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Your regulatory compliance partner

in Medical
and In Vitro
Diagnostic
Devices

IVDR Implementation – Lessons Learned & Best Practices

Dr. Sandra Reuter

Learn more in the next 20 minutes:

1. IVDR Status Quo: Upcoming Deadlines
2. EU Proposal January 23, 2024: Impact on Legacy Device Timelines
3. IVDR Compliance: Lessons Learned
    1. Common Misconceptions
    2. Technical Documentation

Why are you hearing this from me?

- 2006 – 2020: Working for an international IVD manufacturer: R&D, Regulatory Affairs, Technical Documentation & Performance Studies; extensive experience in IVDs and their approval
- Since 2020: Responsible for Regulatory Affairs and Technical Documentation in Metecon's IVD team
- Since 2024: Team Lead IVD

I am adept at finding the optimal strategy for a smooth approval process, which my team and I will then reliably implement.

Dr. Sandra Reuter

Regulatory Affairs & Technical Documentation at Metecon,

Team Lead IVD

Get everything from a single source:

We have been active and familiar with the regulatory requirements for MD & IVD for 25 years:

- 60+ team members - flexible and powerful,
- full service consultants,
- in touch with all the players in the industry.

"We listen, think, and create individual solutions for the compliant international approval of medical devices and IVDs."

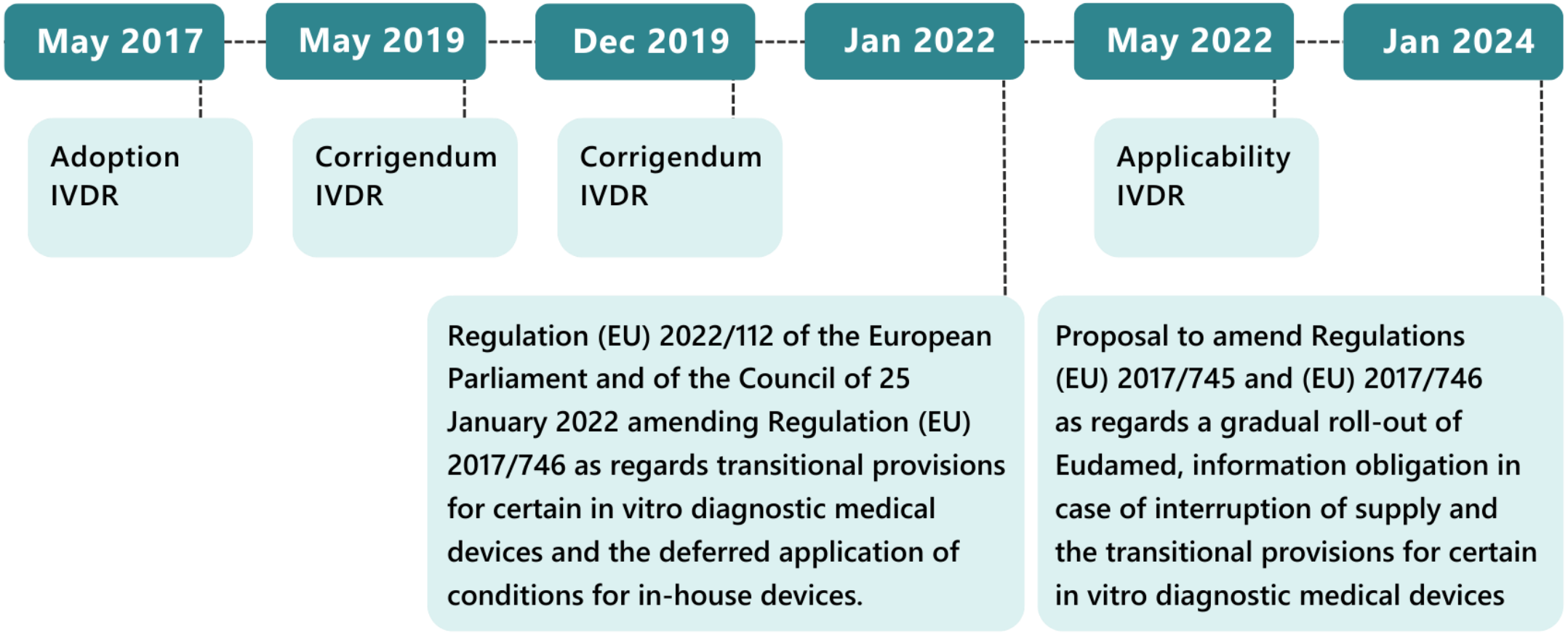
Our Experience: In-Depth and Comprehensive

