Preparing for IVDR

Association of Medical Diagnostics Manufacturers (AMDM) 2022 Focus Meeting Los Gatos, California

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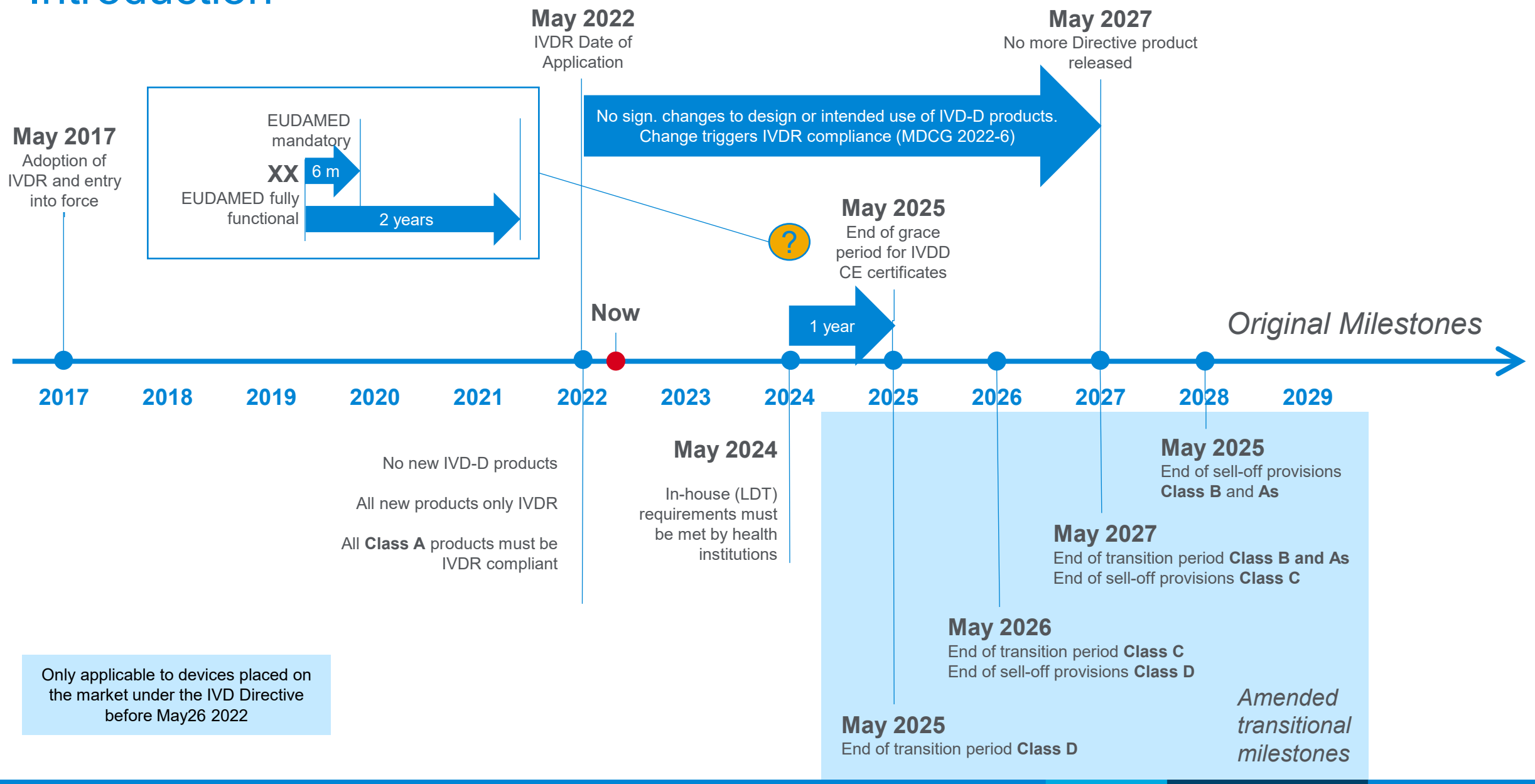
Introduction



IVDR implementation continues to be a moving target

- IVDR is in effect
- Implementation guidance has been missing
  - but is currently publishing in abundance
- Interpretation of requirements is shifting
- Increasing amounts to national IVDR implementing tools; e.g.
  - Device and Economic Operator registration
  - IVD performance study authorization

AGENDA

- Introduction
- Common challenges
- Recent guidance updates
- EUDAMED
- Closing remarks

Challenge #1 – misunderstanding review requirements

Misconception:

All IVDR technical files* must be submitted to notified body before (IVDR) CE-marked

- Dec 2019: MDCG 2019-13 clarified level of sampling

Annex IX example	Class B	Class C
NB involved in CE marking	Yes	Yes
Sampling	Yes per device category	Yes per generic device group
Sampling plan before certification	≥ 1 file (Basic UDI-DI) per device category/generic device group	
Sampling plan during surveillance	≥ 1 file / group / year Approx. 15% during certificate lifetime (5y).	

