Transfer of MDR / IVDR / UKCA Certification to BSI

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Poll
Question x 2

Agenda

1. Overall Approach to Transfers
2. PSUR, QMS Onsite & Scheme Manager Reviews
3. Tripartite Transfer Agreements
4. Devices with Medicinal or Biological Substances
5. Transfer + Renewal
6. Transfer of MDR/IVDR Applications for legacy devices
7. Transfer of Appropriate Surveillance
8. How to Get Started
9. Open Q&A Session

MDR/IVDR/UKCA Transfers

Certified Devices

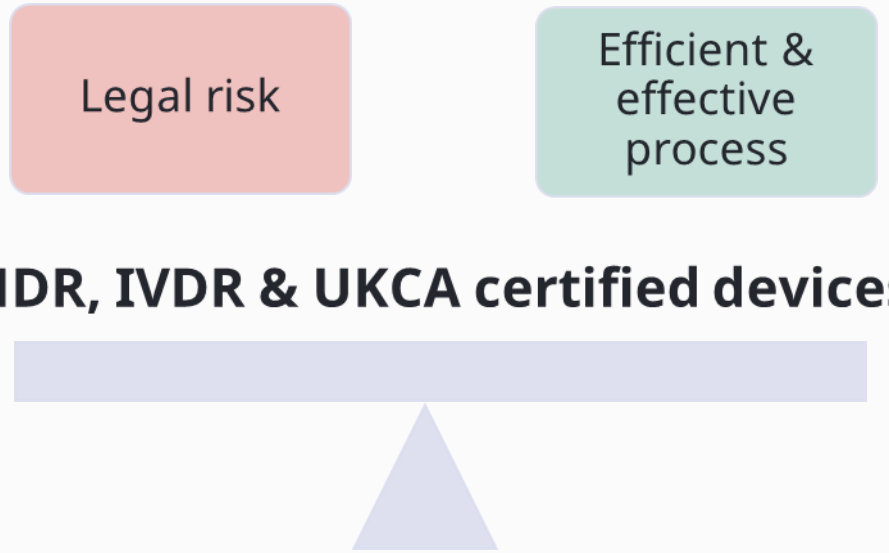
BSI Guiding Principles for Transfers

Assessments from previous Notified/Approved Bodies are **leveraged and not repeated.**

Transfer assessments **targeted to PSUR or renewal assessments to perform due diligence.**

This reduces cost by focusing on reviews that are needed in the certification cycle.

Simple. Predictable. Transparent.



Transfer Process Summary

Transfer Type	QMS Annex Certificates	Product Annex Certificates
QMS Review	1-day Onsite **QMS Transfer Review**	
Transfer Only	**PSUR assessment** – **ONE** device to be sampled **per** product family (DSubC or GDG). **Maximum THREE product families.** **Duration:** 4-8 hours per device.	**PSUR Assessment** – **Every device** to be assessed. **Duration:** 4-8 hours per device.
Transfer + Renewal*	**PSUR assessment** – ONE device to be sampled **per** product family (DSubC or GDG). **Maximum THREE product families.** **Duration:** 4-8 hours per device for PSUR assessments **+** 2-4 days for renewal review.	**Renewal assessment** (5-year certificate validity to be given at transfer). **Duration:** 2-4 days per device* *0.5 to 1 day for devices with medicinal agents, animal tissue or human tissue.

*This includes an option for Specific High-Risk Devices (see next slide)