- Various classes of medical devices and IVDs
- Projects of varying duration and complexity
- Customers of various sizes

IVDR Status Quo

Upcoming Deadlines

IVDR History

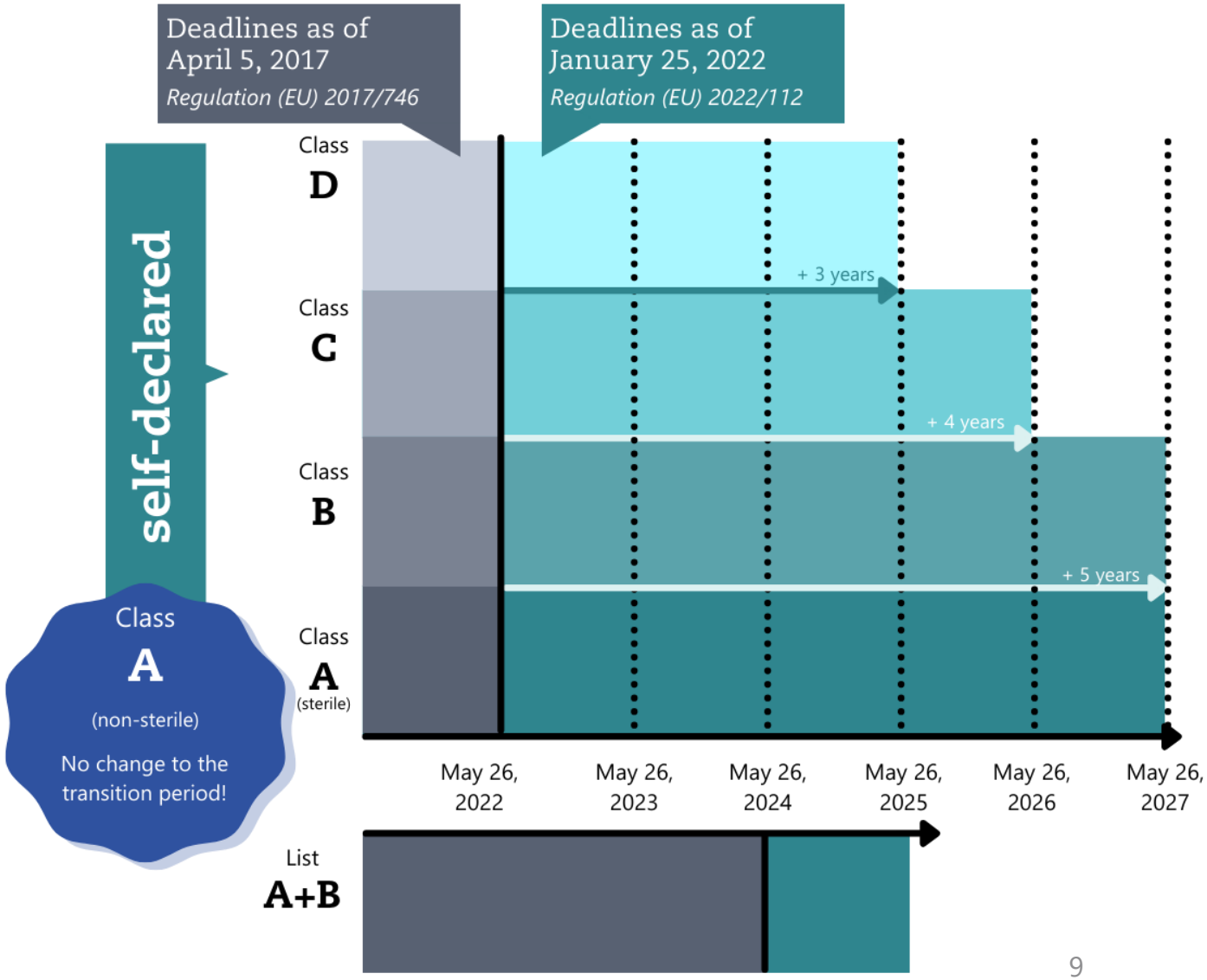


Current Transition Periods for IVD Legacy Devices

Transition periods have been extended for most product classes.

