(EU) 2023/607 amending MDR and IVDR as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

29 March 2023

Jayanth Katta, Regulatory Director & Head of Medical Devices NB
Suzanne Halliday, VP Regulatory

Disclaimers

Information presented within this webinar is based on BSI's current understanding and interpretation of the amending regulation (EU) 2023/607

We don't have all the answers (yet)!

Subject to change

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Agenda

The need for the amending regulation

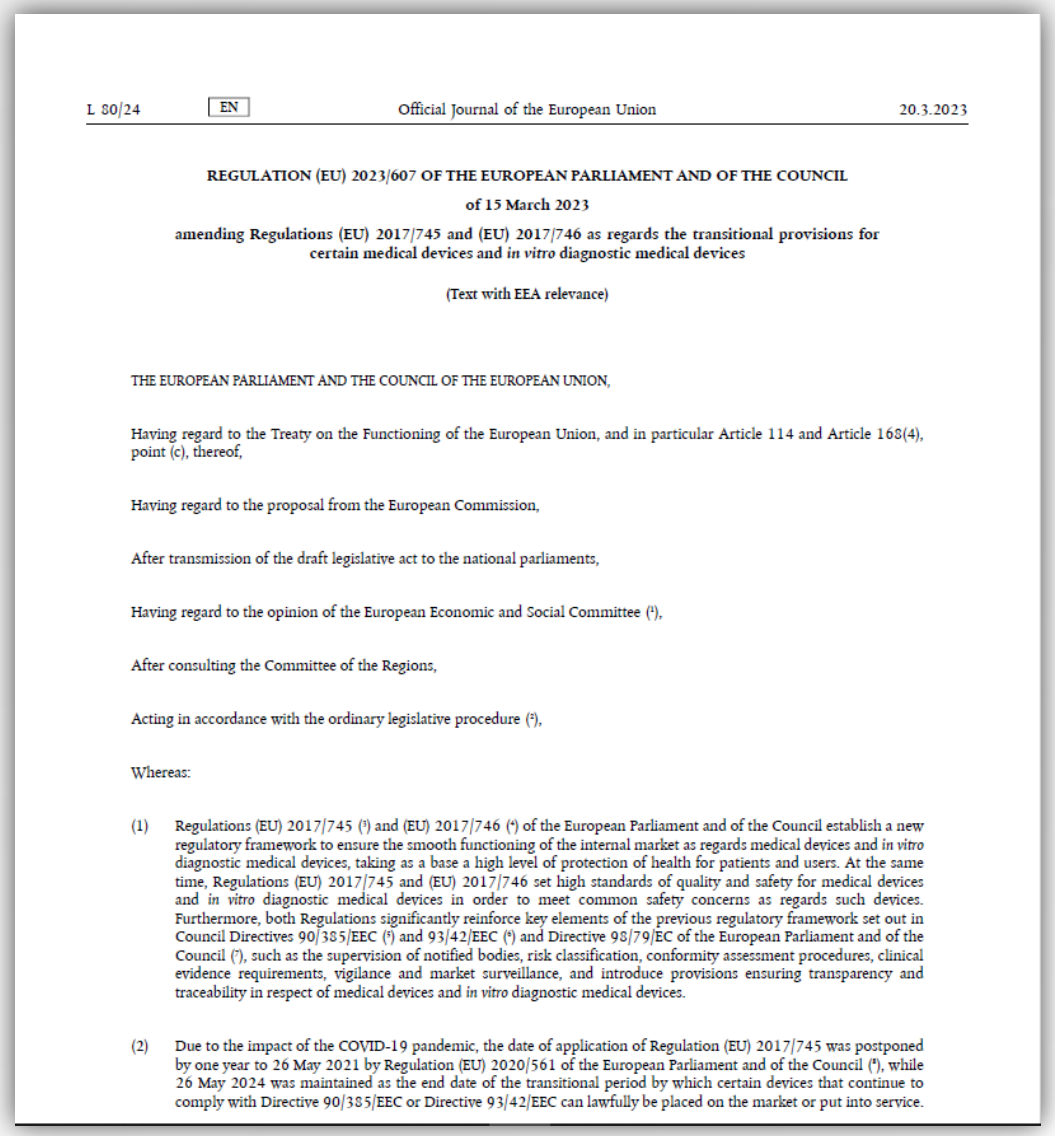
Scope & timelines of the extension of the MDR transitional period

