Renewal

MDR+IVDR+UKCA

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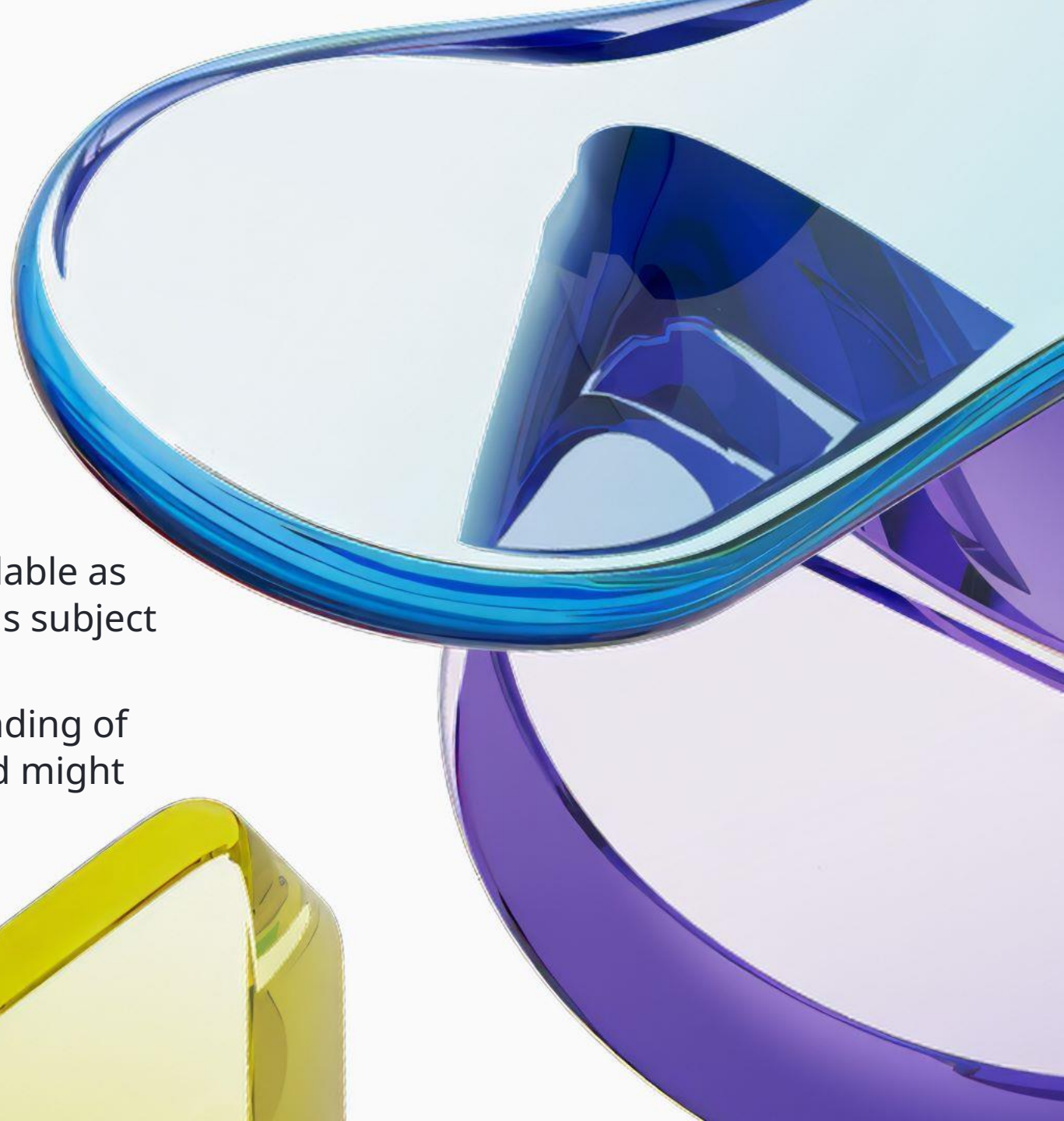
Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter experts.