Class A non-sterile: Must be IVDR compliant since May 26, 2022.

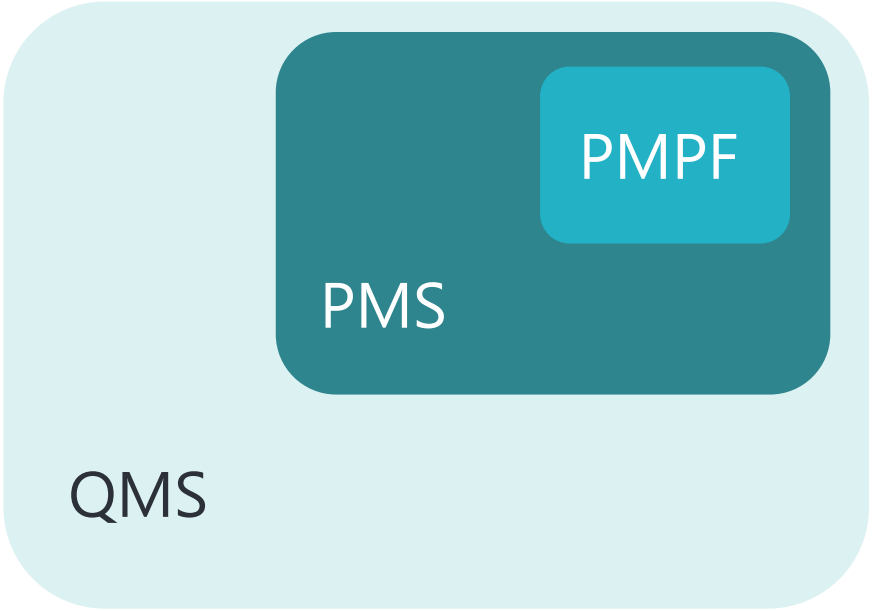
The effective date of the IVDR has **not been postponed**; as of May 26, 2022, some requirements of the IVDR must already be met for all product classes.



Additional Requirements for Legacy Device Manufacturers

Even with extensions of transition periods, legacy devices are subject to the requirements of the IVDR since May 2022 for:

- Post-market surveillance,
- market surveillance,
- vigilance and
- registration of economic operators and devices.



The implementation of these processes is mandatory as of May 2022!

Requirements for Legacy Devices to Benefit from Transition Periods

During the transition period, existing equipment may be put into service or placed on the market if

- it continues to **comply with Directive 98/79/EC**, and
- there are **no significant changes** to the design and intended use.

For further details, see MDCG 2022-6: "Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDD".

CONCLUSIONS Status Quo

- ✓ Find out how long you can leave your legacy device on the market (depending on the classification)!
- ✓ Do not make any significant changes to the device (intended purpose and design).
- ✓ Be aware of the other IVDR requirements for legacy devices (PMS, vigilance, market surveillance, registration) to be implemented from May 2022.
- ✓ Plan and start the revision of the technical documentation.
- ✓ Find a notified body: there is currently free capacity again! The transition period for Class D devices ends on May 26, 2025!