Conditions to be met for benefitting from the extended transition timelines

Appropriate surveillance to be performed by Notified Bodies

BSI implementation plans

Other important considerations for manufacturers



L 80/24 EN Official Journal of the European Union 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Regulations (EU) 2017/745 [3] and (EU) 2017/746 [4] of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC [5] and 93/42/EEC [6] and Directive 98/79/EC of the European Parliament and of the Council [7], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council [8], while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

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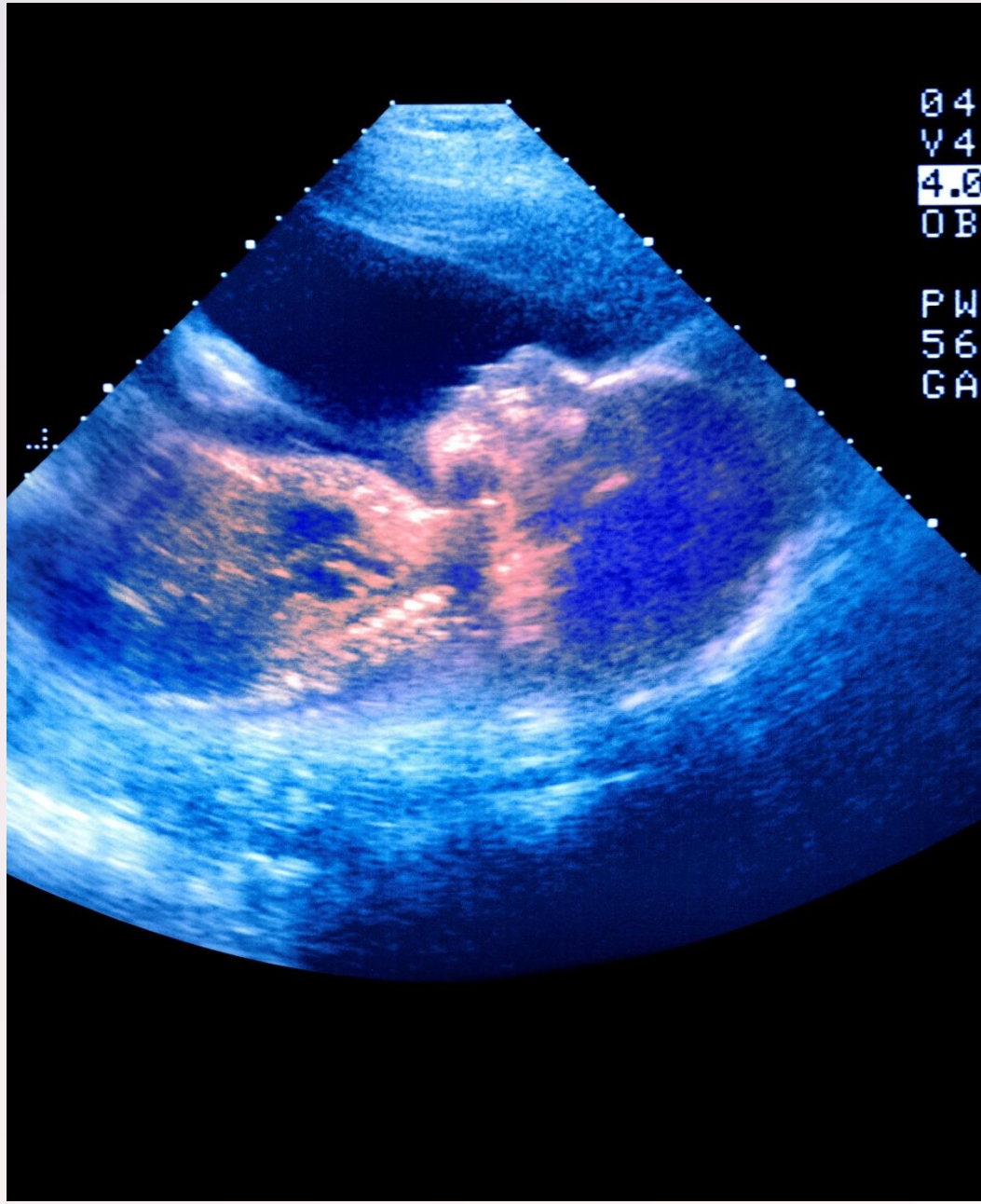
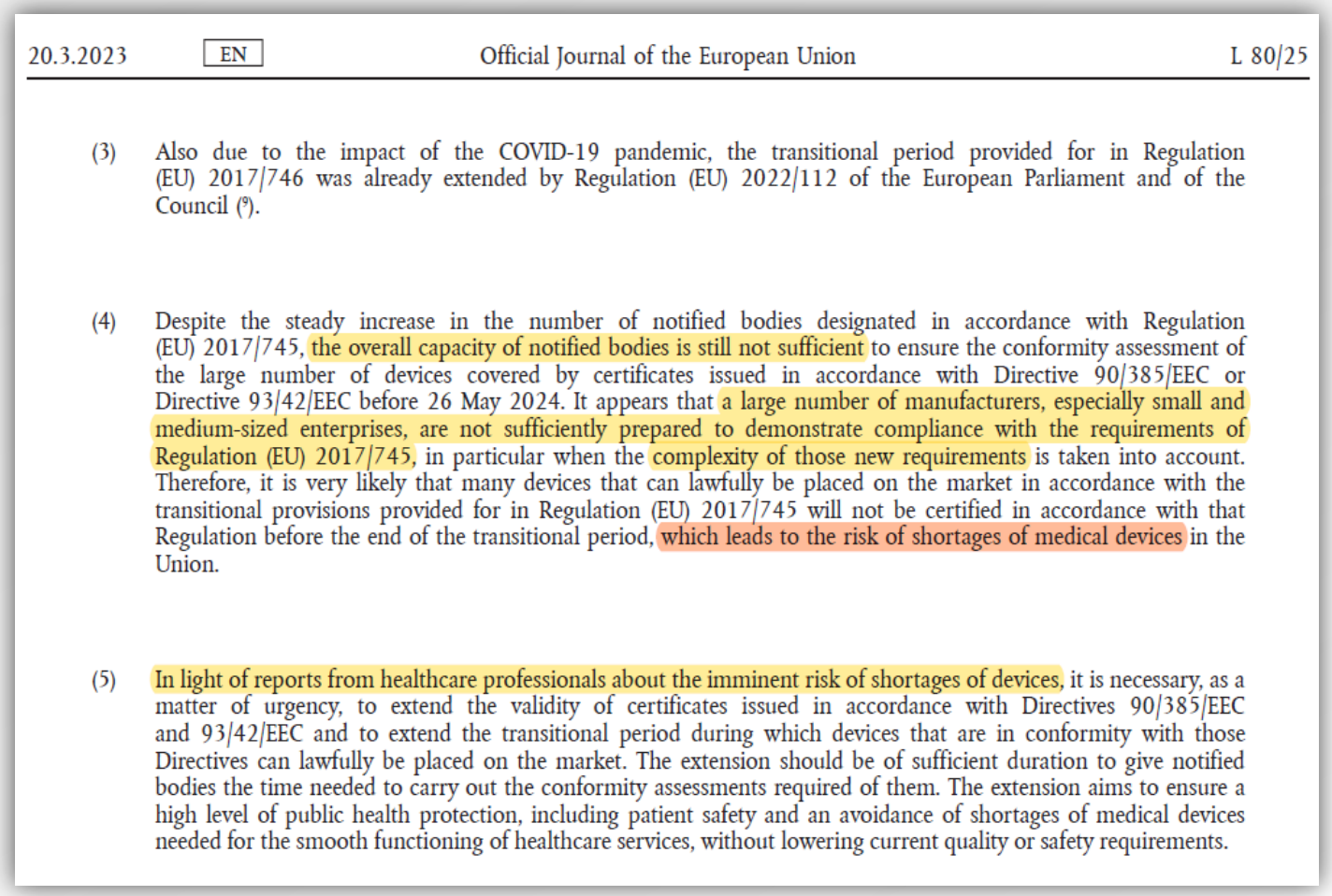
- The need for the amending regulation



When and Why?