This presentation presents personal understanding of the medical device requirements in Europe and might not reflect the view of all Notified Bodies.



Agenda

01 Why are we doing renewals?

02 The Renewal Process

03 Quality Certificates

04 Product Certificates

05 What to look out for?

Why are we doing renewals?

Requirements - MDR/IVDR & UKCA

MDR Annex VII 4.11

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience

(c) experience

(d) experience safety and

(e) experience results of

(f) changes to scientific

(g) changes to documents,

(h) changes in

— new tre

— changes in te

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from clinical investigations with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

MDCG 2019-6 Rev 4

IV.12. What are the applicable requirements for re-certification?

Conformity assessment activities to be carried out in case of renewal of certificates/re-certification are laid down in Article 56(2) of the MDR / Article 51(2) of the IVDR, where the Regulations establish that the notified body can extend the validity of the certificate for further periods based on a re-assessment in accordance with the applicable conformity assessment procedures (i.e. as described in annexes IX-XI). In addition, Section 4.11 of Annex VII states that the notified body must use the same methods and principles for the decision on re-certification as for the initial

Furthermore, results of the notified body's evaluation of additional scientific and clinical data and clinical evaluations and post-market information as well as the outcome of latest technical documentation assessments on sampling basis and product tests have to be considered.

For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

UKCA regulation mirrors MDD (Article 11) / IVDD (Article 9)

MDD Article 11 Section 11

11. Decisions taken by the notified bodies in accordance with ►M5 Annexes II, III, V and VI ◄ shall be valid for a maximum of agreed in ls of a

ordance for a ded on t signed ve years.

Certification cycle & maintenance activities

Maximum 5-year validity

Planned Surveillance

- **QMS**
  - CAV/Recert
  - Supplier verification audit
- **Micro**
- **Technical**
  - TD Sampling
  - PSUR
- **UAV**

