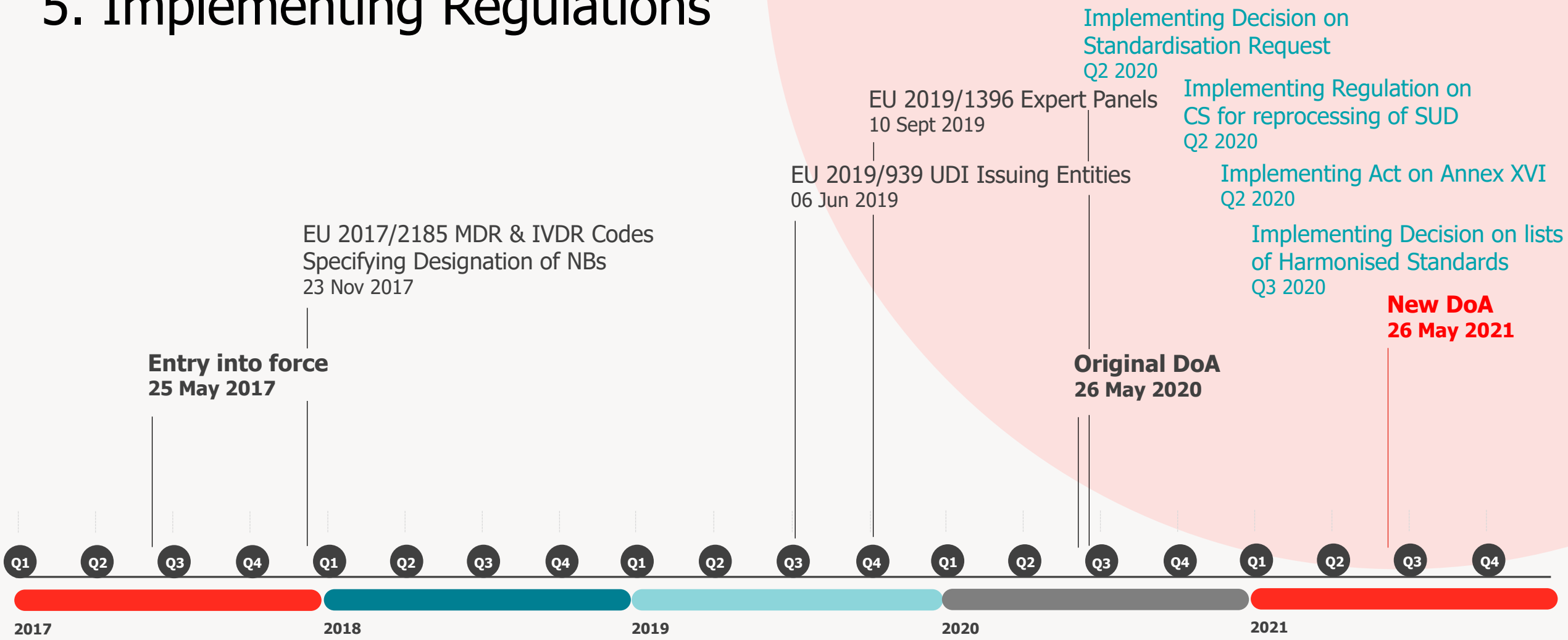
1. Orthopaedics, traumatology, rehabilitation, rheumatology
2. Circulatory system 
3. Neurology
4. Respiratory system, anaesthesiology, intensive care 
5. Endocrinology, diabetes
6. General surgery, plastic surgery, dentistry 
7. Obstetrics, gynaecology, reproductive medicine
8. Gastroenterology, hepatology 
9. Nephrology, urology
10. Ophthalmology 
11. *In-vitro* diagnostic medical devices (IVD)