*Specific High-Risk Devices

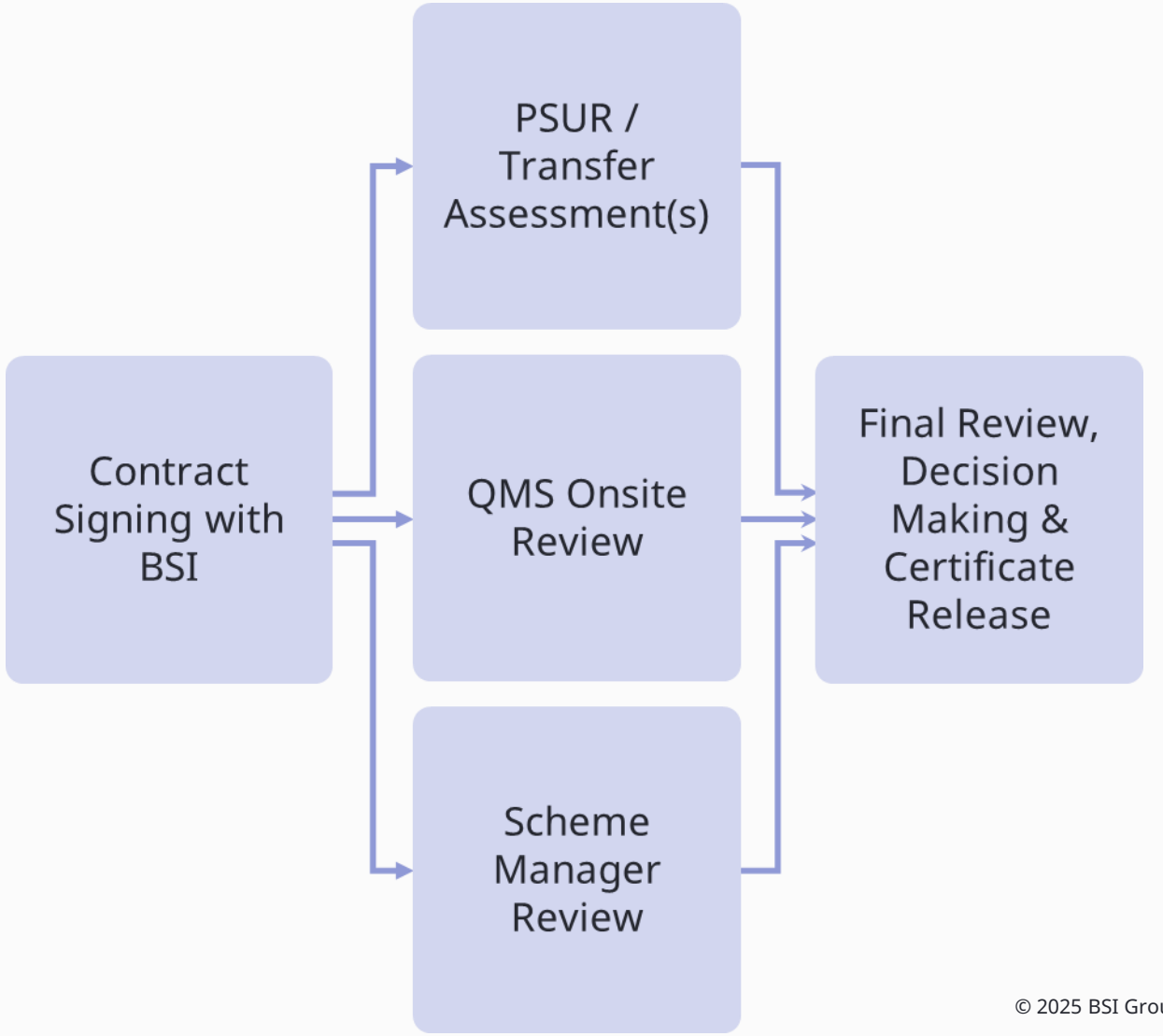
Currently a lot of **scrutiny from health authorities** – in Europe & across the globe for:

Pelvic floor mesh
Textured breast implants
Metal-on-metal joint replacements

This list is subject to change in future

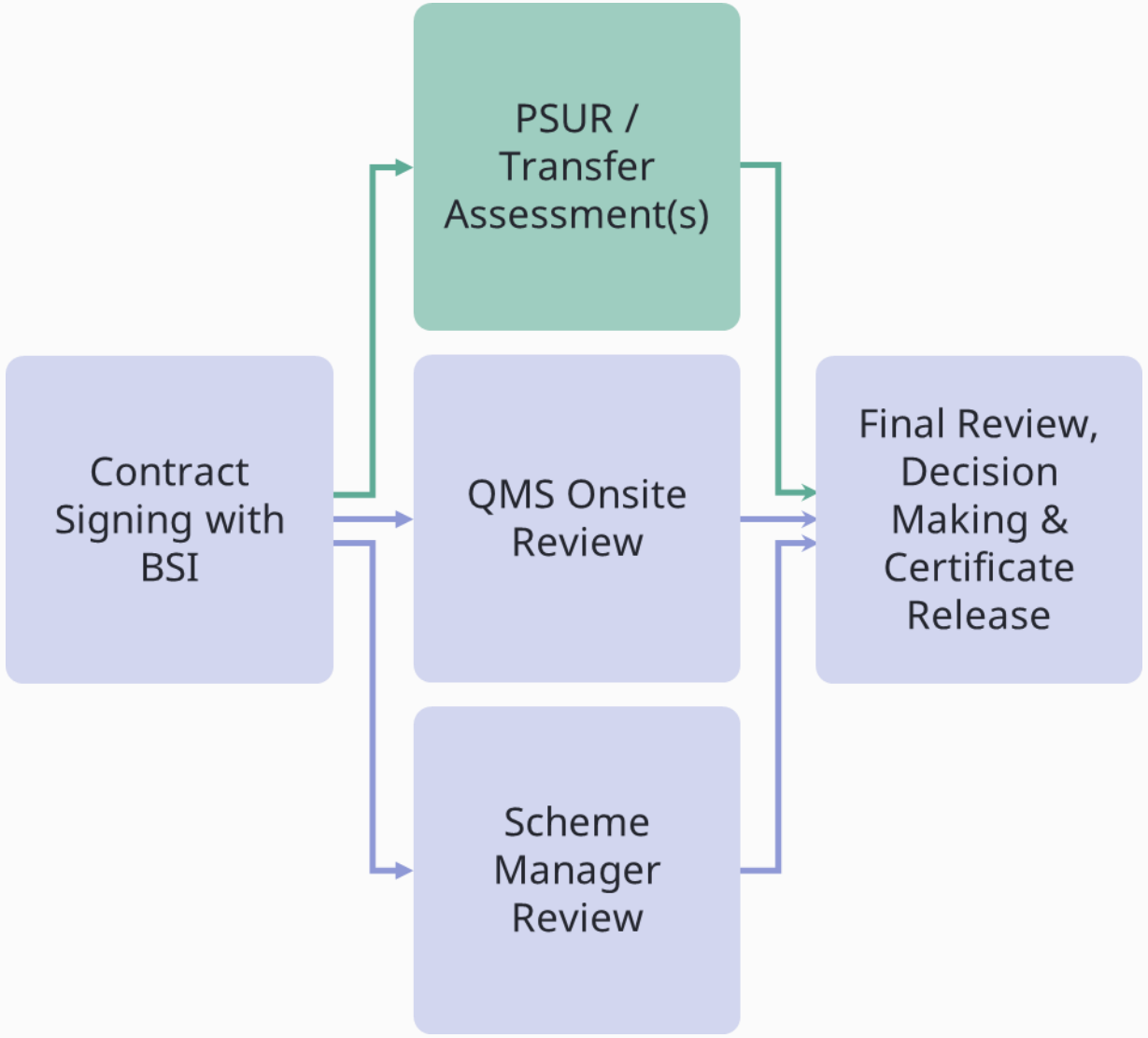
- ✓ These specific devices require a **Transfer + Renewal:**
  - ✓ **Full clinical** review (**no PSUR only** review)
  - ✓ Benefit of **full 5-year certificate validity** at Transfer

