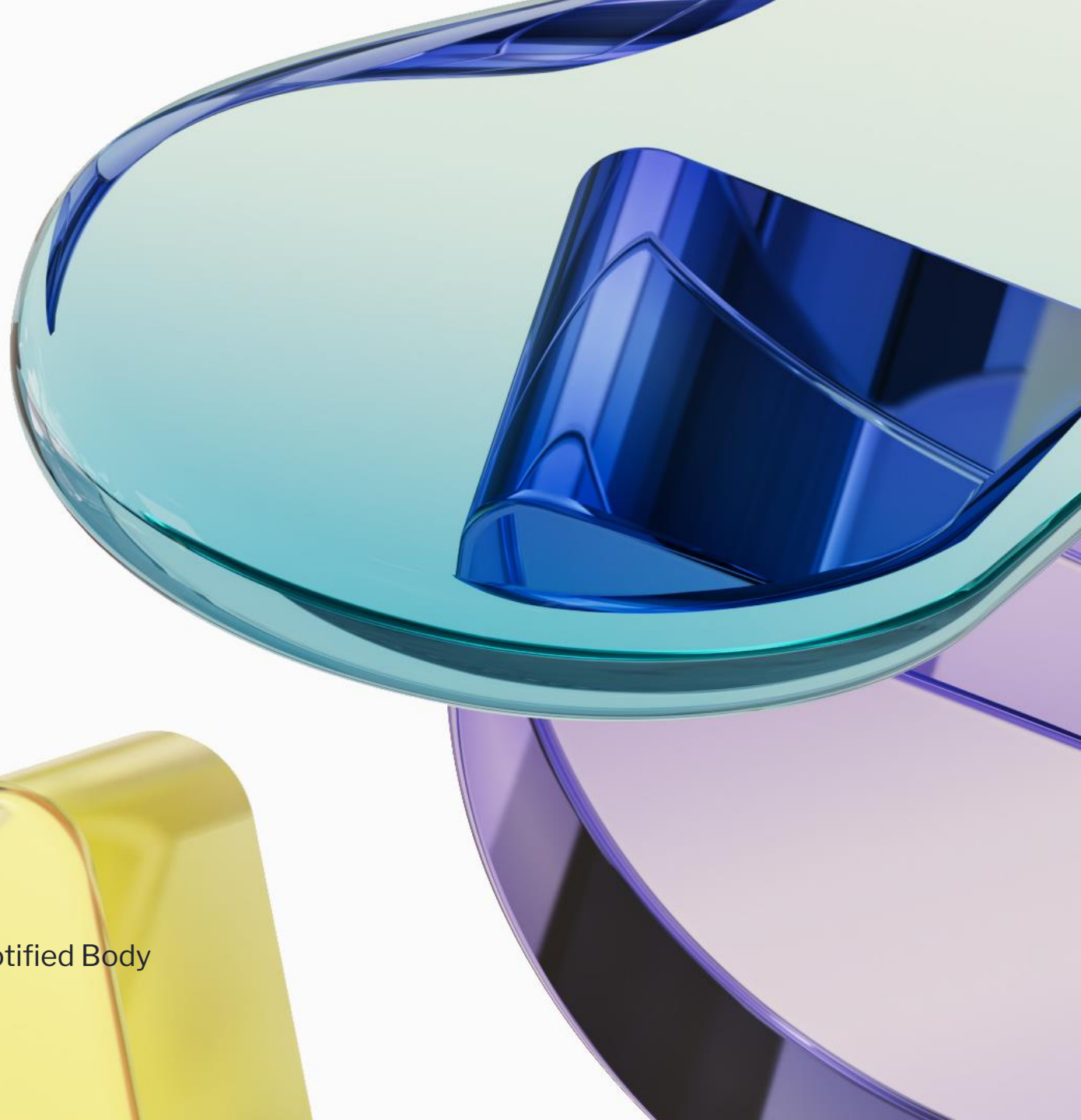
Amending Regulation (EU) 2023/607 and possible pitfalls



Maddalena Pinsi

Sr. Regulatory Lead & Associate Head of Medical Devices Notified Body

26 March 2024

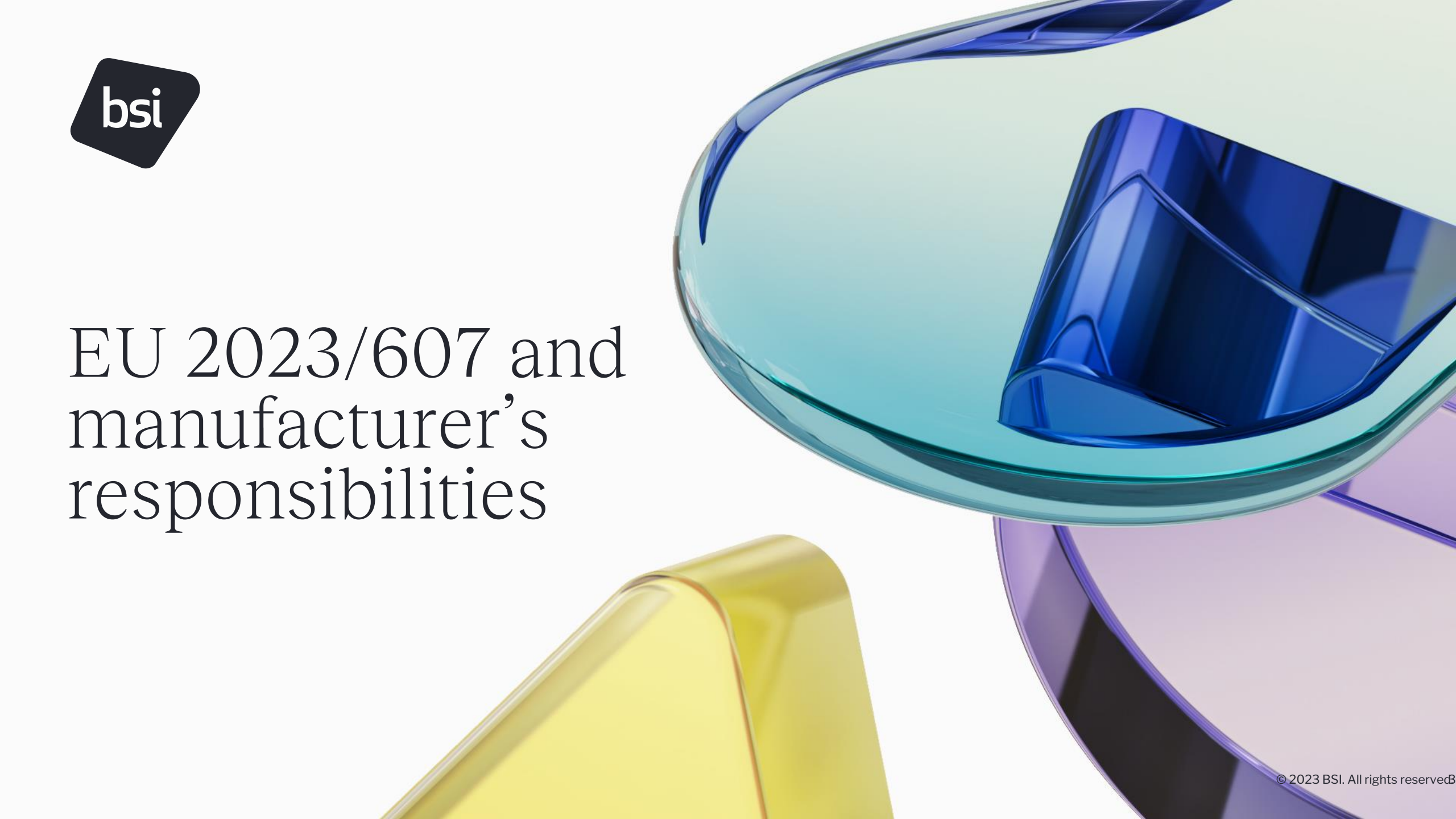
Agenda

01
EU 2023/607 and manufacturer’s responsibilities

02
EU 2023/607 Non-compliance – NB Actions and consequences

03
BSI implementation of EU 2023/607

EU 2023/607 and manufacturer’s responsibilities



EU 2023/607

Published and came into effect on the 20th March 2023

Extend the validity of AIMDD/MDD certificates and the transitional period

AIMDD/MDD certificate validity automatically extended by law to end of 2027 or 2028 (based on classification under MDR) if certain conditions are met