Published and came into effect on the 20th March 2023

To avoid imminent risk of shortage of devices due to…



20.3.2023 EN Official Journal of the European Union L 80/25

(3) Also due to the impact of the COVID-19 pandemic, the transitional period provided for in Regulation (EU) 2017/746 was already extended by Regulation (EU) 2022/112 of the European Parliament and of the Council (9).

(4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

EC proposal 06 Jan 2023

Adoption by EU Parliament 16 Feb 2023

Adoption by EU Council 07 Mar 2023

Publication in OJEU 20 Mar 2023

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How to deter the imminent risk of shortage of medical devices?

Extend the validity of MDD/AIMDD certificates,

Extend the transitional period

(for legacy devices transitioning to MDR or substitute devices subject to certain conditions)

AND

Abolish the sell-off provisions in MDR and IVDR – Devices once placed on the market under the Directives can be further made available and put into service for unlimited time

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.

Do devices already certified under MDR benefit from the extended validity of the corresponding directive certificates? **Yes, if all the applicable conditions are met**

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Does it mean that NBs have to change the expiry dates of their MDD/AIMDD certificates or renew them?

No

'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

The language indicates that certificates will be considered as valid even after the expiry dates printed on the certificates rather than suggesting changing/extending the dates on the MDD/AIMDD certificates

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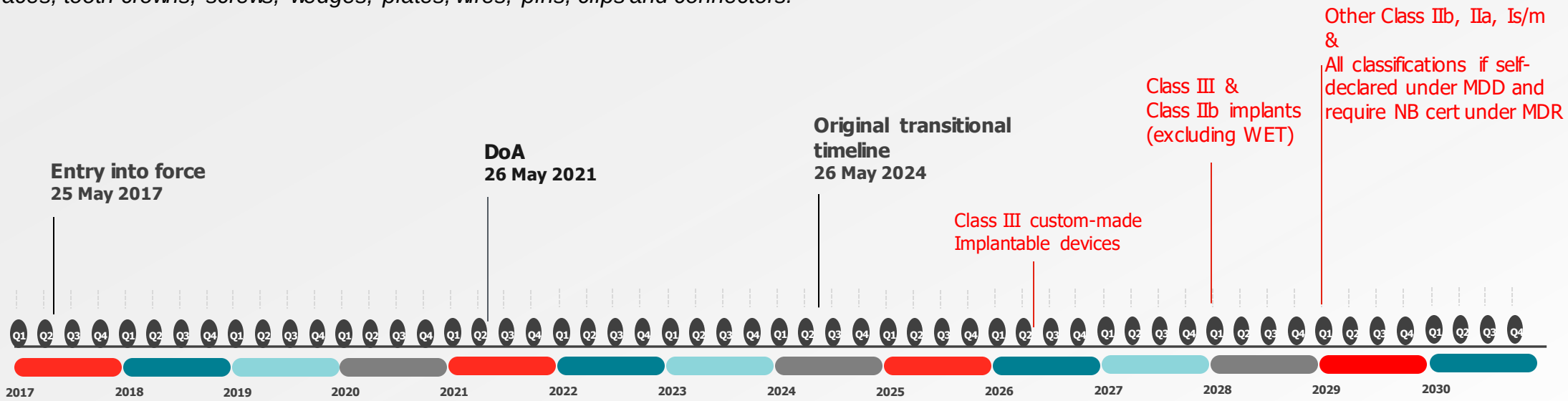
- Scope & timelines of the extension of the MDR transitional period