Structure of Transfer Process



PSUR Review

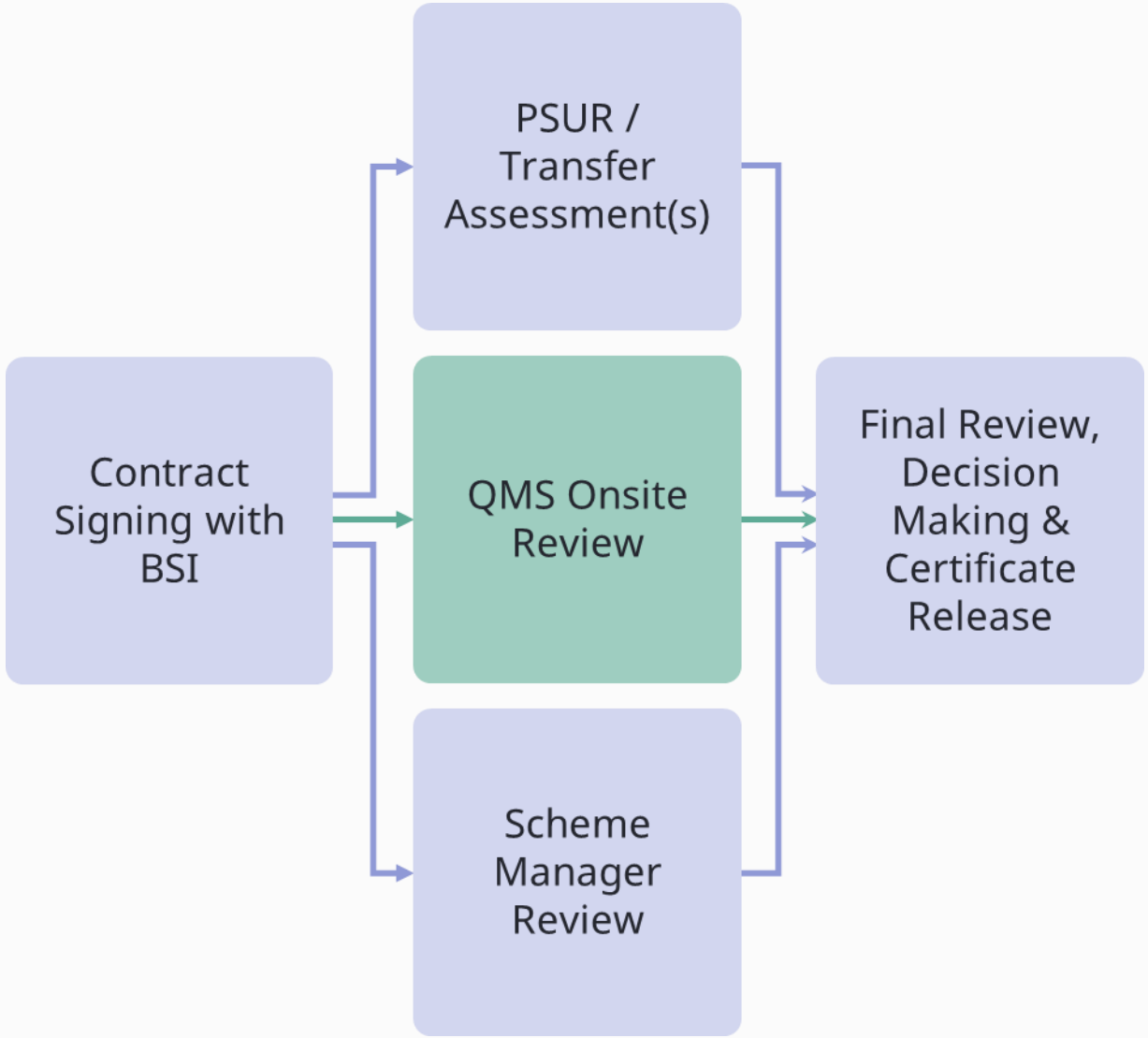
- Reviews and assessments are **run in parallel** to reduce time.
- Performed to ensure that there are **no post-market safety, or performance, concerns.**
- **PSUR Reports uploaded to EUDAMED for Class III and Implantable devices** to count toward the certificate cycle.
- If a PSUR is not available, **equivalent PMS data** can be reviewed.
- A **post-hoc review** can be performed **if concerns are raised**. Any **additional reviews** will be discussed **prior to start**.



QMS Onsite Review

- **One Day Onsite Review**, like a Stage 1 QMS audit, covering high level items (e.g. check for NCs, any CAPAs in place, audit reports supporting the devices to be transferred).

- **Open NCs** from the previous Notified / Approved Body **reviewed**:
  - **MAJOR NCs** – **Must be closed** by the previous NB/AB **prior to Transfer** recommendation.
  - **MINOR NCs** – **Closed by previous NB/AB** if possible.