Unplanned Surveillance

- Vigilance reviews
- Substantial change reviews

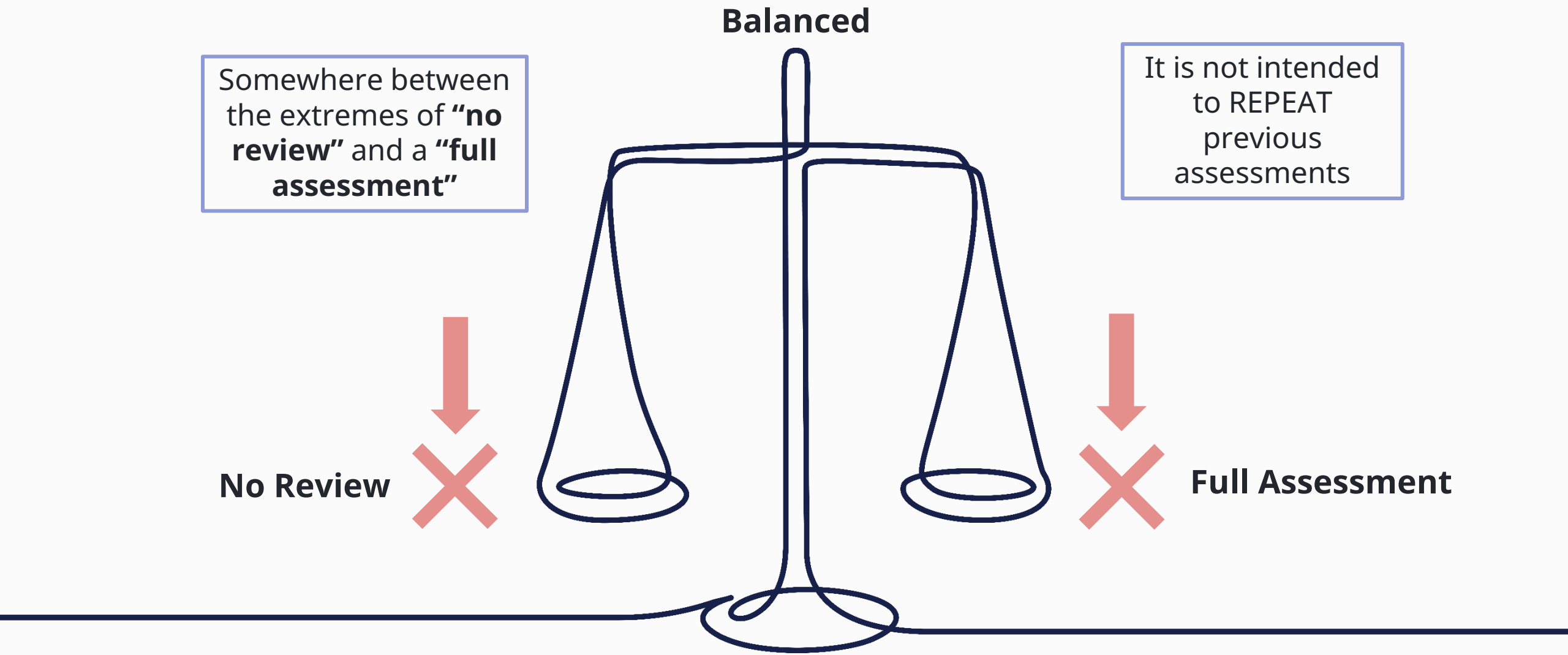
New maximum 5-year validity

Applicable to medical device and *in vitro* diagnostic devices

What is our Approach?

Somewhere between the extremes of **“no review”** and a **“full assessment”**

It is not intended to REPEAT previous assessments



The Renewal Process

Renewal Process Overview

*Reminders sent at 12 and 9 months prior to certificate expiry

Tips

- Submit changes separately not part of renewals
- Consultations with competent authority may be required *(ensure you submit documentation on time)*
- A certificate can be re-issued up to 3 months in advance and maintain the prior expiration date +5 years

Quality Certificates

What needs to be reviewed?

Quality System Certs

- **Summary of all reviews in the 5 years cycle:**
  - Audit Cycle
    - QMS audits
    - Microbiology Audits
    - Unannounced Audits (UAVs)
  - Tech Doc Sampling
    - Tech Reviews, PSURs, SS(C)Ps, PMCF
  - Non-Conformity Status
  - Vigilance / FSCAs

- **List of changes**

- **Clinical Oversight** ***(w/ clinician recommendation)***

<u>As per MDCG and MDR/IVDR:</u>

1. Risk Management
2. Vigilance
3. PMS
4. PMCF
5. UAVs
6. Surveillance Audits
7. Product Tests
8. Scientific and Clinical Data
9. Open NCs
10. Post Certificate Actions and Entropy

Product Certificates

What needs to be reviewed for a renewal?

Technical Doc Certs

- All changes
  - non-substantial & reviewed substantial*
- Risk Management
- Compliance updates (GSPR, standards, etc.)
- PMS + PSUR + SS(C)Ps
- Clinical Evaluation & State of the Art
  - incl. recommendation from clinician

**Not yet implemented substantial changes will be reviewed separately.*

As per MDCG and MDR/IVDR:

1. Risk Management
2. Vigilance
3. PMS
4. PMCF
5. Scientific and Clinical Data
6. Clinical evaluations
7. Changes

What to look out for?

Key things to look out for

1. Be PRO-ACTIVE
2. CHECK what certificates you have that are expiring over the next 12-15 months
3. Be AWARE of any NCs, Follow-Up Actions, Change Notifications, Change in Full-Time Employee #'s *(this can affect audit durations)*, etc.
4. AVOID the pressure of dealing with an expired certificate that may have to be cancelled.