Scope and timelines

Devices	Transition timelines
Class III custom-made implantable devices	**26 May 2026**
Devices covered by valid MDD/AIMDD Certificates (as of 20 March 2023) and that are Class III, or Class IIb implantable devices excluding well-established technologies (WET)* under MDR	**31 December 2027**
Devices covered by valid MDD/AIMDD Certificates (as of 20 March 2023) and that are Class IIb devices (excluding Class IIb implantable non-WET), or Class IIa devices, or Class I sterile devices or Class I devices with a measuring function; Devices that did not require Notified Body certification under the MDD and for which the declaration of conformity was drawn up prior to 26 May 2021, but now require Notified Body certification under the MDR	**31 December 2028**

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



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Poll – Number of manufacturers with one or more expired Directive certificates

Do you have one or more devices covered by Directive certificates that expired before 20 March 2023 and are yet to be certified under MDR?

Option 1: Yes

Option 2: No

Option 3: N/A

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Scope and timelines

What if the MDD/AIMDD certificates expired before 20 Mar 2023? Will devices covered by such certificates benefit from the longer transition timelines?

Yes, only if..

Certificates were not withdrawn prior to the certificate expiry, and

Manufacturer submitted a formal application and completed the written agreement with an MDR NB prior to the certificate expiry

(And other conditions are met – see later slides)

or

Manufacturer has a derogation/exemption approved by a CA under MDR Article 59 or Article 97 by the 20th March 2023

(and other conditions are met – see later slides)

Will the manufacturer benefit from the full length of the new transition timelines even if their derogation/exemption was for a limited period?

Yes, provided the derogation/exemption was received by the 20th March 2023 and the other conditions are met

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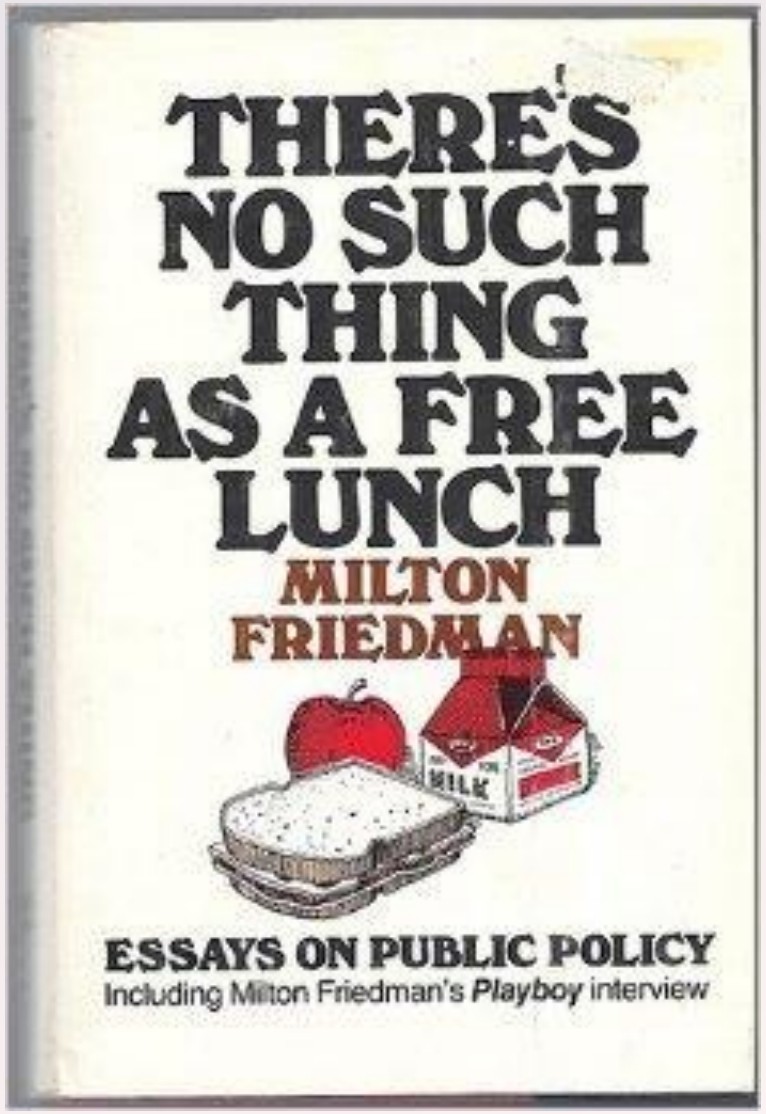
Conditions to be met for benefitting from the extended MDR transition timelines

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.