NBs WON'T change the expiry dates of their AIMDD/MDD certificates nor renew them

Transfer of appropriate surveillance

Allows transfer of appropriate surveillance under Directives to the MDR NB (mandatory by the 26 Sept 2024 for legacy devices transferring to MDR)

Sell-off provisions in MDR and IVDR abolished

Once placed on the market under the Directives, devices can be further made available for unlimited time

EU 2023/607 – Extended transitional timelines

AIMDD/MDD certificate validity automatically extended by law to end of 2027 or 2028 (based on device classification under MDR) if certain conditions are met

[1] Only for legacy devices whose Declaration of Conformity (DoC) was signed by 26 May 2021 (e.g., Class Ir)

[2] The sell-off period has been removed. Legacy devices placed on the market before the end of the transition period can be made further available on the market without legal time restrictions

Well-established technologies (WET): sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

EU 2023/607 - Scenarios

Manufacturer <u>does NOT intend to transition</u> legacy device to the MDR

<u>Directive Certificate was valid</u> at the time of the publication of the Amending Regulation (EU) 2023/607 (20 March 2023)	*<u>Directive Certificate expired</u>* prior to the publication of the Amending Regulation (EU) 2023/607 (20 March 2023)

Manufacturer <u>intends to transition</u> legacy device to the MDR

<u>Directive Certificate was valid</u> at the time of the publication of the Amending Regulation (EU) 2023/607 (20 March 2023)	*<u>Directive Certificate expired</u>* prior to the publication of the Amending Regulation (EU) 2023/607 (20 March 2023)

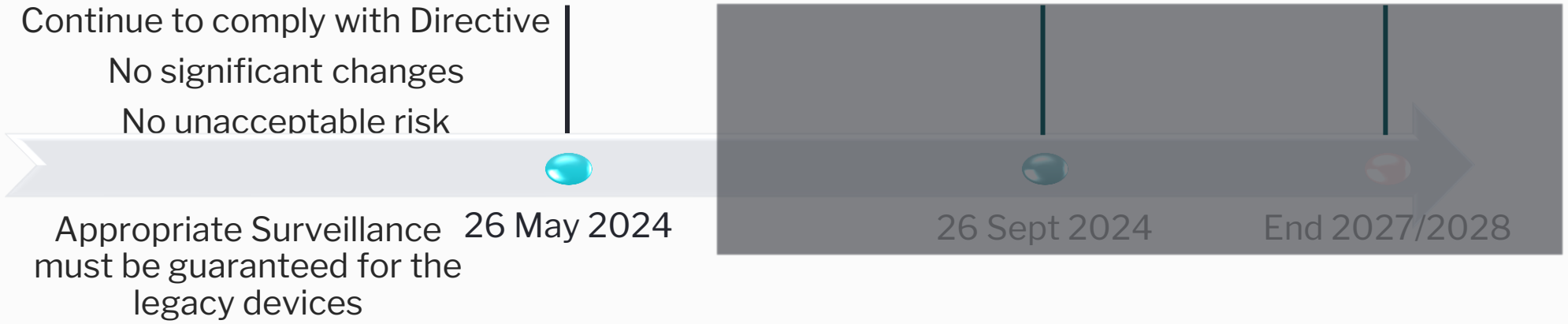
Leaflet on BSI website
https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-application-deadline-en-gb.pdf

Refer to EU Commission flowchart *"Conditions and deadlines for placing 'legacy devices' and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607"* to assess whether or not a device is covered by the extended transitional period.

EU 2023/607 - Scenarios

Manufacturer does not intend to transition legacy device to the MDR

Allowed to continue placing on the market legacy devices until **26 May 2024**, if the below conditions are met:



If the *Directive Certificate expired* prior to 20 March 2023

A derogation/exemption must have been granted by a Competent Authority under either Article 59(1) or Article 97(1) of the MDR before 20 March 2023

Manufacturer's responsibilities for benefitting from the extended transitional timelines

Until 26 May 2024

Legacy device continues to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable

Manufacturer needs to ensure that the appropriate surveillance for the legacy devices they intend to place on the market is maintained by the NB

No significant changes in the design or intended purpose are allowed (MDCG 2020-3 rev.1)

Legacy device does 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 intention to transfer to MDR

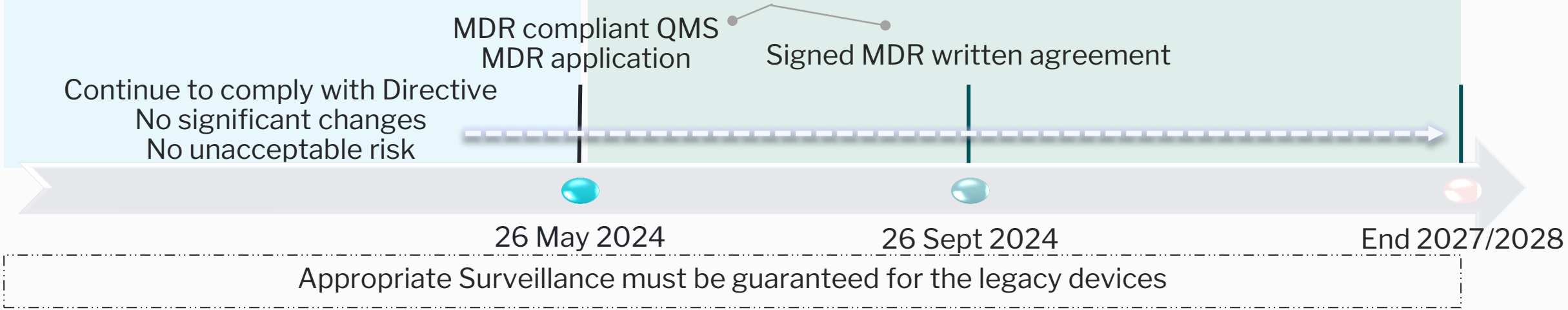
Legacy devices not transitioning to MDR cannot be placed on the market after the 26 May 2024

EU 2023/607 - Scenarios

Manufacturer intends to transition legacy device to the MDR

Allowed to continue placing on the market legacy devices until **26 May 2024**, if the below conditions are met:

They can also benefit from the longer validity of Directive Certificates **(until the end of 2027/2028)** if the following additional conditions are met:



If the *Directive Certificate expired* prior to 20 March 2023

Derogation/exemption granted by a C.A. [MDR Art.59(1) or Art.97(1)] before 20 March 2023
OR
MDR application and signed MDR written agreement prior to Directive certificate expiry

Manufacturer's responsibilities for benefitting from the extended transitional timelines

Condition	Up to the 26 May 2024	From 27 May 2024 and up to the 26 Sept 2024	From the 27 Sept 2024 until the end of 2027/2028
Legacy device continues to comply with applicable Directive	✓	✓	✓
Manufacturer to ensure that the appropriate surveillance for the legacy devices they intend to place on the market is maintained by the NB	✓	✓	✓
No significant changes in the design or intended purpose are allowed (MDCG 2020-3 rev.1)	✓	✓	✓
Legacy device does not present an unacceptable risk	✓	✓	✓
Manufacturer's quality management system in compliance with MDR Article 10(9)	In place by 26 May 2024	✓	✓
Lodged a formal application for MDR conformity assessment in respect of the legacy device or in respect of a device intended to substitute that device	Lodged by 26 May 2024		
The manufacturer and the NB (MDR NB) has signed a formal agreement for MDR conformity assessment		By the 26 Sept 2024	
Appropriate surveillance of legacy devices to be placed on the market is transferred to the MDR NB (where different from the Directive NB)		By the 26 Sept 2024	Maintenance of appropriate surveillance for eligible legacy devices

POLL QUESTION N.1

If you intend to transition your legacy devices to MDR, have you already applied with a Notified Body under MDR conformity assessment?