Amendment Proposal for 2017/745 & 2017/746

January 23, 2024

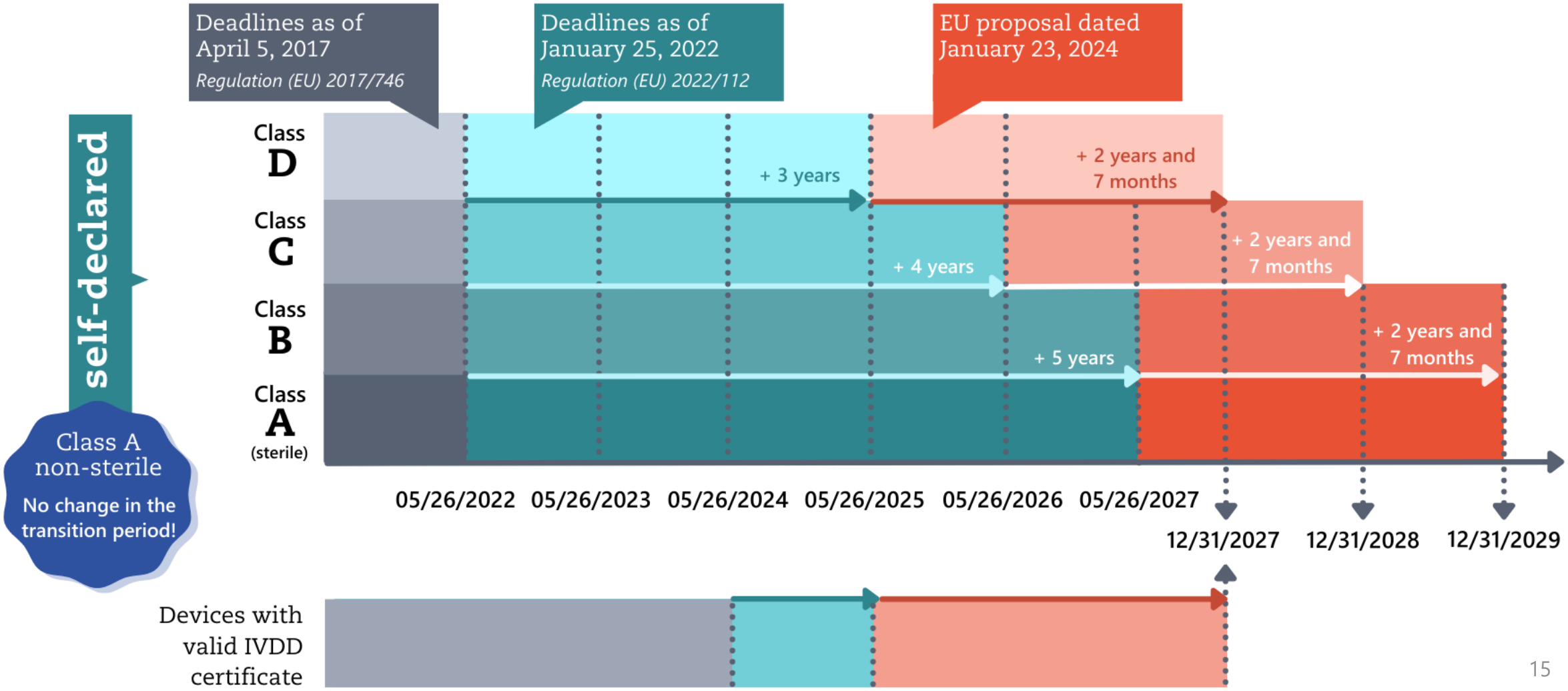
Key Motivation

Security of Supply

In order to ensure the availability of in-vitro diagnostics for patient care, in particular the provision of "high-risk products", the EU Commission wants to grant manufacturers more time for the transition to Regulation 2017/746 on in-vitro diagnostics (IVDR) under certain conditions.

Significant Changes

Transition Period



Transition Periods: Requirements (1/2)

All classes:

Implementation of a QMS in accordance with Article 10(8) of the IVDR

no later than 05/26/2025

Class D & devices with valid IVDD certificates:

Formal application for conformity assessment. Within four months, application must be covered by a written agreement between the notified body and the manufacturer.

no later than 05/26/2026

Class C:

Formal application for conformity assessment. Within four months, application must be covered by a written agreement between the notified body and the manufacturer.

no later than 05/26/2027

Class B and Class A (sterile):

Formal application for conformity assessment. Within four months, application must be covered by a written agreement between the notified body and the manufacturer.

Transition Periods: Requirements (2/2)

- The devices must continue to comply with Directive 98/79/EC. This condition is already part of the current Article 110(3).
- The devices do not undergo significant changes in the design and intended purpose. This condition is already part of the current Article 110(3).
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- No later than May 26, 2025, the manufacturer has put in place a quality management system (QMS) in accordance with Article 10(8) of the IVDR.
- Formal application in accordance with Annex VII, Section 4.3, of the IVDR for conformity assessment by a specific date (May 26, 2025, May 26, 2026, or May 26, 2027, depending on the risk class). Within four months, such an application must be covered by a written agreement between the notified body and the manufacturer.

Transition Periods: Can we throw you a lifeline?