Manufacturer Responsibilities for Recertification

The Legal Manufacturer must provide:

- Approval to conduct the renewal and confirm what certificates / devices are not to renew
- Complete relevant forms requested by the NB
- List of all products currently CE marked
- ISO 13485 certification for all critical subcontractors and crucial suppliers
- Summary of vigilance incidents over last 5 years
- EU rep (if not already present on certificate)
- Changes in the device design, PMS, state of the art, clinical data, etc.

Thank you!

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Transfer

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January 2025

Add value.
Inspire trust.

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Why Transfer?

Common Reasons:

1. Broader or more relevant expertise at the new Notified Body
2. Service Quality – Manufacturer seeks faster review timelines or better communication.
3. Withdrawal or suspension of a Notified Body’s designation
4. Product Scope Expansion – Expansion to new markets or product categories. The current Notified Body does not have expertise in a newly developed product line (e.g., combination products).
5. Cost or Resource Considerations – High costs of maintaining certification or better terms offered by another Notified Body.
6. Others..

Types of Transfer

ISO **13485** Transfer

MDR Transfer – full scope

Transfer of Surveillance (MDD-MDR) – **Confirmation Letter**

- **Transfer of certification due to (EN) ISO 13485:** The change of the Certification Body (“CB”) for the scope of certification assessment procedure and the related transfer of certificates from another CB into the responsibility of a new CB according to the standard (EN) ISO 13485.

- **Transfer of certification due to MDR**: The change of the Notified Body (“NB”) for the scope of conformity assessment procedure and the related transfer of certificates from another NB into the responsibility of a new NB according to MDR.

- **Voluntary transfer:**
  - The manufacturer parts with the outgoing NB/issuing CB although the outgoing NB/issuing CB can continue to provide its service, or
  - the outgoing NB/issuing CB parts with the manufacturer although he continues to produce the same devices the outgoing NB/issuing CB has certified (e. g. dissolution of service agreement),

- **Enforced/Involuntary (unintended) transfer:** e. g. because of conflicts between client and outgoing NB/issuing CB resulting in withdrawal of certification, refusing the execution of any surveillance by outgoing NB/issuing CB

MDR Transfer – voluntary change of Notified Body

MDCG 2019-6 Rev4

Questions and answers:

Requirements relating to notified bodies

Revision 4 - October 2022

Medical Devices

Medical Device Coordination Group Document MDCG 2019-6-Rev.4

performed is traceable and available from e.g. report(s) which are mentioned in the certificate.

IV.4. What are the applicable requirements for voluntary certificate transfer under MDR Article 58 / IVDR Article 53?

While MDR Article 58(1) / IVDR Article 53(1) sets out the requirements for a transfer agreement, it does not specify the conformity assessment activities to be performed by the incoming NB.

The incoming NB may decide not to carry out full conformity assessment activities according to Article 52 MDR / Article 48 IVDR, as long as it does have sufficient information in respect to the conformity activities performed by the outgoing NB.

For quality management system certificates, the incoming NB needs to perform appropriate on-site audit(s) and assessments to ensure that the manufacturer in question applies the approved QMS and the post-market surveillance plan prior to the issue of any certificate. In respect to the assessment of technical documentations on a sampling basis, the incoming NB shall review the previous assessment results together with a sample of a technical documentation and draw up or amend a sampling plan.