*except for Class A-nonsterile

Challenge #2 – EU representatives

Confusion

EU authorised representative vs. authorised rep PRRC	
Natural person or Legal entity	Named person
Mandated to act on behalf of manufacturers outside the EU	Overseeing that AR meeting obligations
Obligations listed in Article 11 (IVDR)	Article 15.6 (IVDR) + MDCG 2019-7
Named on labeling	Named in EUDAMED

Obligations of the EU Authorised Representative may or may not be conducted by the AR-PRRC

PRRC: Person responsible for Regulatory Compliance

Challenge #3 – effectuating changes to IVDD devices

Misconception:

No changes can by implemented for “legacy devices” placed on the market before May 26,2022 and utilizing the amended transitional provisions of IVDR Art. 110

- ”NO CHANGES ALLOWED” – not practicable for extended time
- MDCG 2022-6 clarifies changes on and out of scope of Article 110(3) IVDR
- Guidance contains examples of significant and non-significant changes
- Guidance contains flowcharts to assess changes

MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR May 2022

Challenge #3 – effectuating changes to IVDD devices

Examples of changes not concerning the design or intended purpose (MDCG 2022-6, section 4.2)

Based on guidance it may be possible to implement changes in the below areas if conditions of guidance is met

- the manufacturer's name, address or legal
- the authorised representative;
- relocation or addition of new ma turing sites;
- changing the supplier of a material, ingredient or component;
- adding or replacing a new material number;
- changes to outer packaging;

Update Declaration of Conformity?

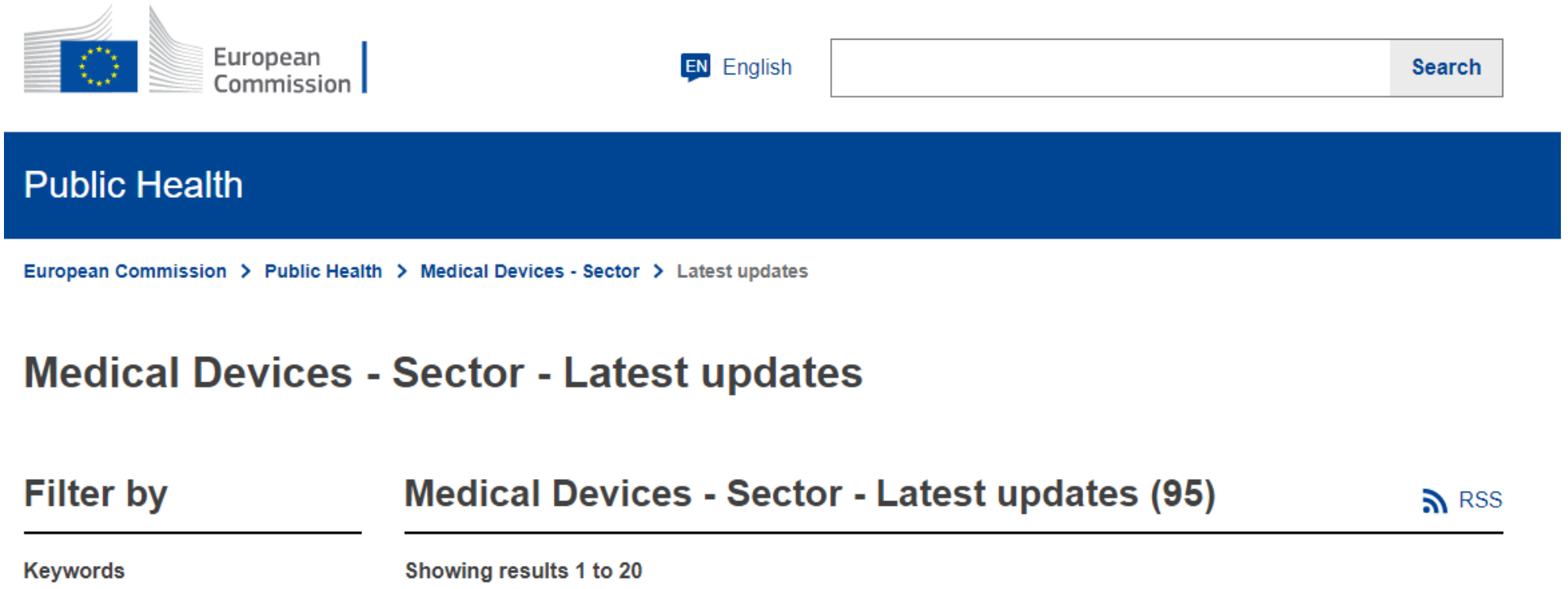
Examples of non-significant changes to labeling (MDCG 2022-6 4.3.2.1)