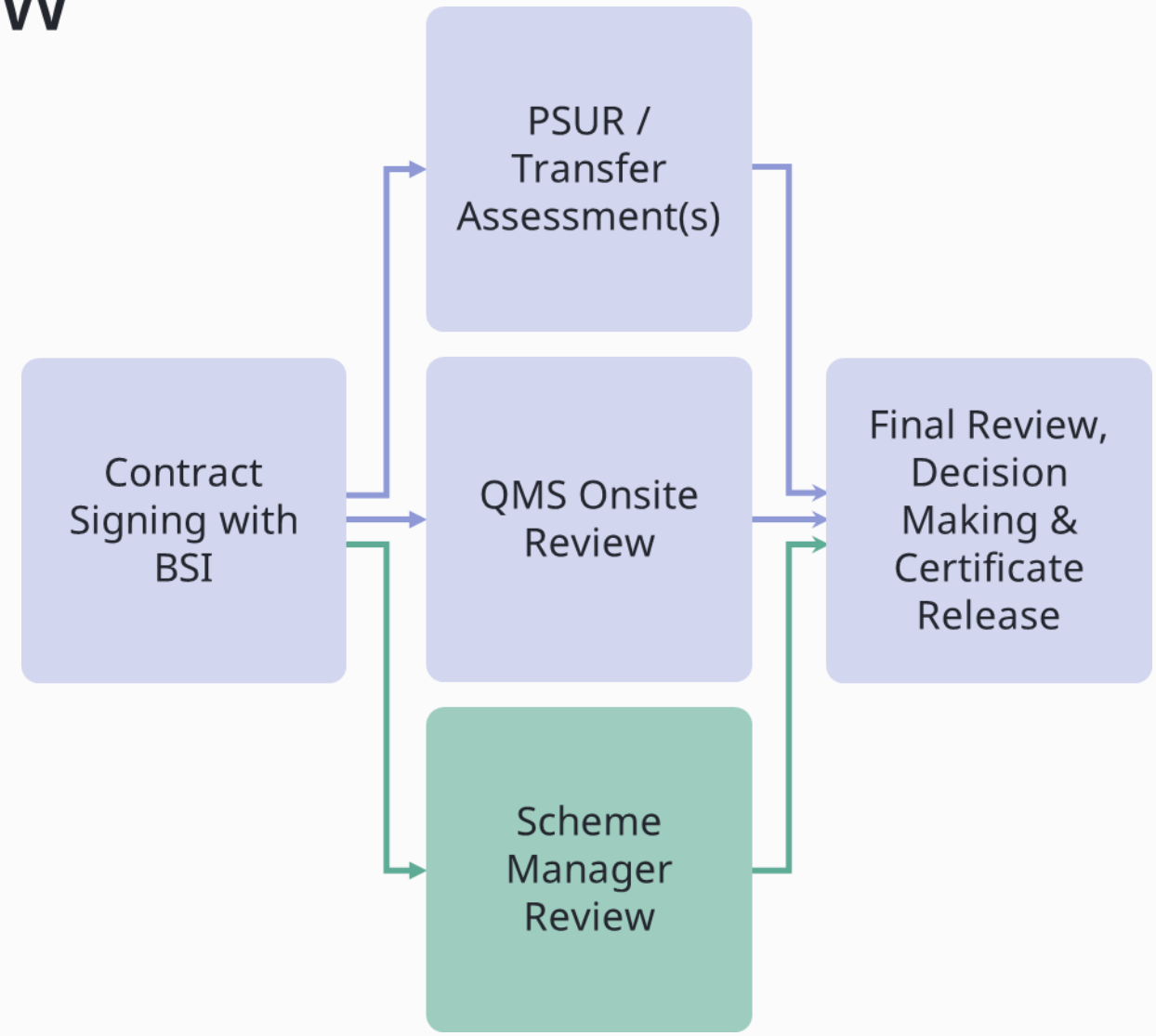
Role of the Scheme Manager

- Introduces themselves to the manufacturer and acts as main contact point for the transfer.
- Conducts the pre-transfer review.
- Ensures that appropriate competence is used for the pre-transfer review and calls on assistance where required.
- Submits the completed transfer review to the Decision Making team.

BSI Structured Dialogue available for Transfer Process

Scheme Manager Review

- **Main** point of **contact** for the Transfer.
- **Ensures** that **all reviews** have been **completed**.
- **Review** of current **certificates**, manufacturing **sites** and **subcontractors**.
- **Coordinates tripartite agreement** between manufacturer, previous NB/AB and BSI. **Required** unless not practicable.
- Prepares the **recommendation for Transfer**.