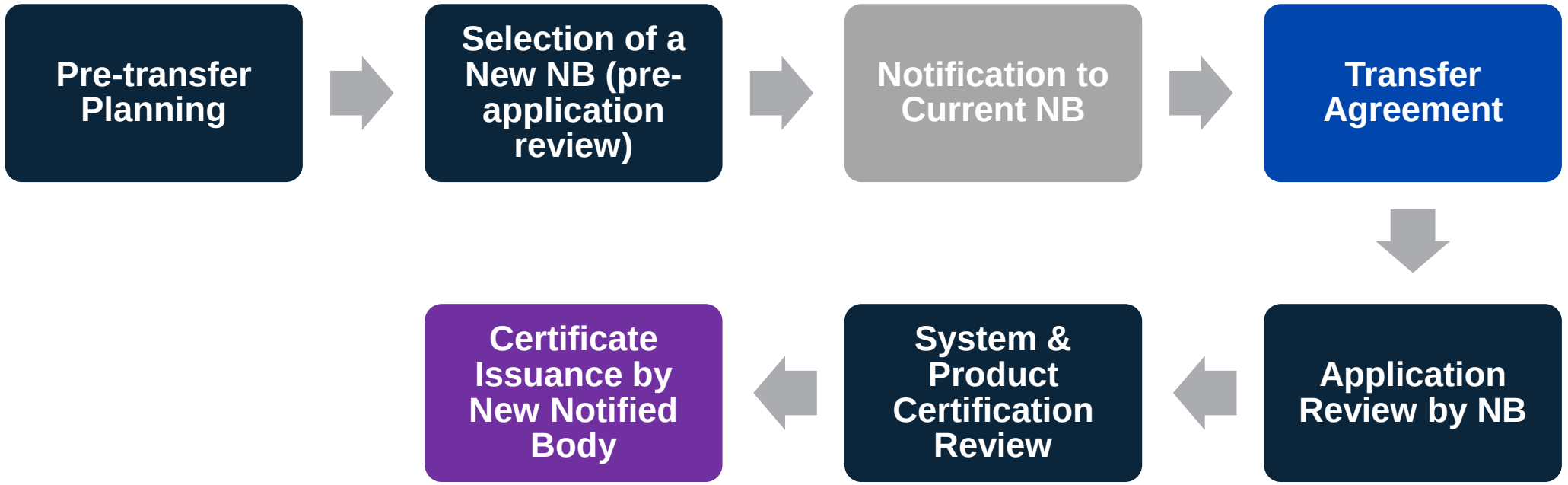
QMS

For product certificates (Annex IX Chapter II/Annex X), new certificates without a comprehensive (initial) review may be issued as long as the documentation received does not identify ongoing existing or other concerns.

Product

The incoming NB assumes full responsibility for the new certificates issued following the transfer.

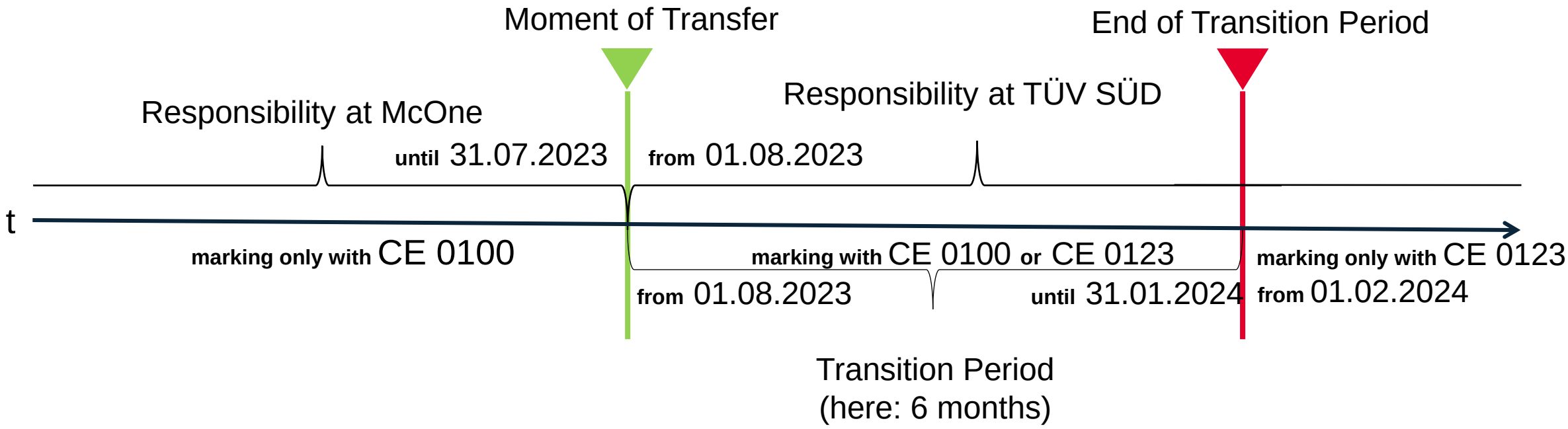
Key Steps in the MDR Transfer Process



MDR: Transition Period

Example:

- Applicant wants to transfer from Notified Body McOne (CE0100) to TÜV SÜD (CE0123),
- Moment of Transfer: 31.07.2023 / 01.08.2023,
- Transition Period by default: 6 Months (but can be negotiated individually).



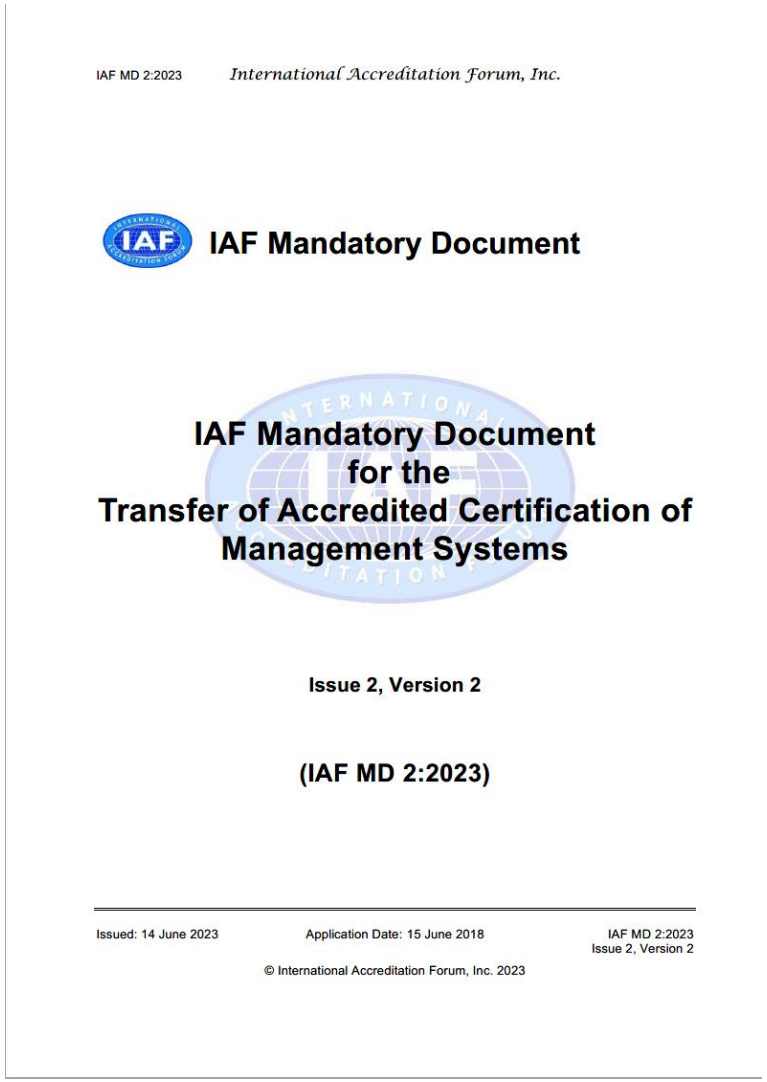
MDR Transfer of Surveillance –
Confirmation Letter Transfer

- 15. March 2023: the EU Commission released Regulation 2023/607, revising Article 120, Regulation (EU) 2017/745 (MDR)

- The regulation allows both the NBs and the manufacturers of medical devices to extend the transition period for the implementation of the MDR from May 2024 to the end of 2027 or the end of 2028