- Yes
- No

EU 2023/607 – Manufacturer Implementation

EU Commission Q&A on practical aspects related to the implementation of (EU) 2023/607

EU Commission Q&A, Q. 7

The manufacturer should be able to provide a **self-declaration** confirming that the conditions for the extension are fulfilled, stating the end date of the transition period

Manufacturer Self-Declaration

We declare that the following devices comply with..

a) Cont. compliance to Directives

b) No sign changes in design or intended purpose

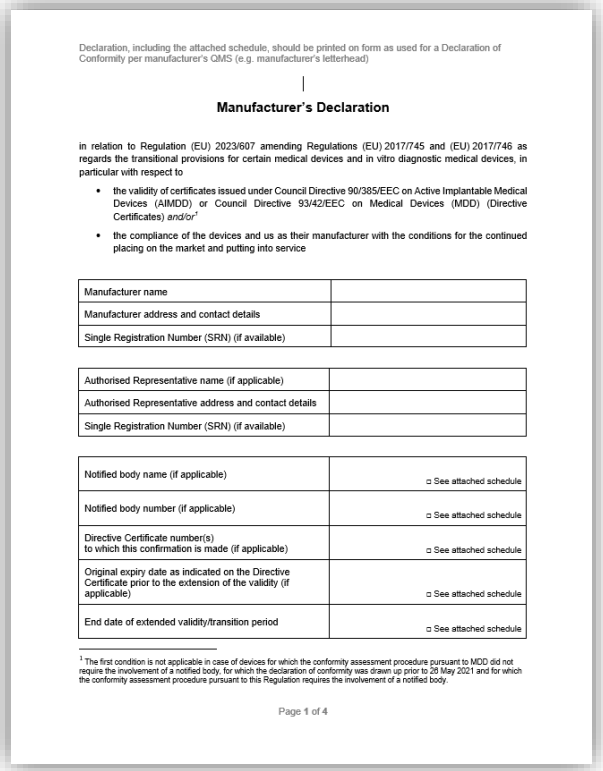
c) No safety concerns

d) MDR compliant QMS by 26 May 2024

e) MDR application by 26 May 2024 and written agreement by 26 Sep 2024

XXXXX YYYY/MM/DD

Template for self-declaration



Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	
Manufacturer address and contact details	
Single Registration Number (SRN) (if available)	

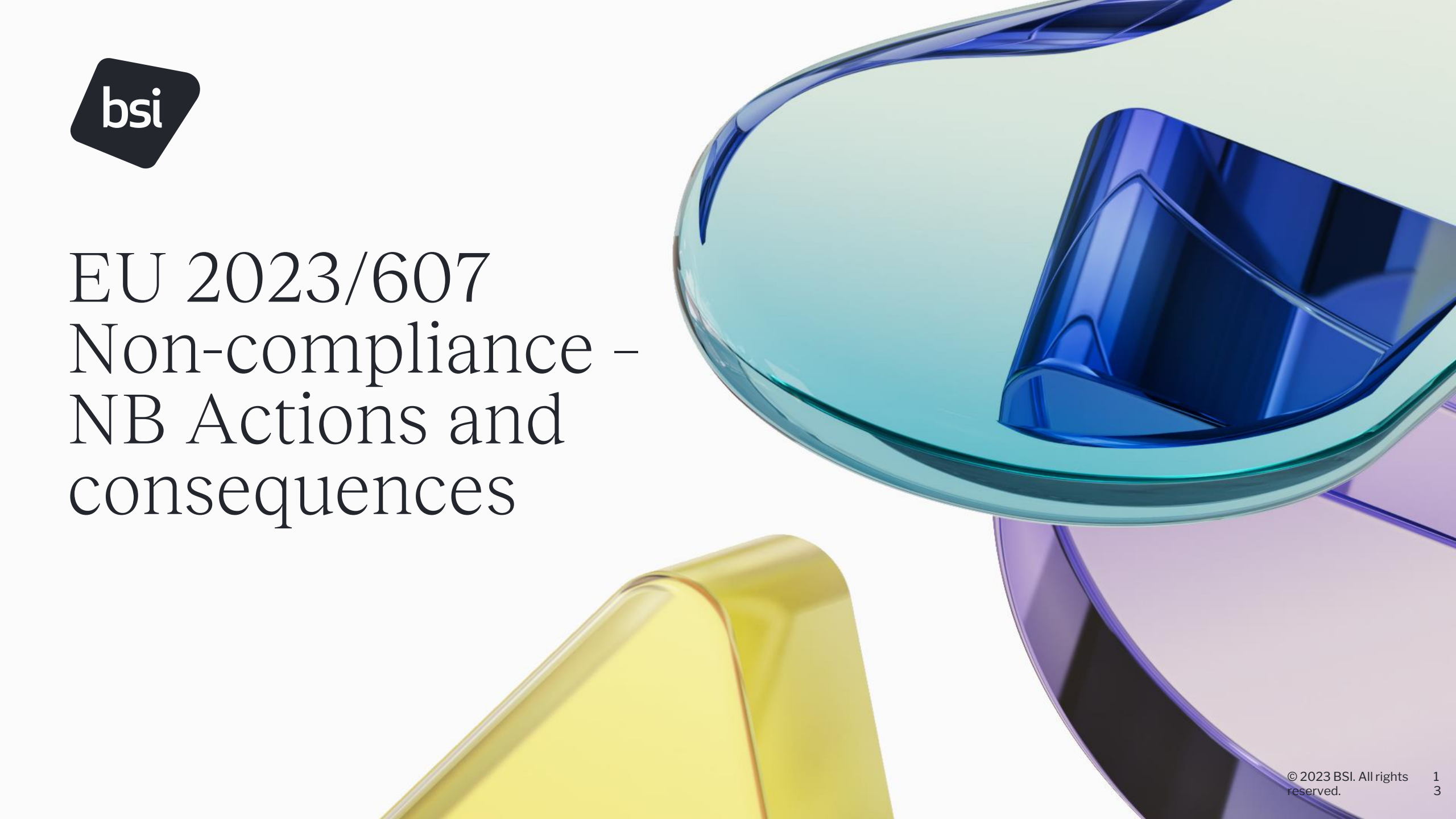
Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	☐ See attached schedule
Notified body number (if applicable)	☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☐ See attached schedule
End date of extended validity/transition period	☐ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Page 1 of 4