Lessons Learned

Common Misconceptions Concerning Timelines and Notified Bodies

Common Misconceptions (1/3)

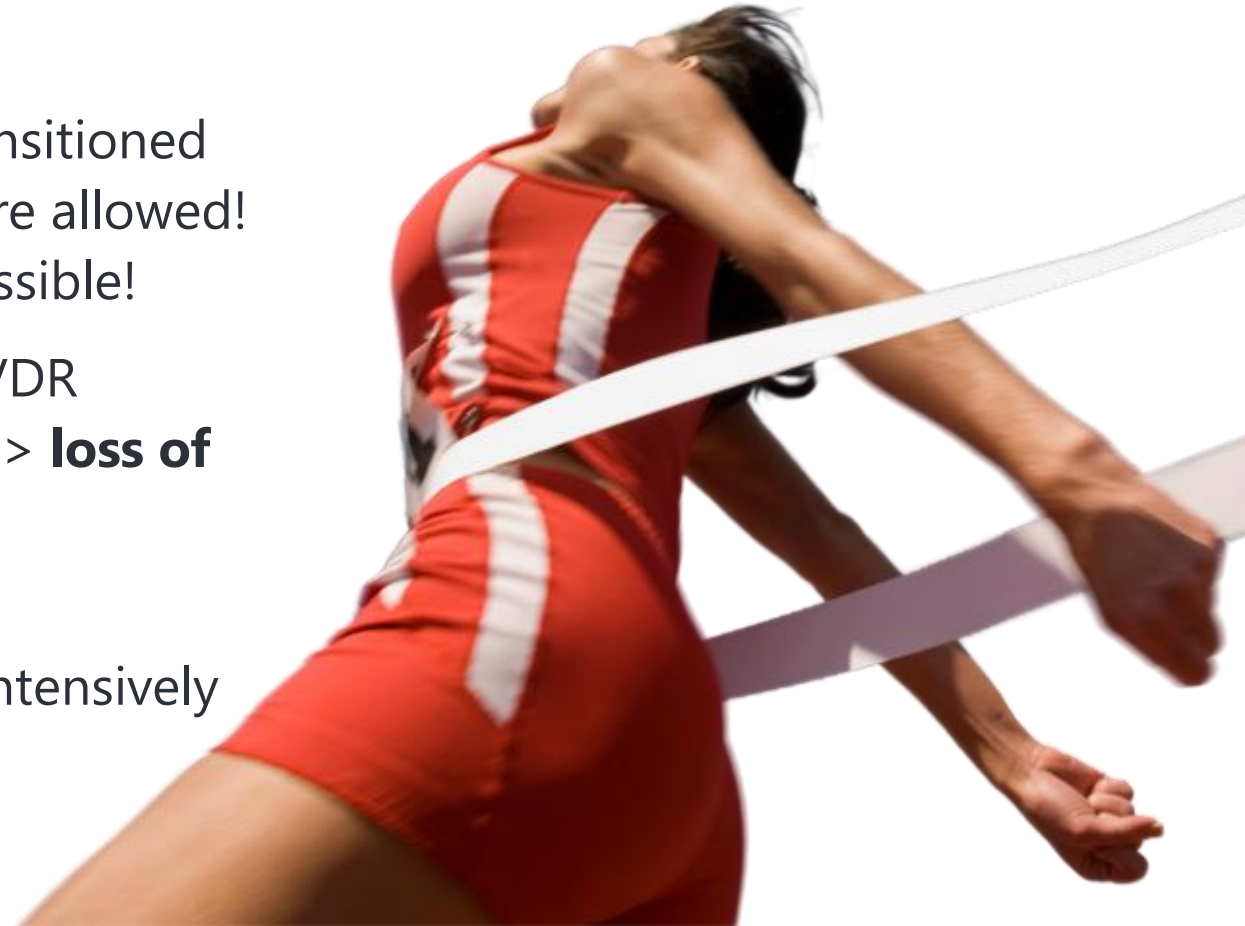
Do not extend transitional periods to the extreme:

- Experience has shown that notified bodies experience bottlenecks before approaching deadlines.
- Deadline May 2025 for Class D means that you must have the certificate in your hands from this date => Submit your technical file at least 1 - 1.5 years in advance, preferably earlier.
- Not all notified bodies have full scope, and experts for certain product codes may be booked up more quickly than others.
- If you haven't already done so, contact a notified body and reserve a time slot for your device so that you get your certificate on time.
- At the moment, all notified bodies are advertising free capacities! If in doubt, contact several.