- Transfer of Surveillance due to EU Regulation 2023/607 → change of responsibility for surveillance activities from a NB (outgoing NB) to another NB (incoming NB) for “legacy devices”.
  - Tripartite Agreement (“Transfer Agreement for Surveillance of Legacy Devices”),
  - Manufacturer and NB must have **signed an agreement** by 26. September 2024,
  - There is no need of a successful Application Management Review – this can also be performed while transition period (until end of 2027 / end of 2028).
  - New Confirmation Letter issued by incoming NB
  - Responsibility of Surveillance is transferred to incoming NB

Transfer of Certification due to EN ISO 13485 – change of CB



IAF MD 2:2023 *International Accreditation Forum, Inc.*

IAF Mandatory Document

IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

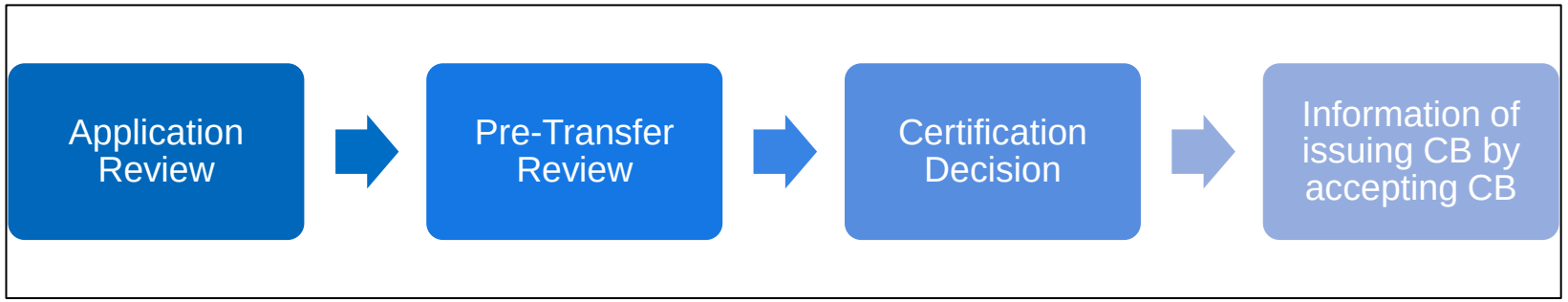
Issue 2, Version 2

(IAF MD 2:2023)

Issued: 14 June 2023 Application Date: 15 June 2018 IAF MD 2:2023 Issue 2, Version 2