EU 2023/607 Non-compliance – NB Actions and consequences



EU 2023/607 Non-compliance - NB Actions and consequences

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

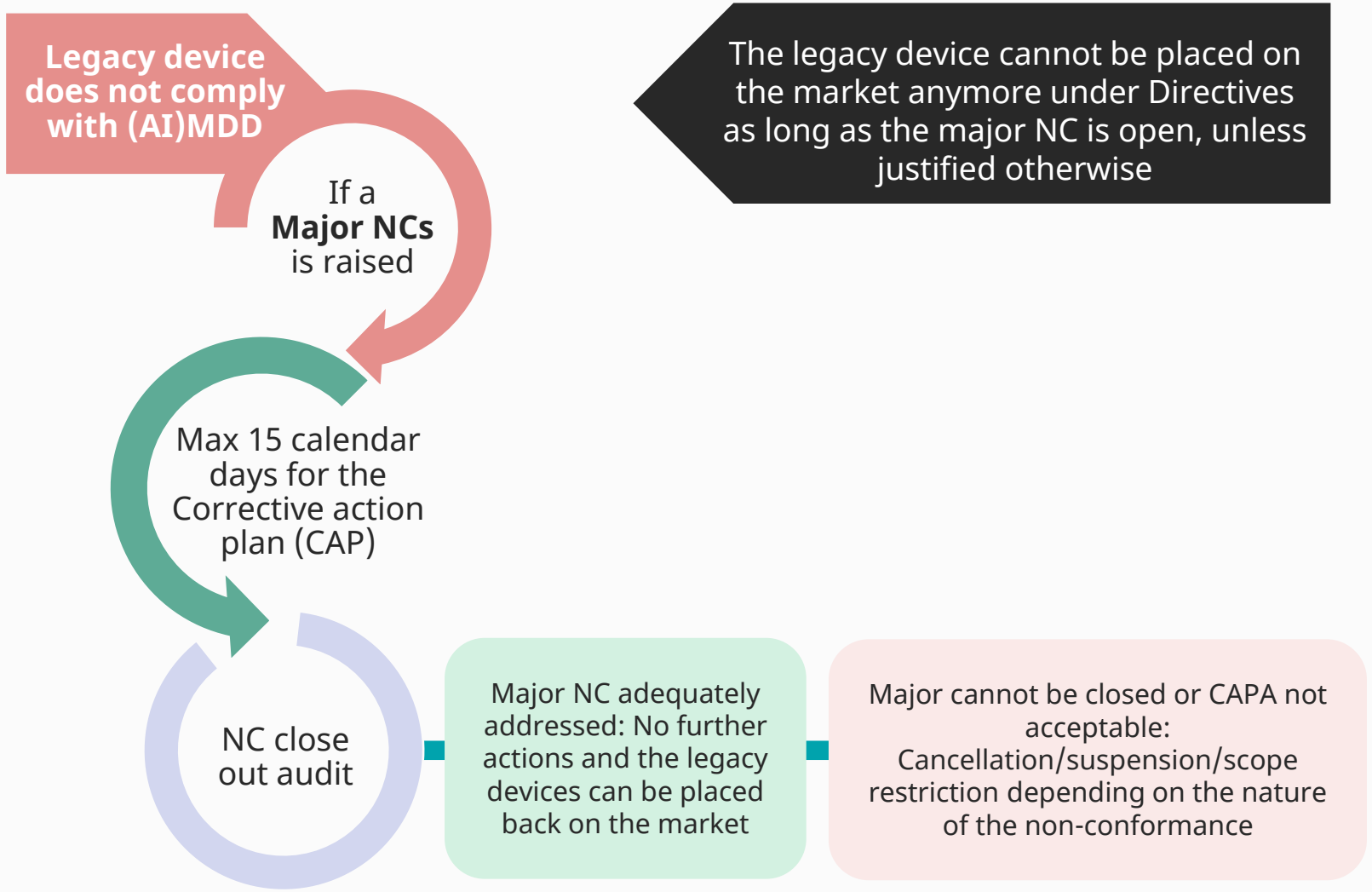
a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

b) there are no significant changes in the design and intended purpose;

c) 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;

d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.



EU 2023/607 Non-compliance – NB Actions and consequences

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

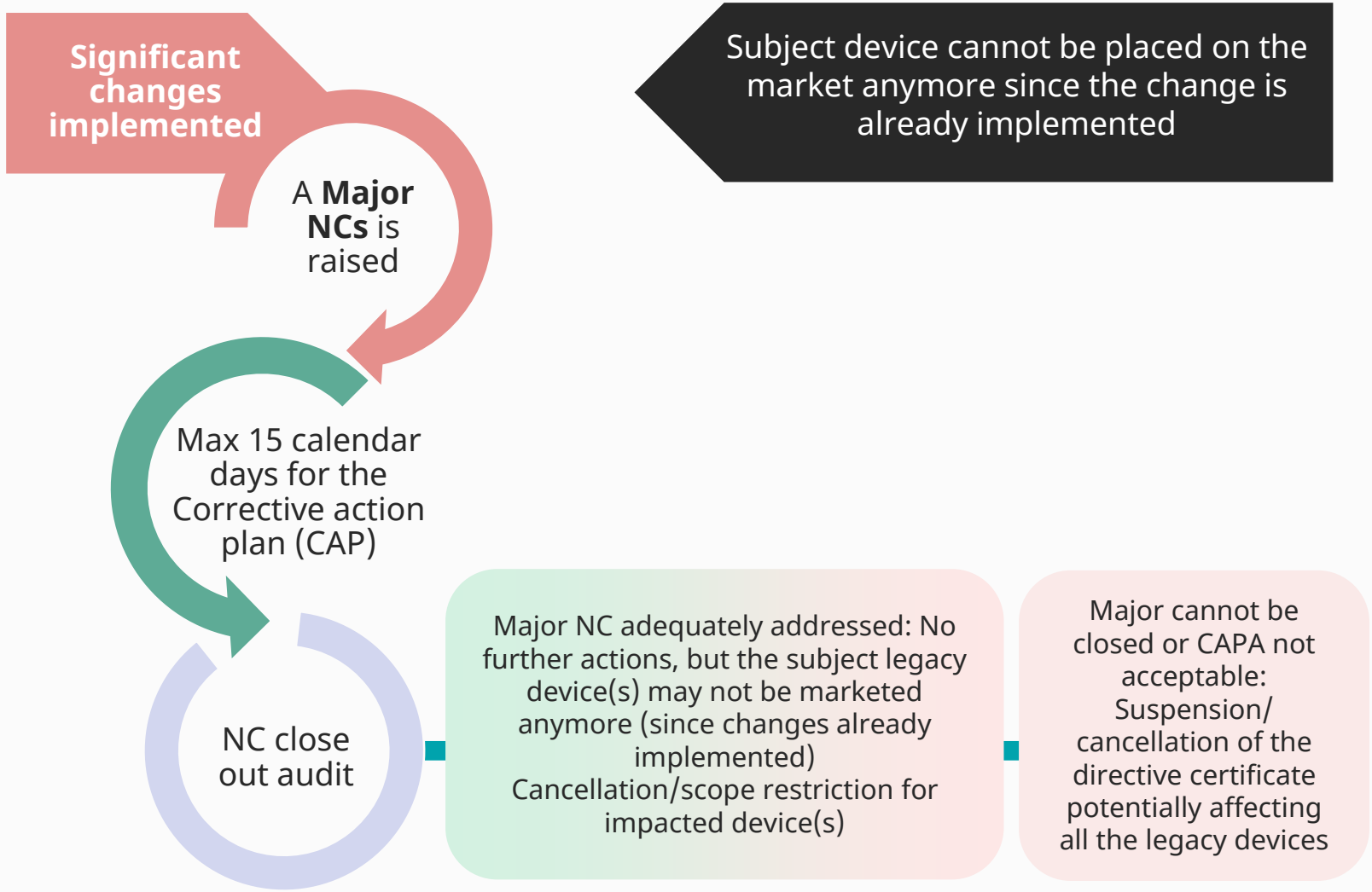
a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

b) there are no significant changes in the design and intended purpose;

c) 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;

d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.



Legal manufacturer changes and consequence on legacy devices

EU Commission Q&A, Q. 9.2

Administrative changes concerning the manufacturer's organisation (e.g. changes of the manufacturer's name, address or legal form, including a merger or acquisition involving the manufacturer) should generally not be considered as changes in the design or intended purpose[12]. They are therefore possible without impact on the transitional period.

Not covered are situations where the manufacturer certified under the MDD/AIMDD transfers device(s) covered by those MDD/AIMDD certificate(s) to another manufacturer who intends to place those device(s) on the market under the MDR, unless the manufacturer indicated on the MDD/AIMDD certificate and the manufacturer seeking MDR certification are part of the same larger organisation.