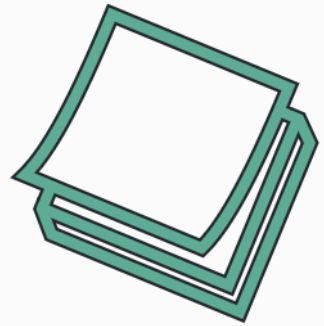


Tripartite Transfer Agreement

- **BSI Tripartite Agreement** is based on Team-NB Transfer Agreement V02-20240702. The scope has been expanded to cover UKCA.
- **Prior to signing**, any requested changes must be **approved by the BSI Legal Department** or **Head of NB/AB**.
- The **Appendices** of the Transfer Agreement **include details of the certificates and devices to be transferred**, along with **transition timing**.
- **BSI** will generally **sign last** to ensure that all information included in the Appendices is **accurate at the time of signing**.

Appendix 1 – Certification Subject to Transfer

Current and valid OUTGOING NB certificate number and revision (see § 1 (3))	Scheme	Scope, or part thereof, to be transferred - as displayed on the current OUTGOING NB certificate	Imposed restrictions on the valid and not-suspended certificate or other relevant information	Agreed TRANSFER DATE (see § 1 (4))
		☐ Full Scope ☐ Partial scope:		☐ Not yet known
		☐ Full Scope ☐ Partial scope:		☐ Not yet known
		☐ Full Scope ☐ Partial scope:		☐ Not yet known

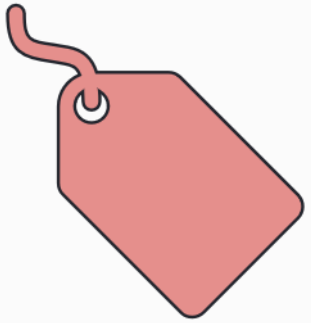


Tripartite Transfer Agreement - Labelling Transition

- BSI **Scheme Manager** will liaise with the **Manufacturer** to **agree on the transition timing for device labelling** with the outgoing NB/AB number. This also **applies to brochures and promotional materials**.
- The **last lot/serial number** that the outgoing NB/AB is responsible for is **documented on the BSI Tripartite Agreement**.
- The transition period **should not exceed 6 months**. In justified cases this period may be prolonged.

Appendix 2 – Transition Provision

Device in the scope of certification subject to transfer	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed TRANSITION PERIOD (see § 3 (4)) If not explicitly specified, the TRANSITION PERIOD is 6 months from the TRANSFER DATE.	Agreed SELL-OFF DEADLINE (see § 3 (4)) If not explicitly specified, the SELL-OFF DEADLINE is the end of TRANSITION PERIOD.
	☐ Not yet available	☐ Not explicitly specific	☐ Not explicitly specific
	☐ Not yet available	☐ Not explicitly specific	☐ Not explicitly specific
	☐ Not yet available	☐ Not explicitly specific	☐ Not explicitly specific



Devices with Medicinal or Biological Substances

Review **limited** to **confirmation** that required **consultations** have taken place.

If required consultations were not performed by the previous Notified/Approved Body, **consultation may need to be completed before transfer**.

For reviews transferring to BSI **during the application process, BSI can take over the consultation** from the previous Notified/Approved Body.

Transfer + Renewal

Renewal form is completed by the manufacturer and reviewed by a BSI expert reviewer.

The following are reviewed:

- Manufacturing sites and subcontractors
- Changes to the device since original certificate issue
- PSUR reviews and SS(C)P revalidation during the certificate cycle
- Review of risk management file and PMS data
- Recertification Assessment of Clinical Data.
  Focused on changes during the certification cycle, PMS/ PMCF data and changes in the state of the art.

Dedicated Interactive Review available for Transfer & Renewal

5 Steps to a Smooth Certificate Transfer

CE / UKCA Transfer Process

Step 1: *Understanding, planning and documentation*

Goals for transfer defined.
Device schedule provided.

Step 2: *Contract Signed*

Scheme manager and reviewers assigned.
Reviews scheduled.