Common Misconceptions (2/3)

You gain neither time nor competitive advantages through longer transition periods:

- The work **remains the same** and has to be done sooner or later anyway.
- As long as the legacy devices have not been transitioned to IVDR, no significant changes to the devices are allowed! **No innovation, no further development** is possible!
- Manufacturers who have made their products IVDR compliant are able to file change notifications => **loss of competitiveness, loss of innovation, and a disadvantage** for all those who come later.
- Fast manufacturers can focus earlier and more intensively on new developments.



Common Misconceptions (3/3)

Have the courage to contact the notified body:

- They are not allowed to advise, but they do offer **discussions**.
- Use discussion opportunities, e. g. for a preliminary **discussion of the strategy** or **for clarification of deficiencies** during the review phase.
- The **tools** provided, such as checklists, IVDR structure, etc., are rarely used.

Lessons Learned

Technical Documentation

Consistency, completeness, and high quality of your technical documentation will speed up the conformity assessment process.

IVDR, Annex II/III

1. Device description and specification, including variants and accessories
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benfit-risk analysis and risk management
6. Product verification and validation
7. Technical documentation on post-market surveillance

Technical Documentation

Structural & Formal Issues

Use structural templates or checklists provided by the Notified Body.

if not available, stick to the structure provided by IVDR, Annex II

Naming of documents

logical / unambiguous names

Findability of the data

table of contents, overview of folder structure

Check for completeness

use provided checklists and/or IVDR Annex II/III

Use the IVDR nomenclature

to avoid misunderstandings

Technical Documentation

Consistent Content

Product name: should be consistent in all documents

If older documents contain obsolete names, provide a rationale.

Intended use: consistent content and wording

Provide a separate document for the intended use. All other documentation references to this.

Technical Documentation

Intended Use

- Frequent Source of Error:
  Incomplete Description of Intended Use
  - User (professional user / lay user)
  - Use environment: important for self tests and near-patient tests
  - Patient population not restricted => Do you have data for all age groups?
- Make sure all claims are proven: clincal data in the use environment for near-patient tests und self tests are often missing
- Intended use vs. marketing claims: make sure not to promise more than is claimed in the intended use

Content of the Intended Use:
IVDR
Annex I, 20.4.1(c) or
Annex II, 1.1(c)

Technical Documentation

Classification

- Implementing and classification rules (Annex VIII), use MDCG 2020-16 Rev.2
- The highest rule that applies to your device determines the risk class.
- Function of the assay: screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction => no impact on classification per se!

Class D device stays class D even if it is just a screening test or an aid to diagnosis and to be confirmed by another lab test.

- Classification depends on the specific disorder, condition, or risk factor of interest, and the associated risk for the patient and the general population.
- User: self tests (lay users) are at least class C.

Technical Documentation

Clinical Evidence

- Scientific validity, analytical performance, clinical performance
- **Clinical peformance: How much evidence is needed?**
  - Clinical study:

    Make sure your study design includes all aspects of the intended use (sample type, patient population, and for self tests and near-patient test: use environment and user)
  - Peer-reviewed publications showing clinical data of your device
  - Other sources: „old“ study data
- Is the data sufficient to **support all claims** of your intended purpose?
- Discuss the acceptability of the **benefit-risk ratio**.
- Make sure your PEP and PER contains all elements listed by the IVDR.

Technical Documentation

Further Missing or Insufficient Evidence

- Electrical safety (test reports)
- Software documentation including cybersecurity assessment
- Usability (documentation, studies)
- Risk management: often missing, incomplete, or not kept up to date
    - Insufficient mitigation of risks: reduction of risks as far as possible without adversely affecting the benefit-risk ratio
    - Insufficient risk control measures: often only warnings/precautions/ contra-indications, but safe design and protection measures come first!
    - Evidence that risk control measures are effective is missing!

CONCLUSIONS Lessons learned

- ✓ Have the courage to contact the notified body.
- ✓ Do not extend transitional periods to the extreme.
- ✓ Be sure your technical documentation is complete.
- ✓ Be sure your clinical evidence consists of all required elements.
- ✓ Be sure that all claims of your intended use have been proven.

Thank You for Your Time!

You'd like to talk? I'd love to hear from you!

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