The additional transition time comes with Conditions

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;

Comply with MDD/AIMDD

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

No significant changes in Design or intended purpose; (Non-significant changes allowed)

(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;

Devices are safe with no safety concerns

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

An MDR compliant QMS by 26 May 2024

(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 by 26 May 2024 and signed written agreement by 26 Sep 2024;

Device under MDR application could be a substitute device to the legacy device

Remember that all devices (irrespective of whether transitioning to MDR or not) must comply with the MDR Article 120 requirements related to PMS, vigilance, market surveillance and registration of actors and devices since 26 May 2021

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Conditions – who is responsible for what?

Manufacturer

is responsible for demonstrating and documenting compliance to the requirements before they apply the longer transition timelines

Manufacturers to issue a **Self-declaration*** documenting compliance

Manufacturer Self-declaration

*Industry organisations working on developing a harmonised template

Notified body

involvement in verification of compliance to conditions at the time of application is expected to be minimal, and mainly limited to checking the QMS documentation (in some instances; see later slides) and confirming the receipt of a signed application and signed written agreement (contract) via a Notified Body Confirmation Letter

Notified Body Confirmation Letter

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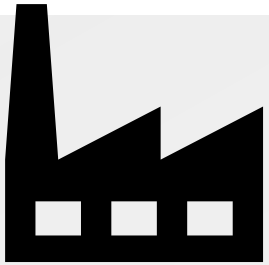
Conditions - Art 120.3c.(a)

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

Manufacturer

Responsible for demonstrating continued compliance to MDD/AIMDD



Notified Body

Has an obligation to continue appropriate surveillance

May require updated Terms and Conditions of contract (being assessed by NB legal teams)

What does continued compliance to MDD/AIMDD mean?

Continue to undertake all activities that support the signed declaration of conformity (DoC) to MDD/AIMDD including any applicable transitional provisions from MDR and the requirement for appropriate surveillance activities by NBs (if relevant).

Re-starting appropriate surveillance for expired certificates is not stated as a condition to benefit from the longer transition timelines. However, continued compliance to MDD/AIMDD is required (which will require NB surveillance). Clarity is being sought from Authorities on this seeming contradiction.

BSI Interim process – We will re-initiate appropriate surveillance at the time of issue of the NB confirmation letter

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Conditions - Art 120.3c.(b), (c)

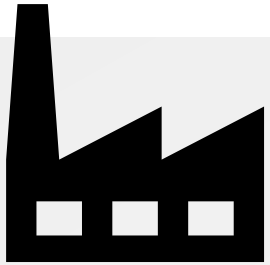
(b) there are no significant changes in the design and intended purpose;
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

Manufacturer

Responsible for demonstrating and documenting compliance to these conditions -

No significant changes to design or intended purpose (MDCG 2020-3)

Devices continue to remain safe



Notified Body

No specific check at the time of application or issuing the NB confirmation letter for application and contract;

Verify compliance as part of the appropriate surveillance activities (QMS, Micro, Unannounced audits, vigilance report reviews etc) and take appropriate action on certificates using routine processes

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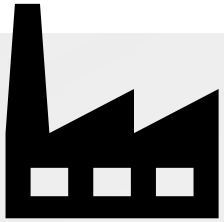
Condition Art 120.3c.(d) – MDR compliant QMS by 26 May 2024

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

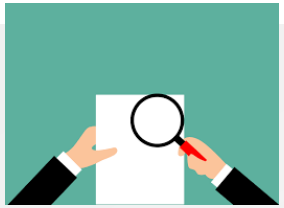
Manufacturer

Responsible for ensuring that a QMS is put in place in accordance with MDR's QMS requirements (Article 10(9)) **by** 26 May 2024