[12] ***MDCG 2020-3*** *Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023), section 4.2. and footnote 17.*

MDCG 2020-3 Rev.1

Changes concerning the manufacturer's organisation (administrative changes) or changes concerning the manufacturing process should generally not be considered changes in the design or intended purpose within the meaning of Article 120(3c), point (b) MDR, even if they need to be reflected in the information to be supplied with the device (e.g. label or instructions for use).

This includes for example:

- changes of the manufacturer's name, address or legal form, including a merger or acquisition involving the manufacturer[17]

[17] *This does apply only in cases where the legal entity certified under the directive(s)* ***continues to exist****. Not covered are situations where the manufacturer certified under the directive(s) will transfer device(s) covered by those directive certificate(s) to another manufacturer who will place these device(s) on the market under the MDR.*

AIMDD/MDD Legal manufacturer different than MDR Legal Manufacturer

AIMDD/MDD Legal Manufacturer

- Can request the NB to **restart/continue appropriate surveillance** for the legacy devices
- The AIMDD/MDD Legal Manufacturer cannot request a confirmation letter, but just the restart/continuation of appropriate surveillance

MDR Legal Manufacturer

- Can request the NB to issue a **confirmation letter**
- The confirmation letter will list the devices under MDR application and the corresponding AIMDD/MDD devices/certificates issued to the AIMDD/MDD Legal Manufacturer

EU 2023/607 Non-compliance – NB Actions and consequences

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

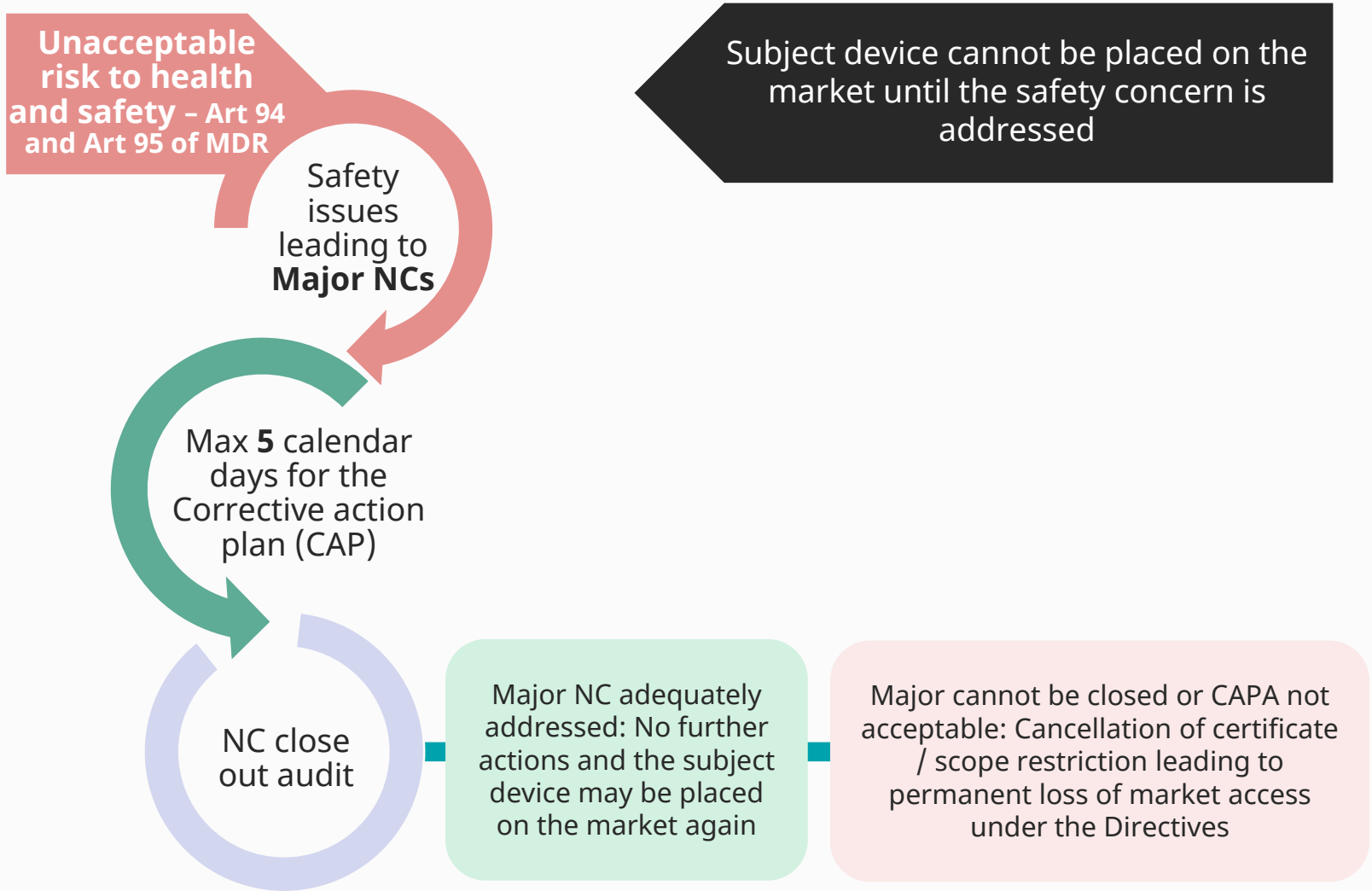
a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

b) there are no significant changes in the design and intended purpose;

c) 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;

d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.



EU 2023/607 Non-compliance – NB Actions and consequences

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

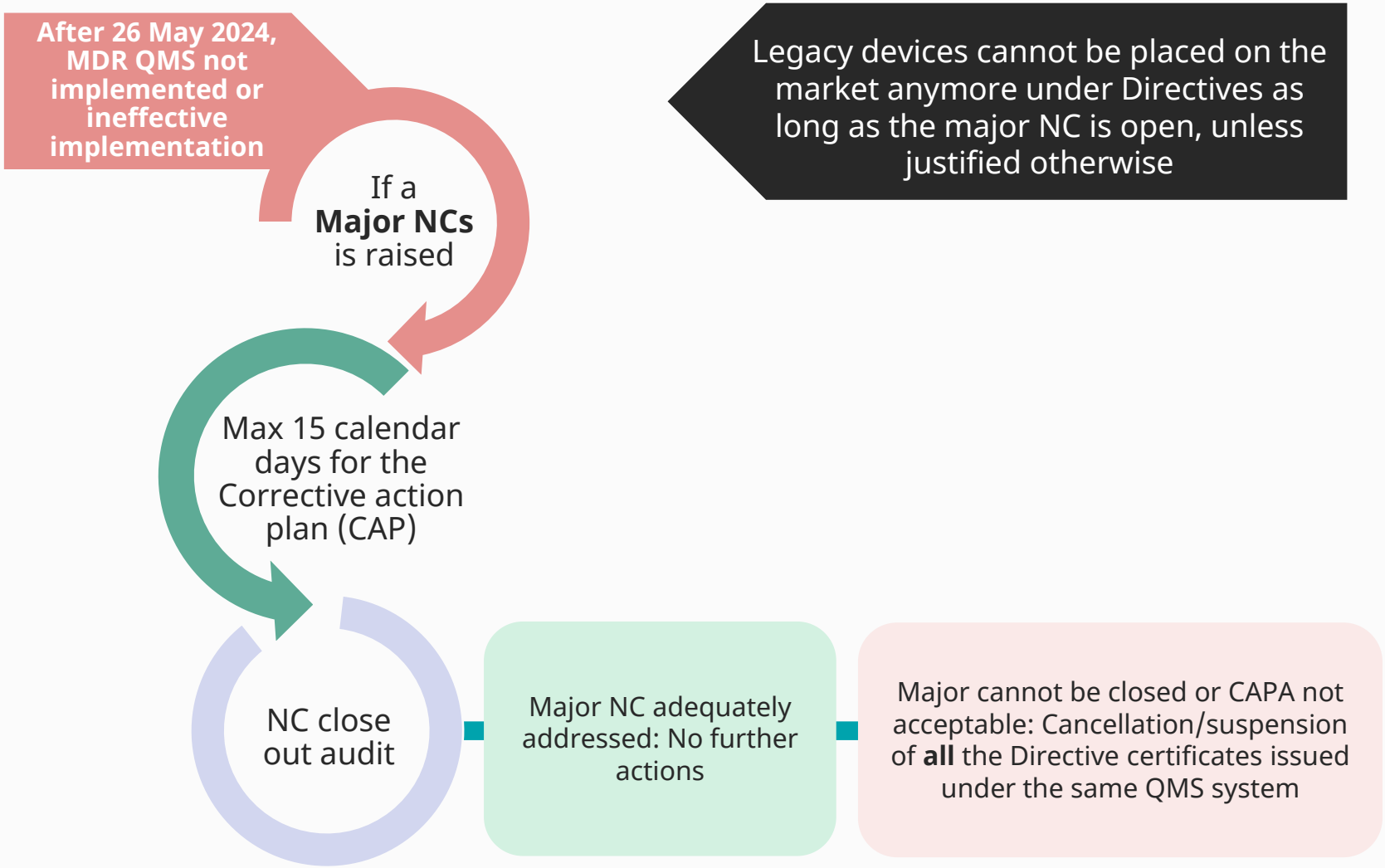
a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