Step 3: *BSI Due Diligence*

PSUR or renewal review(s).

Scheme manager review of certificates, sub-contractors and documentation.

Onsite QMS review.

Step 4: *Certificate & decision making*

Mock certificate(s) signed.
Final review and Panel Review

Step 5: *Certificate Issuance*

Receive BSI certificate.
Devices can be placed on market with notified body number.

ISO 13485 Transfer Process

Step 1: Transfer Onsite review

Step 2: Certification review

Step 3: Certificate decision

Step 4: Certificate awarded

Step 5: Continuous audit visit cycle resumes

MDR/IVDR Transfers

Legacy devices in application

EXTENSION OF THE MDR TRANSITIONAL PERIOD AND REMOVAL OF THE 'SELL OFF' PERIODS

Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices
REV. 2

JULY 2024

Health and Food Safety

It is possible to transfer MDR/IVDR Applications (without losing legacy certificate validity) if the transfer is not due to non-compliances (potentially) leading to refusal from previous NB

9.1. What happens if the application is withdrawn or the written agreement terminated?

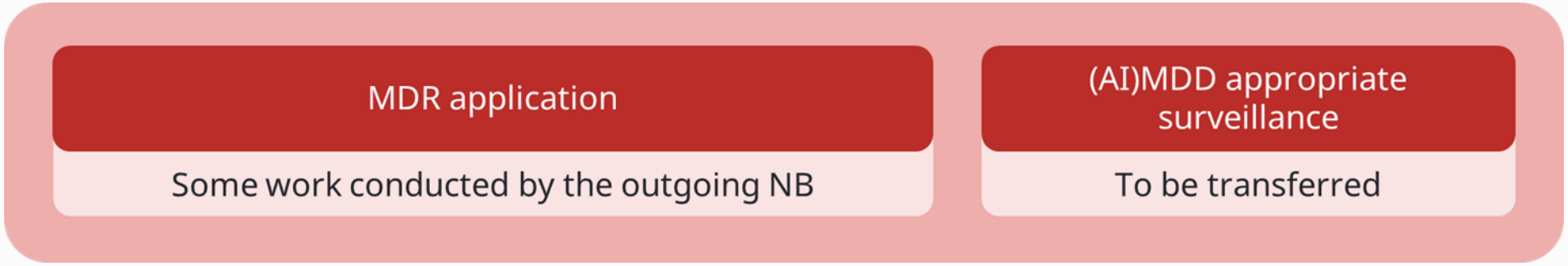
If, after the relevant deadlines, the manufacturer withdraws its application for conformity assessment, or if the written agreement between notified body and manufacturer is terminated, the conditions set out in Article 120(3c), point (e), MDR are not met any more; the transitional period therefore ceases to apply. However, if the manufacturer or the notified body terminates the written agreement and the manufacturer simultaneously enters into a written agreement with another notified body, to which the application is transferred, the conditions set out in Article 120(3c), point (e), MDR are considered to be still met and the transitional period continues to apply, provided that also the other conditions are met. The arrangements for the change of notified body should be defined in an agreement between the manufacturer, the incoming notified body and the outgoing notified body in analogy with the principles laid down in Article 58 MDR. This kind of change of notified body may occur, for example, when the manufacturer intends to make use of available capacity of another notified body e.g. when the incoming notified body has been newly designated under the MDR or when the outgoing notified body has capacity constraints. The manufacturer should make sure that the documentation demonstrating that its legacy device benefits from the extended transitional period is updated after the change of notified body, such as its self-declaration and the notified body's confirmation letter (see question no 7 of this document).

In contrast, the transitional period should not continue to apply where, after the relevant deadlines, the manufacturer changes the notified body as a reaction to the notified body's reasoned decision to refuse the manufacturer's application or to refuse the issuance of a certificate due to non-compliance with relevant MDR requirements.

Scenarios

Scenario n.1

Scenario n.2



These scenarios are also applicable for IVDR application & IVDD appropriate surveillance

MDR/IVDR Transfers – Legacy devices in application

Scenario n.1

No conformity assessments completed by the previous NB

All activities/assessments typically required for a new device:

- QMS – Stage 2 scope extension audit (after initial transfer review)
- Micro audit if required
- TD assessments as per usual processes
- Medicinal, Animal, EURL etc. as per usual processes for new devices

Key Principle: Treat devices 'in application' as **new devices** with some exceptions as shown in Scenario n.2...