DAkkS

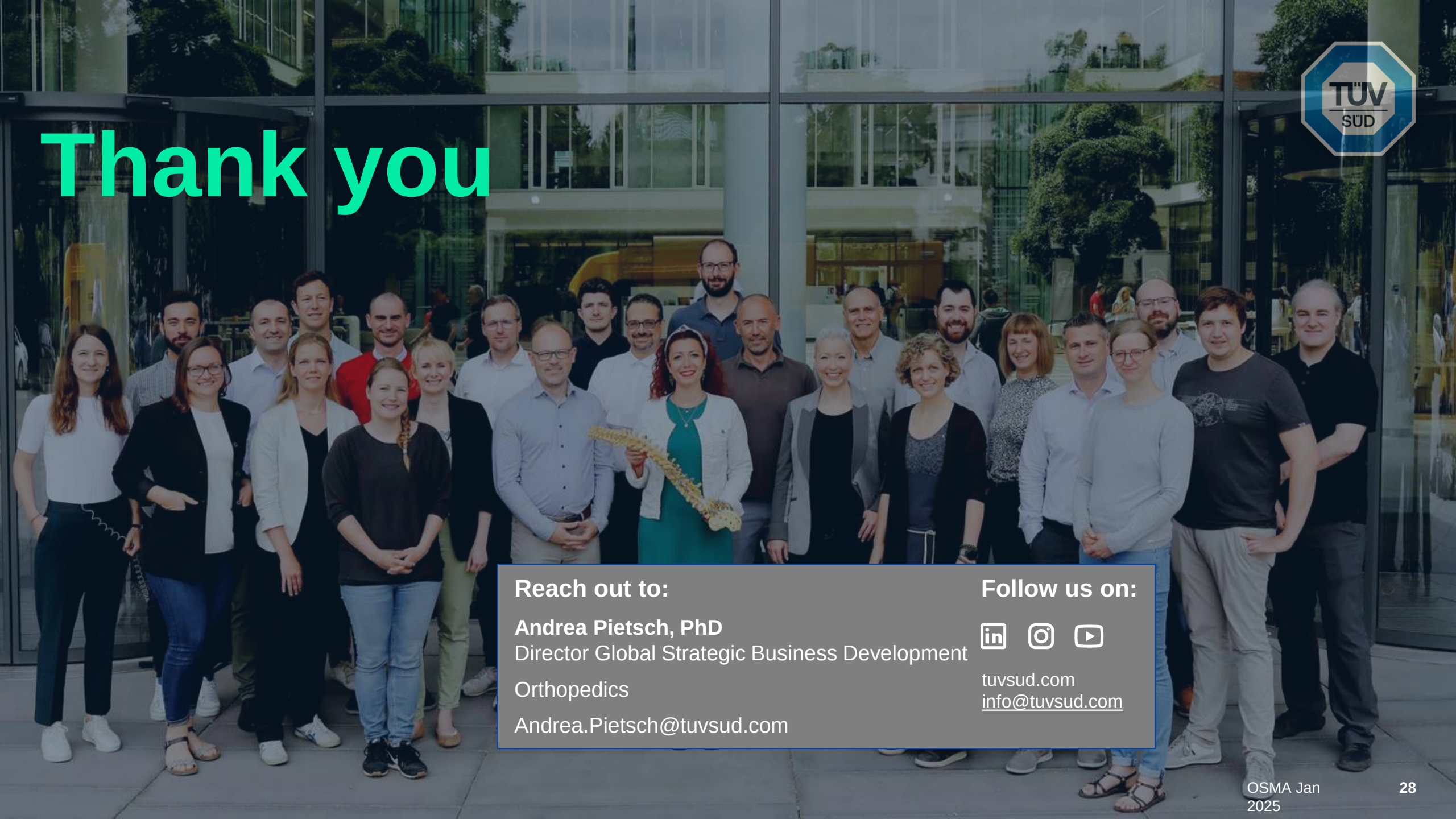
- Documents define basic requirements for transfer of certification
- Multiple certification is not encouraged / not supported by IAF and DAkkS
- A Transfer Agreement is not needed for the transfer of certificate(s) due to EN ISO 13485
- Pre-transfer visits are possible if there are outstanding major NCs / confirmation of certification is needed.



Transfer: Summary & Key takeaways

- Transferring a Notified Body under MDR is a complex but manageable process if done with proper planning.
- Key success factors include early preparation, internal readiness, and strong **communication**.
- For high-risk devices like orthopedic implants, early engagement with a designated NB/CB and thorough documentation review are critical to avoid regulatory gaps during the transfer process.
- A full conformity assessment according to Article 52 MDR is **not** necessary as long as sufficient information in respect to conformity activities performed by the outgoing Notified Body is available
- a transfer of certification after expiry / loss of validity of the certificate to be transferred is not possible. Instead of a transfer an initial certification must be performed.
- ISO 13485: no transfer agreement is needed!
- Post-Transfer Activities: Update all relevant documentation (e.g., QMS, declarations of conformity, labeling) to reflect the new NB details (name and number). Prepare for any follow-up audits required by the new NB.

Thank you



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TÜV SÜD: A Holistic Approach for Medical Devices

Testing

Biocompatibility

Chemical Characterization

Microbiology

Packaging

MRI Safety

Electrical Safety

Mechanical

EMC

Environmental

Functional Safety

Wireless

Cybersecurity

Certification

MDR

IVDR

MDSAP

ISO / EN ISO 9001, 13485

UKCA

Notified Body Transfer