b) there are no significant changes in the design and intended purpose;

c) 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;

d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.



Legacy devices cannot be placed on the market anymore under Directives as long as the major NC is open, unless justified otherwise

EU 2023/607 Non-compliance – NB Actions and consequences

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

b) there are no significant changes in the design and intended purpose;

c) 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;

d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

MDR Application not submitted by 26 May 2024 and written agreement not signed by 26 September 2024

Subject legacy devices cannot be placed on the market anymore

Withdrawal of MDR application/termination of MDR written agreement

EU Commission Q&A, Q. 9.1 - What happens if the MDR application is withdrawn or the written agreement between the manufacturer and the NB is terminated?

If , **after the relevant deadlines**, the manufacturer **withdraws its MDR application**, or the **written agreement** between NB and manufacturer is **terminated**

→ The conditions set out in Article 120(3c), point (e), MDR are not met anymore; **the transitional period therefore ceases to apply**

If the manufacturer or the MDR NB **terminate the written agreement <u>AND</u>** the manufacturer simultaneously enters into a **written agreement with another NB**, to which the **application is transferred**

→ **The transitional period continues to apply**

This can happen even after 26 Sept 2024

→ If this is done by the **manufacturer** since they **realise the device is going to be refused** → The transitional period **ceases to apply**

Impact of MDR refusals/scope restrictions/ cancellations or withdrawals of MDR application on legacy devices

If the NB refuses to issue an MDR certificate, restricts the scope of an MDR certificate or cancels an MDR certificate etc...

If the manufacturer withdraws the MDR application/cancels the certificate or restricts the scope of an MDR certificate

The MDR written agreement in relation to those affected devices is terminated

Potential impact on related legacy devices based on when the MDR refusals/scope restrictions/cancellations or withdrawals of MDR application happens

Impact of MDR refusals/scope restrictions/ cancellations or withdrawals of MDR application on legacy devices

AIMDD/MDD certificate expired on or before 19 March 2023

Up to the 26 Sept 2024	If legacy devices are covered by a **derogation/exemption** granted by a C.A. [MDR Art.59(1) or Art.97(1)] **before 20 March 2023,** then **the extended transitional period continues to apply** provided that an MDR application is lodged by the 26 May 2024 and the MDR written agreement is signed by the 26 Sept 2024
	If legacy devices are **NOT** under a derogation/exemption granted by a C.A. [MDR Art.59(1) or Art.97(1)] before 20 March 2023, then **the extended transitional period ceases to apply** for the impacted legacy devices
From the 27 Sept 2024	**The extended transitional period ceases to apply** for the impacted legacy devices

Impact of MDR refusals/scope restrictions/ cancellations or withdrawals of MDR application on legacy devices

AIMDD/MDD certificate expired on or after 20 March 2023

Up to the 26 Sept 2024	**The extended transitional period continues to apply** provided that an MDR application is lodged by the 26 May 2024 and the MDR written agreement is signed by the 26 Sept 2024
From the 27 Sept 2024	**The extended transitional period ceases to apply** for the impacted legacy devices

EU 2023/607 - Manufacturer Self-Declaration

Does the manufacturer have a process for updating/re-issuing the self-declaration and implementing other actions such as pausing/ ceasing to place legacy devices on the market based on the factors/outcomes/data that affect compliance to the five conditions specified in EU 2023/607?

Manufacturer Self-Declaration

We declare that the following devices comply with..

a) Cont. compliance to Directives

b) No sign changes in design or intended purpose

c) No safety concerns

d) MDR compliant QMS by 26 May 2024

e) MDR application by 26 May 2024 and written agreement by 26 Sep 2024

XXXXX YYYY/MM/DD

Continued compliance with Directive

Outcomes from NB Directive appropriate surveillance and NB actions on Directive certificates

No significant changes

- Change control process outputs
- NB assessment of change history

No unacceptable risk

- Post-market surveillance
- C.A. market surveillance
- NB actions on Directive certificates – suspensions, scope restrictions etc