Notified Body

Full assessment of the QMS as part of the MDR QMS audits (not at the time of application)



Although compliance to MDR QMS is required by 26 May 2024, remember that certain QMS documents demonstrating compliance to MDR (Annex IX Section 2.1) are required at the time of MDR Application and maybe assessed by the NB (see next slide)

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Condition Art 120.3c.(e) – formal application by 26 May 2024 and signed agreement by 26 Sep 2024

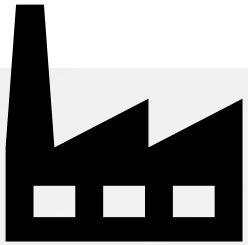
(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or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

Manufacturer

If yet to apply, submit the MDR application by 26 May 2024, and have a signed written agreement (contract) by 26 Sep 2024

No expectation on submission of technical documentation for all devices as part of the application; However, a plan for submission timelines should be provided

QMS documentation (as per the Annex IX Clause 2.1 requirements) to be submitted as part of application



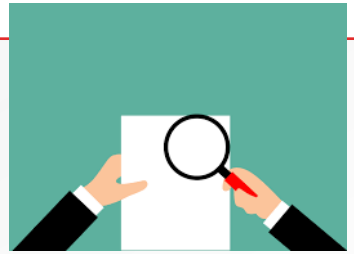
Notified Body

Ensure a plan for submission of Technical Documentation is received (if not submitting all TDs);

A risk based approach to QMS documentation assessment at the time of application review

- Manufacturers with one or more devices already certified to MDR or MDR QMS audits completed with no major concerns identified – No further need for any QMS documents or NB checking of QMS documentation
- Manufacturers with no prior MDR audit history – Top-level QMS document review to gain confidence at the time of application

Confirm receipt of application and written agreement via a **NB Confirmation Letter**



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What is a substitute device?

(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.

No definition of a 'substitute device'

A 'substitute device' may differ from the legacy device including significant changes to its design or intended purpose, with a view to replace the legacy device

It is up to the manufacturer to document a rationale as to why the device under MDR application qualifies as a substitute device to the legacy device

'Substitute device' must undergo full MDR conformity assessment before it can be placed on the market

The corresponding legacy device may be placed on the market until end of 2027 or 2028 if all the conditions are met

More guidance anticipated in the future on 'substitute device'

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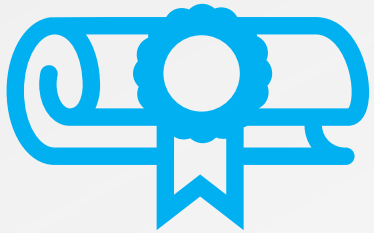
How does a manufacturer demonstrate that their legacy devices can benefit from the longer transition timelines?

Manufacturer's Self- declaration
(confirming the fulfilment of the conditions specified in the MDR Article 120.3 as amended by (EU) 2023/607)

Minimum content of the self-declaration:

- Unambiguously identify the devices and certificates
- State the applicable end dates of the transition period
- Confirm that the conditions for extension are fulfilled

Additional evidence to support the self-declaration



MDD/AIMDD Certificate (or) For self-declared devices, a copy of the signed Declaration of Conformity issued before 26 May 2021

Notified Body Confirmation Letter
(confirming receipt of application and signed written agreement)