As a general rule, the following changes in design and/or intended purpose should not be regarded as 'significant':

- changes related to corrective actions !assessed and accepted by the competent authority
- editorial and clarifications
- Updates that are required by law other than the IVDR
  - e.g. CLP Regulation (EC) 1272/2008

Complete and document robust assessment of proposed changes based on flow charts/guidance in MDCG 2022-6

Challenge #4 Implementation of the continued flow of new guidance/implementation documents



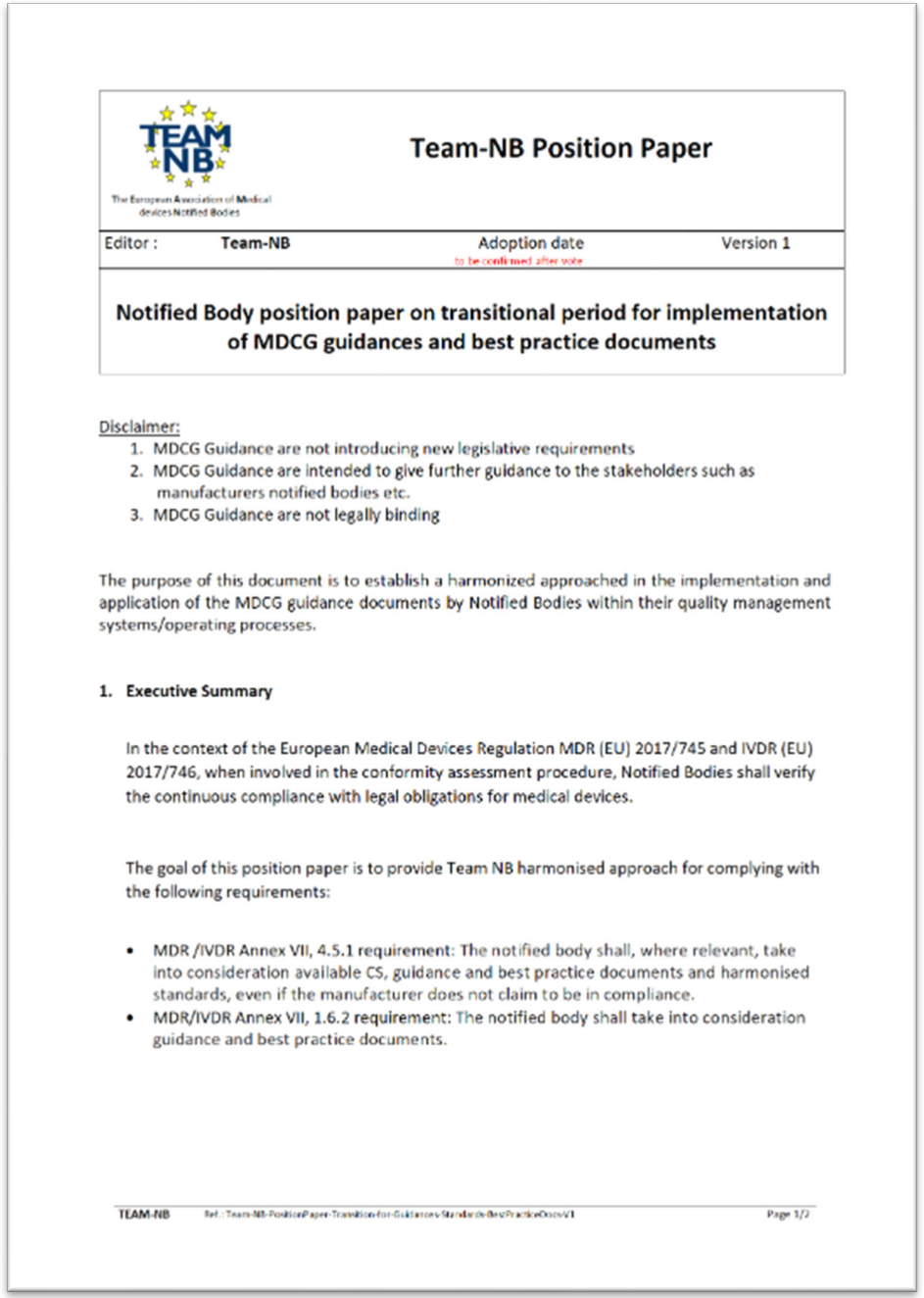
List of publications since May 2022

Date	Title
14 SEP 2022	MDCG 2021-22 rev.1 - Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017 (September 2022)
14 SEP 2022	MDCG 2022-15 - Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD (September 2022)
26 AUG 2022	MDCG 2022-14 - Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs
10 AUG 2022	MDCG 2022-13 - Designation, re-assessment and notification of conformity assessment bodies and notified bodies
5 AUG 2022	Call for EU reference laboratories sent to Member States
13 JUL 2022	MDCG 2022-12 - Harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for IVDR)
5 JUL 2022	Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications in accordance with Regulation (EU) 2017/746
13 JUN 2022	MDCG 2022-11 - MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements
25 MAY 2022	MDCG 2022-10 - Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
25 MAY 2022	Public health: Stronger rules for placing medical tests on the market
24 MAY 2022	Notice to stakeholders: Status of the EU-Switzerland Mutual Recognition Agreement (MRA) for in vitro diagnostic medical devices
20 MAY 2022	MDCG 2022-7 - Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746
20 MAY 2022	MDCG 2022-8 - Regulation (EU) 2017/746 - application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC
20 MAY 2022	MDCG 2022-9 - Summary of safety and performance template
4 MAY 2022	MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR

Timeline for implementing

- MDCG guidance is not legally binding
- NBs may/do issue findings if MDCG guidance is not followed

- TEAM NB proposes implementation timelines:
  - **4 months** - gap analysis
  - **8 months** - impact assessment + system updates
  - **12 months** - roll-out including training



Team-NB Position Paper

Editor : Team-NB | Adoption date (to be confirmed after vote) | Version 1

Notified Body position paper on transitional period for implementation of MDCG guidances and best practice documents

Disclaimer:

1. MDCG Guidance are not introducing new legislative requirements
2. MDCG Guidance are intended to give further guidance to the stakeholders such as manufacturers notified bodies etc.
3. MDCG Guidance are not legally binding

The purpose of this document is to establish a harmonized approached in the implementation and application of the MDCG guidance documents by Notified Bodies within their quality management systems/operating processes.

1. **Executive Summary**

In the context of the European Medical Devices Regulation MDR (EU) 2017/745 and IVDR (EU) 2017/746, when involved in the conformity assessment procedure, Notified Bodies shall verify the continuous compliance with legal obligations for medical devices.

The goal of this position paper is to provide Team NB harmonised approach for complying with the following requirements:

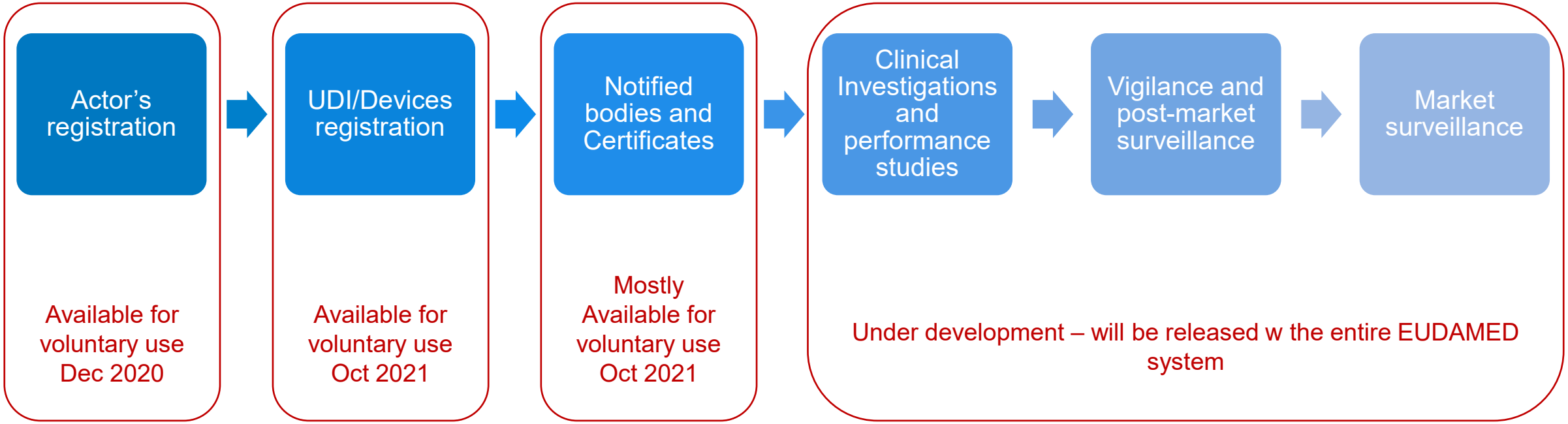
- MDR /IVDR Annex VII, 4.5.1 requirement: The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.
- MDR/IVDR Annex VII, 1.6.2 requirement: The notified body shall take into consideration guidance and best practice documents.