MDR/IVDR Transfers – Legacy devices in application

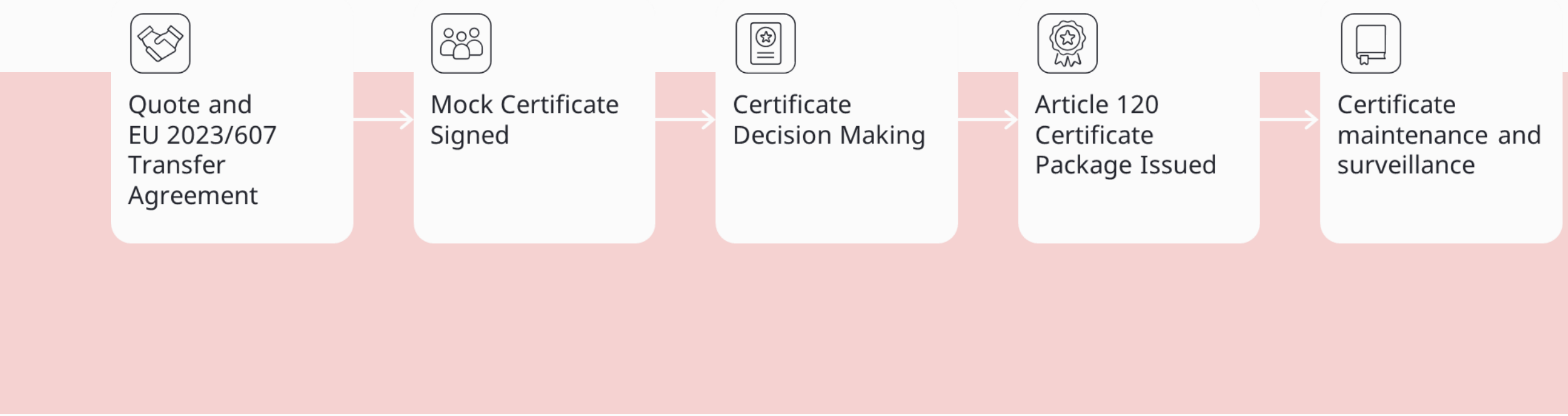
Scenario n.2

Partial conformity assessments completed by previous NB

All activities/assessments typically required for a new device unless detailed TDAR/CEAR/Assessment forms/consultation reports that provide sufficient detail are available:

- QMS – Stage 2 scope extension audit (after initial transfer audit); Durations may be reduced if detailed QMS audit reports available.
- Micro audit if required.
- TD assessments as per usual unless detailed reports/forms available that allow verification of compliance to requirements.
- External consultations – Medicinal, Animal, EURL testing, PECP, CECP – Leverage where possible if already completed. If not completed, undertake as per new device.

Transfer of Appropriate Surveillance for Legacy Devices



The Benefits of BSI Transfer Reviews

Transfer reviews are design to be as efficient as possible to accelerate the transfer process.

Transparent

BSI Scheme Manager assigned to answer any questions during the transfer.

Project Manager assigned to track all reviews and activities.

Predictable

A start to finish User Guide is available to walk manufacturers through the transfer process.

All required documents are listed, so the manufacturer knows what to provide and when it is needed.

Flexible

The manufacturer can choose transfer only or transfer + renewal based on the certificate cycle.

Minor changes can be reviewed in parallel with the transfer.

Leadership

Sets BSI apart as a leader in our field delivering a truly premier service.

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BSI Medical Devices

Certification services to support global market access goals.

A leading full scope Notified Body (2797)

A leading full scope UK Approved Body (0086)

A recognized Auditing Organization under the Medical Device Single Audit Program (MDSAP)

A Conformity Assessment Body and a registered Certification Body in many global markets

An accredited ISO 13485 Certification Body

Incorporated by Royal Charter. The first UK National Standards Body.

Next Steps …

For enquiries, please write to

medicaldevices@bsigroup.com

Q&A

Thank you for joining us today