4. Expert Panels



Future Publications

5. Implementing Regulations



Future Publications

3. Lessons learned from initial audits

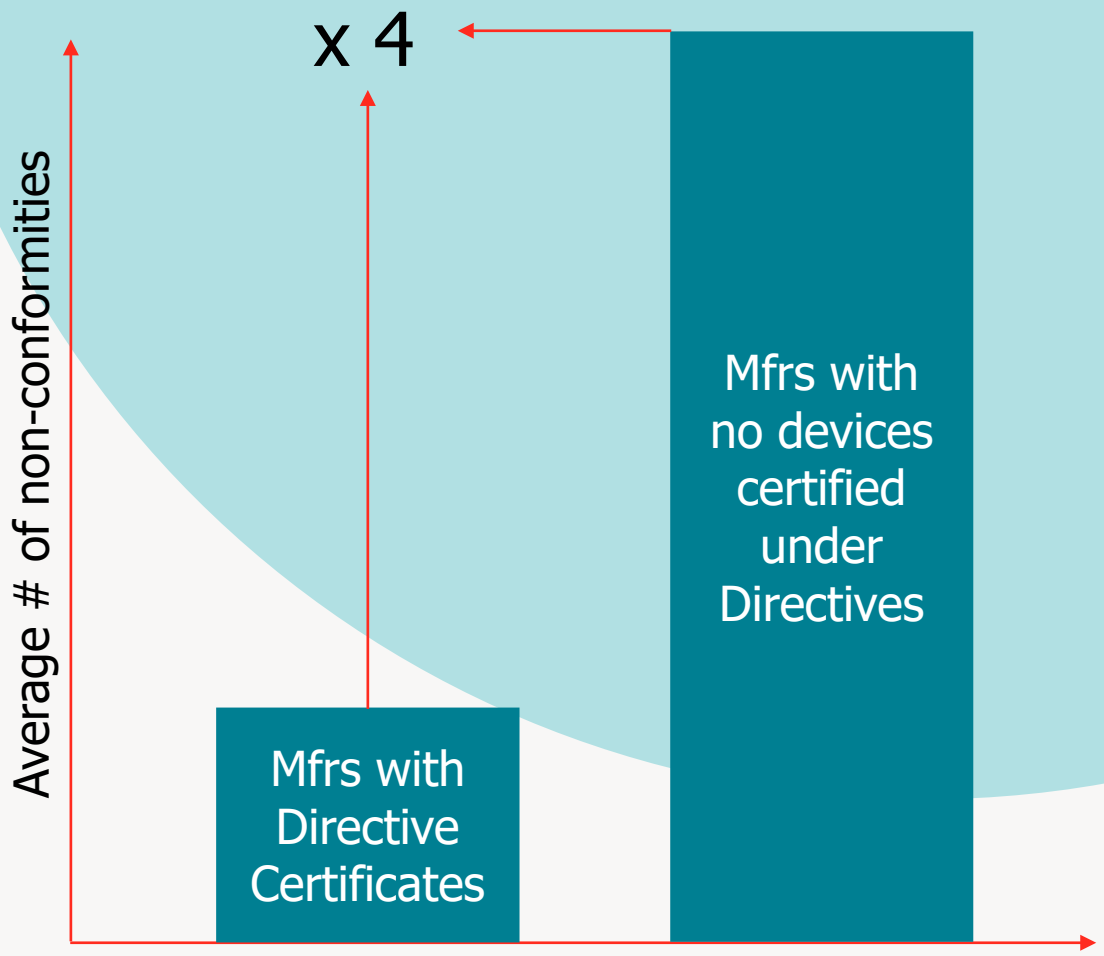
MDR QMS Audits – General Trends

Most Manufacturers well prepared

- Although majority of applications in the early phase appear to be from Manufacturers with detailed plans in place for MDR compliance and early preparation

Manufacturers with Directive Certificates appear to be better prepared than those without

- Although very few applications have been received from the latter



Note - These are early trends and may change with time and more experience

MDR QMS Audits – Top 5 areas of NCs

Internal Audit

- Failure to perform an Internal Audit
- Failure to include MDR requirements in the Internal Audit

Economic Operators

- Agreements with EU Rep, Importers etc not covering all the legal requirements

PMS

- Absence of plans
- Inadequate plans
- PSUR processes not well defined

UDI

- Assignment not defined clearly
- Not captured in appropriate locations

Technical Documentation

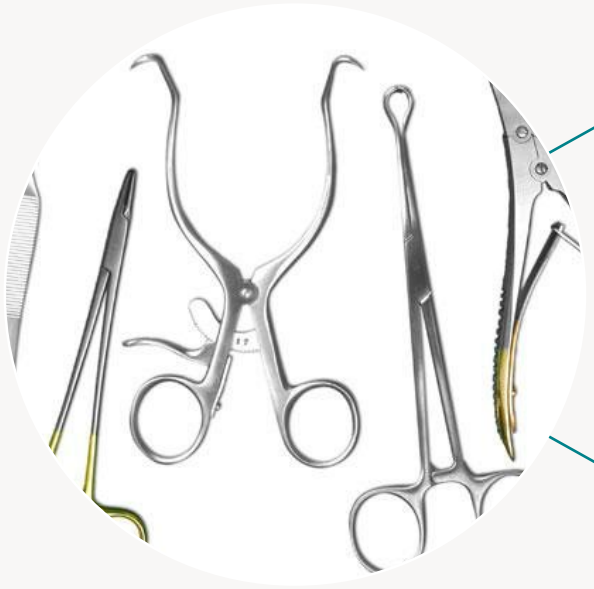
- Processes/procedures for generating TD inadequate

Other Areas

Record Retention
Document Control
GSPR Checklists
Supplier Controls
PRRC
Clinical
Vigilance
Declaration of Conformities
Labelling
Training
Change Management
Registrations
Risk Management

Note - These are early trends and may change with time and more experience

Focusing on Class I re-usable surgical instruments



Most manufacturers well-prepared

- 0.5 non-conformities per audit

Most common NC areas

- Disconnect between cleaning/disinfecting/sterilisation validations conducted and the instructions provided in the IFU
- Risk Management – failure to document specific risks related to re-usable elements

Note - These are early trends and may change with time and more experience

Technical Documentation – Slightly different story!