TEAM-NB

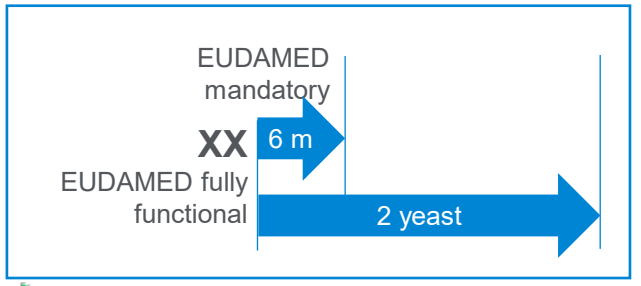
https://www.team-nb.org/team-nb-position-paper-on-time-to-implement-guidances/

EUDAMED

MDR EUDAMED is structured around 6 interconnected modules and a public site.



EUDAMED



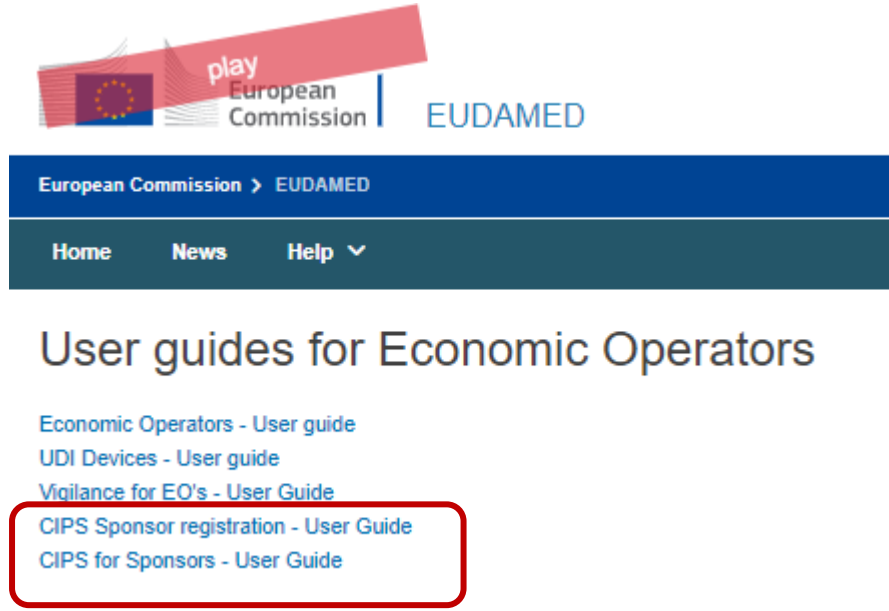
The European Commission planning – June 2022

Q4 2023	Q1-Q2 2024	Q2 2024	Q2 2024	Q4 2024	Q2 2026
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit. **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)** The full EUDAMED system (all 6 modules) is released.	End of 6 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

[1] EUDAMED Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.

https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf

EUDAMED training modules



- Eudamed ”playground” testing environment available
- Useful for testing machine to machine uploads and SOP writing
- All 6 modules available in ”playground”
  (not all modules available to manufacturers)
- Links

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

  Login: https://webgate.ec.europa.eu/eudamed/landing-page#/

  ”Play”: https://webgate.training.ec.europa.eu/eudamed-play/landing-page#/

- Note guides for the Performance Evaluation module published in July.

  CI/PS Sponsor registration - User guide (europa.eu)
  CI/PS for Sponsors - User guide (europa.eu)

Closing remarks

Do

- Keep up to date and make use of guidance as it publishes
- Make use of multiple sources
  - MDCG / Competent authorities / IMDRF
  - ISO …
  - MedTech Europe, Advamed, AMDM
- Ensure timely implementation to allow document update
- Accept that all stakeholders are learning as legislation matures

Don’t

- Wait
  - for EUDAMED
  - to initiate IVDR dialogue with notified body
- **Expect to have ”pre-sub” discussions with your notified body**

Thank you for your attention

Agilent

Trusted Answers