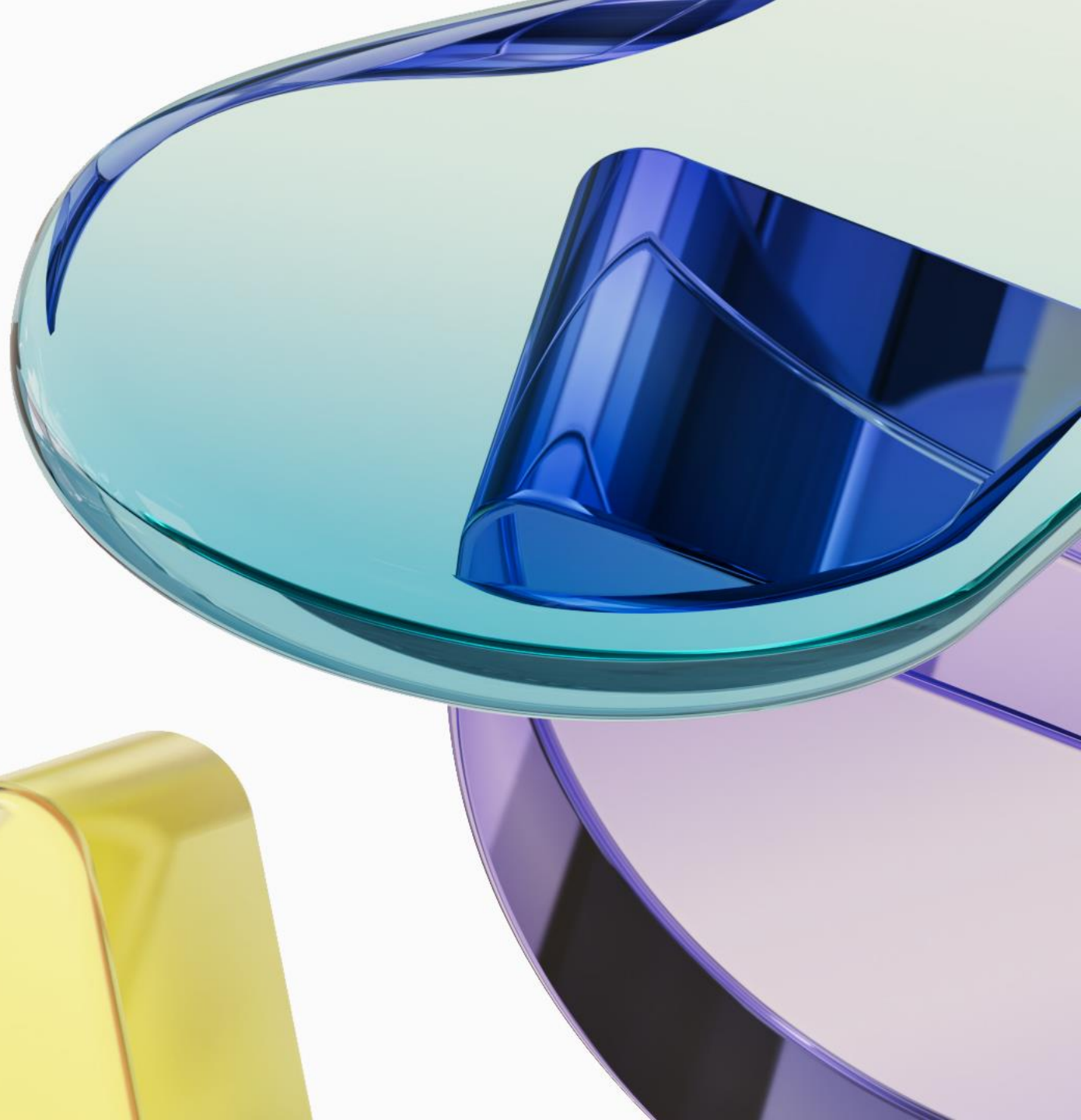
MDR compliant QMS by 26 May 2024

- Outcomes of NB MDR QMS audits
- CA audits (in the context of Market Surveillance)

MDR application by 26 May 2024 and written agreement by 26 Sep 2024

MDR application/MDR certification refusals, withdrawals, cancellations

BSI implementation of EU 2023/607



Notified Body Confirmation letter process

BSI process for issuing a confirmation letter

Manufacturer contacts BSI to request the NB confirmation letter

BSI Scheme Manager will forward a form to be completed by the manufacturer

BSI Scheme Manager validates the information received via the form and performs relevant supporting activities

BSI Scheme Manager issues the confirmation letter

BSI will issue one NB confirmation letter per legal manufacturer

The confirmation letter can only be requested by and issued to the legal manufacturer under MDR written agreement

The confirmation letter can include devices already certified under MDR

NB confirmation letter template

The confirmation letter is subject to amendments, as needed

New devices under MDR written agreement

Directive certificate cancelled/ scope restricted

MDR certificate refusal/ scope restriction/cancellation or application withdrawal

POLL QUESTION N.2

Have you already received the Notified Body confirmation letter?

- Yes
- No
- N.A. – No intention to transition to the MDR

Continuation/ restart of appropriate surveillance for legacy devices

It is the manufacturer responsibility to request the NB to continue/restart the appropriate surveillance for the relevant legacy devices.

BSI will NOT restart/continue appropriate surveillance if not requested by the manufacturer.

BSI process for restart/continue appropriate surveillance

Manufacturers with AIMDD/MDD Directives certificates issued by BSI and that qualify for benefitting of the longer transition timelines must request the restart/continuation of appropriate surveillance for the relevant legacy devices, if they want to keep placing legacy devices on the market

Manufacturer requests to restart/ continue surveillance

BSI Scheme Manager will forward a form to be completed by the manufacturer

BSI Scheme Manager validates the information received via the form and performs relevant supporting activities

BSI Scheme Manager will confirm to the manufacturer that the surveillance is restarted/will be continued

Discontinuation of appropriate surveillance

The appropriate surveillance shall be discontinued whenever:

Manufacturer's request

The manufacturer requests the NB to stop the appropriate surveillance.

In this case, the related AIMDD/MDD certificate shall be cancelled or its scope restricted, as appropriate

MDR withdrawal

The manufacturer withdraws a device from the MDR application and subsequent contract (post relevant due dates)

MDR refusal

MDR certification is refused, cancelled or its scope restricted (post relevant due dates)

BSI actions on AIMDD/MDD certs

BSI processes a scope restriction or cancellation for a AIMDD/MDD certificate

Transfer of appropriate surveillance to BSI

Basic principles

AIMDD/MDD NB

3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

MDR NB

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

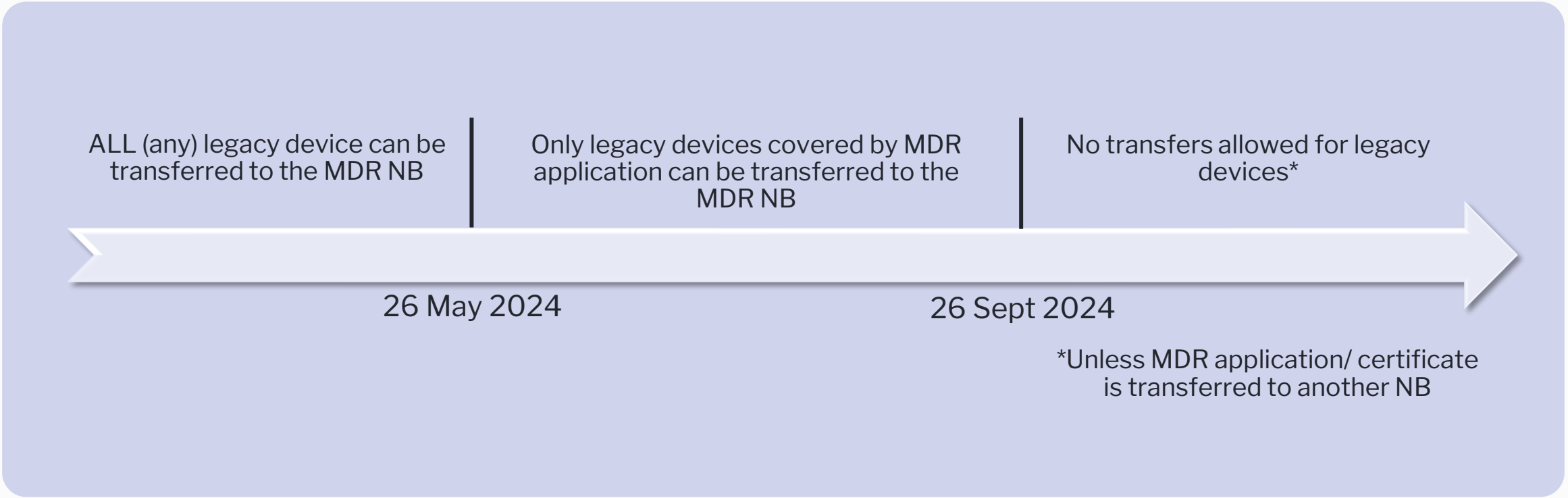
NB that issued the Directive certificates [**AIMDD/MDD NB**] to carry out appropriate surveillance for the extended transition periods

If the MDR application is with a different NB [**MDR NB**], the appropriate surveillance of the legacy devices *(all devices including those that are not transitioning to MDR)* may be taken over by the MDR NB if agreed upon

For devices that are transitioning to MDR, it is mandated that the MDR NB takes over the appropriate surveillance **no later than 26 Sep 2024**

Basic principles - What can be transferred?

- Legacy devices certified under Directives by another NB and covered by an MDR contract with BSI
- Legacy devices certified under Directives by another NB but NOT covered by an MDR contract with BSI (up to 26 May 2024) *(ex. Directive certificate covering some legacy devices transitioning to the MDR and other legacy devices not transitioning to the MDR)*



It is the manufacturer responsibility to request BSI to transfer the appropriate surveillance of those legacy devices they intend to keep placing on the market.

BSI will NOT initiate the transfer of appropriate surveillance unless requested by the manufacturer.

A tripartite transfer agreement is needed.