Scope for improvement in the quality of Technical Documentation

- On average 30 questions raised per submission in the first round of questions

Many incomplete submissions

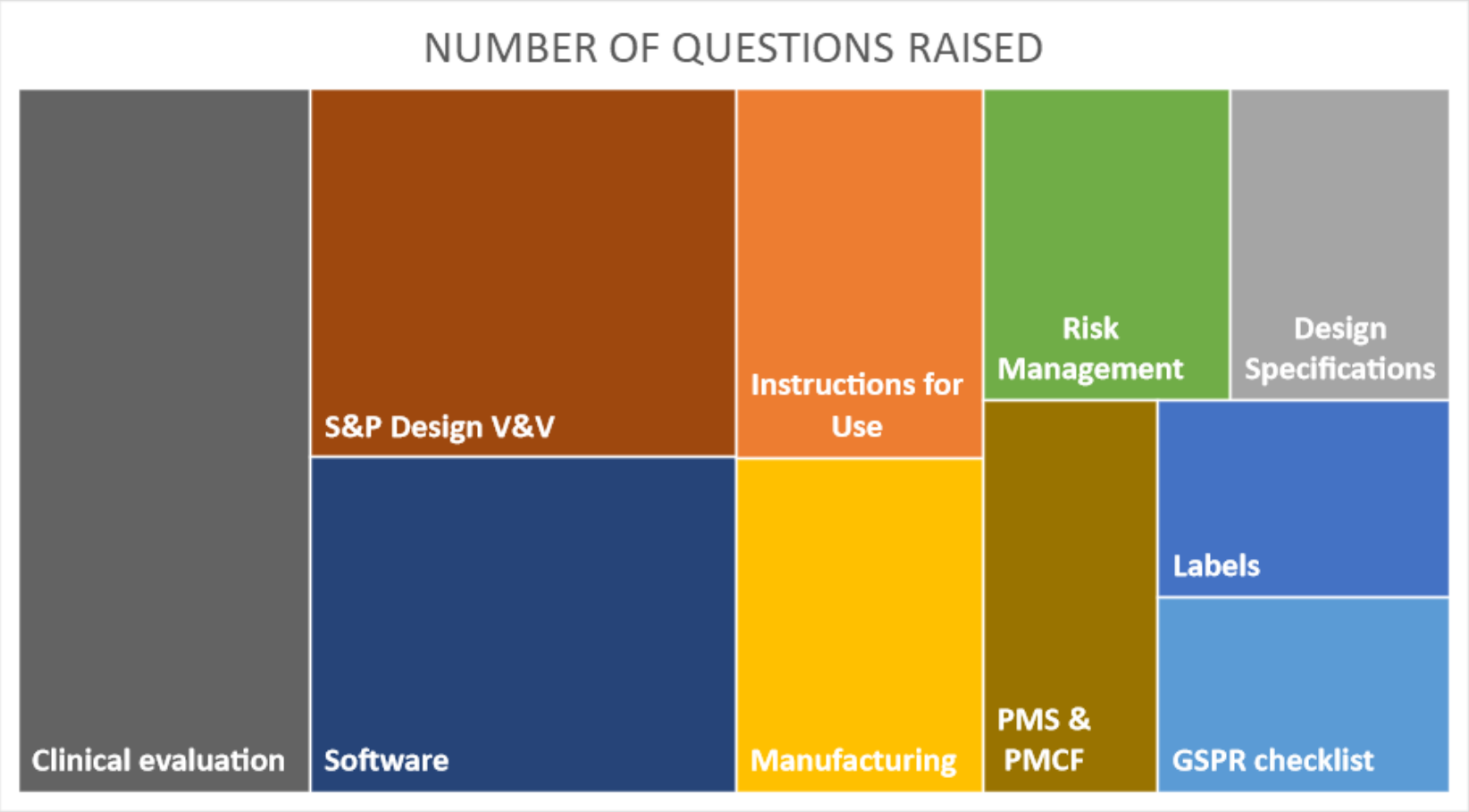
- Many documents missing

"…….We thought we would send you the top-level documents, and then follow up with more as you need them." - Manufacturer

BSI introducing a 'Completeness Check' to ensure a full submission has been received before starting the review

Note - These are early trends and may change with time and more experience

Technical Documentation – Top 10 areas with questions raised



Note - These are early trends and may change with time and more experience

Clinical Evaluation – Some common gaps

- Equivalence not demonstrated
- Incomplete Safety & Performance data with respect to all indications/claims
- Clinical benefits and risks not clearly addressed
- Safety and performance endpoints not clearly defined
- State of the art not clearly established
- Missing or incomplete clinical development plans
- Competence of the CER authors/reviewers
- & many more....

Note - These are early trends and may change with time and more experience

MDR Technical Documentation – You can help us by …

- Implement guidance from various MDCG documents
- Follow BSI Documentation Best Practices Guidelines
- For legacy / established devices, tell a clear story of how testing and clinical data support the current embodiment of the device
- Include all relevant information in first submission to avoid additional requests
- Take note of the questions you have received from the Notified Body in MDD renewals, MDD reviews, and early MDR reviews, and aim to address these for smooth MDR applications

Questions and Answers

April 2020