Process for transferring appropriate surveillance to BSI

Manufacturer contacts BSI to request the transfer of appropriate surveillance

BSI will provide a tripartite transfer agreement to be completed and signed by the manufacturer

BSI will provide the manufacturer an application form and quotation

Manufacturer forwards the completed and signed transfer agreement to BSI

Ensure to contact BSI as soon as possible, to allow sufficient time to process the transfer before the 26 Sept 2024 deadline

The tripartite transfer agreement shall be signed by the manufacturer, the incoming NB (MDR NB - BSI) and, if possible, the outgoing NB (Directive NB)

Quotation will cover transfer activities and certificate maintenance activities

Process for transferring appropriate surveillance to BSI

BSI checks information on the transfer agreement, signs it and send it back to the manufacturer

The manufacturer sends the transfer agreement to the outgoing NB

The outgoing NB checks, signs and send the transfer agreement to the manufacturer and to the incoming NB (BSI)

Transfer activities can start

The transfer date can be added at a later stage, set as 26 September 2024 and/or updated as needed

The transfer agreement lists information/ documentation that the manufacturer and the outgoing NB shall provide to BSI as incoming NB.

Team-NB transfer agreement template

Process for transferring appropriate surveillance to BSI

BSI will perform checks and activities, as needed, to transfer appropriate surveillance

BSI will issue a letter stating that BSI is in charge of appropriate surveillance activities for transferred devices

Standard certificate maintenance

No pre-transfer QMS audit foreseen (unless outstanding NCs inherited from the previous NB).

No pre-transfer Technical documentation assessment (some checks done by BSI as part of transfer activities. If any concerns raise during the transfer process, BSI will follow-up as needed)

BSI will perform surveillance activities for the transferred legacy devices (audits - including unannounced audits, review of changes, review of vigilance reports…)

Transfer agreement

Appendix 1 – Legacy devices subject to transfer of appropriate surveillance

Devices covered by this agreement and for which the incoming NBxxxx is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive

MDD/AIMDD Device name or REF	MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD device	Is the device under MDD/AIMDD replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Device 1	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		

Transfer agreement

Appendix 2 – Traceability table - identification number of the OUTGOING NB to the number of the INCOMING NB

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is xx months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified

BSI will not require to change the NB ID to 2797, so this Appendix is N/A, unless the outgoing NB asks for a change in NB ID on the labelling

Transfer agreement

Considerations for the documents checklist:

Checklist of minimum documents to be submitted to the INCOMING NBxxxx by manufacturer or OUTGOING NB:

- Certificate(s)
- Detailed list(s) of device(s) covered by the certificate
- List of conditions correlated to the certificate(s)
- Prior audit reports incl. their findings lists – time frame minimum current certification cycle
- Prior TD assessment reports / expert reports – time frame minimum current certification cycle
- Consultation reports by authorities
- List of vigilance cases
- List of open / still pending non-conformities and their grading (minor/major)
- List of ongoing change notifications being assessed
- Pending appeals

Additionally, the outgoing notified body provides the following to the incoming notified body <u>directly</u>:

- Sampling plan(s) of the current cycle
- Open items to be followed-up, surveillance notes
- Audit program of the current cycle

Information and documents that BSI (as incoming NB) must receive from the manufacturer and from the outgoing NB

POLL QUESTION N.3

Have you already requested the transfer of appropriate surveillance for legacy devices?

- Yes
- No
- N.A. – The NB that issued the Directive certificate is the same we applied under MDR with

Final remarks

Important points to remember

Do not postpone/delay your MDR plans

Manufacturers are responsible for placing legacy devices on the market lawfully

- Ensure compliance with EU 2023/607 conditions, request the NB to continue/transfer appropriate surveillance
- Stop placing on the market if conditions are not met

Deadlines for legacy devices transitioning to MDR

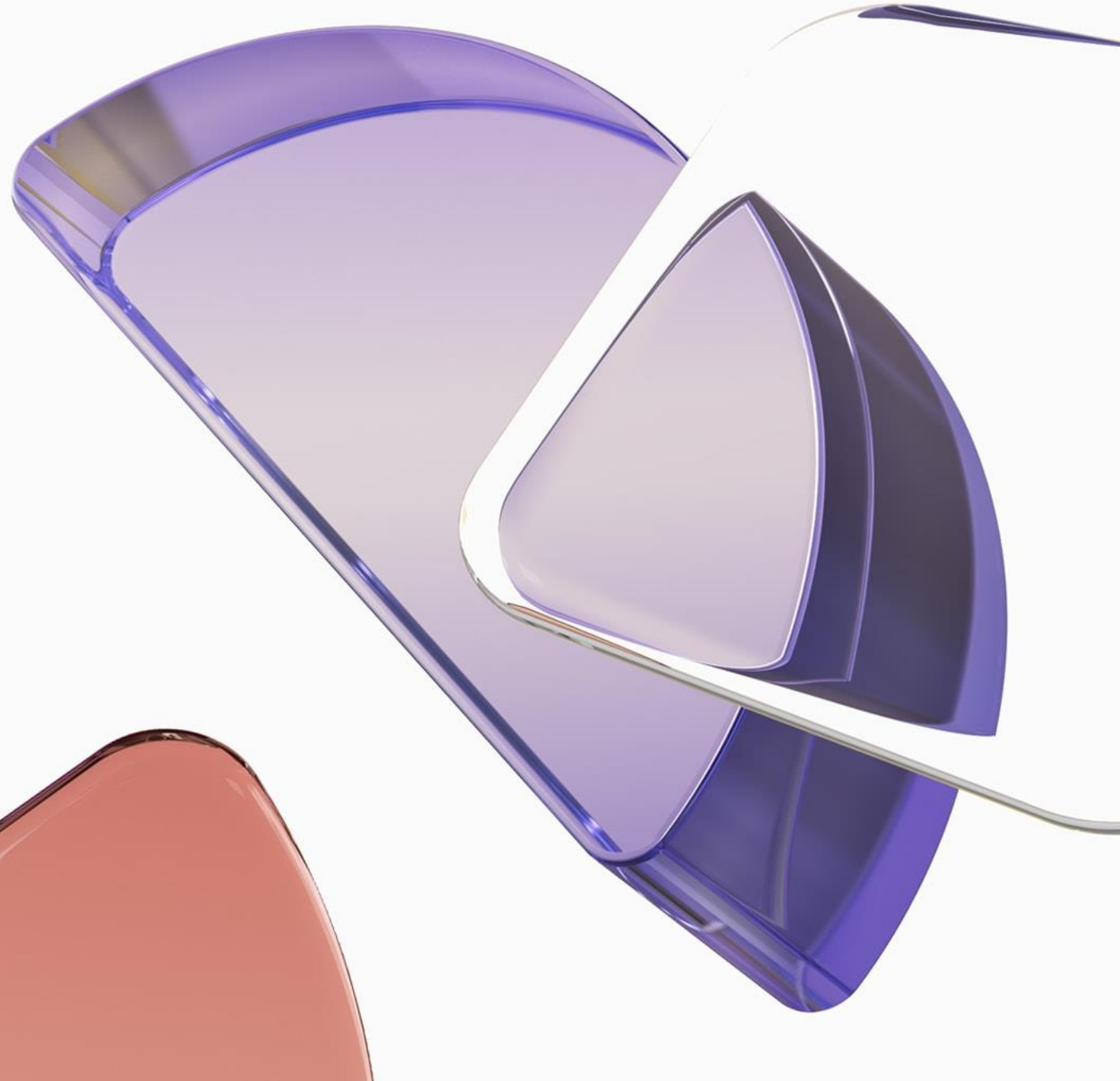
26 May 2024: application under MDR

26 Sept 2024: sign MDR written agreement and complete transfer of appropriate surveillance

MDR Technical Documentation submission

- Provide a TD submission plan to the NB
- Stick to the planned submission date
- Refer to EU Commission dashboard for average time to certification

Q&A



[Medical Devices Regulation | BSI Medical Devices]
[MDR transition guidance]
[Amending Regulation (EU) 2023/607 – FAQs]