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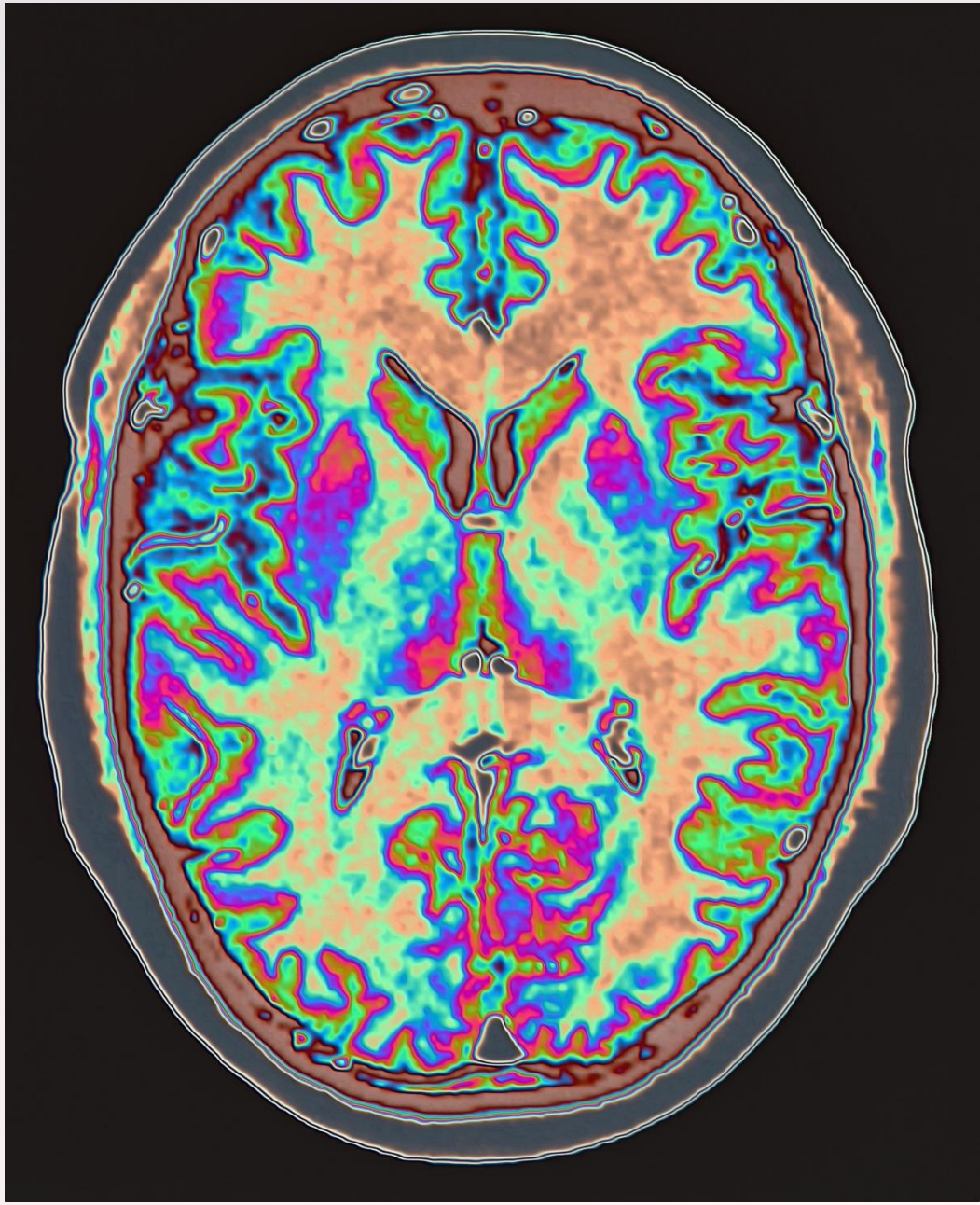
- Appropriate surveillance



Appropriate surveillance

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.

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 to carry out appropriate surveillance for the extended transition periods

If the MDR application is with a different NB, the appropriate surveillance of the Directive certificates (for 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

Transfer of appropriate surveillance requires a **tri-partite agreement** between the Directive NB, manufacturer and the MDR NB

Manufacturers may continue to use the previous NB number without changes to labelling including CE marking even after the transfer of appropriate surveillance

?

What is BSI's interpretation of appropriate surveillance?

Annual QMS audits, Triennial Microbiology audits (if appropriate), Unannounced audits,

Vigilance reviews, approval of substantial changes that do not qualify as significant changes to design or intended purpose

bsi.

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Poll – Number of manufacturers who are changing Notified Body for MDR certification

Are you working with or planning to apply under MDR with a different Notified Body (instead of using the same Directive NB)?

Option 1: Yes

Option 2: No

Option 3: N/A

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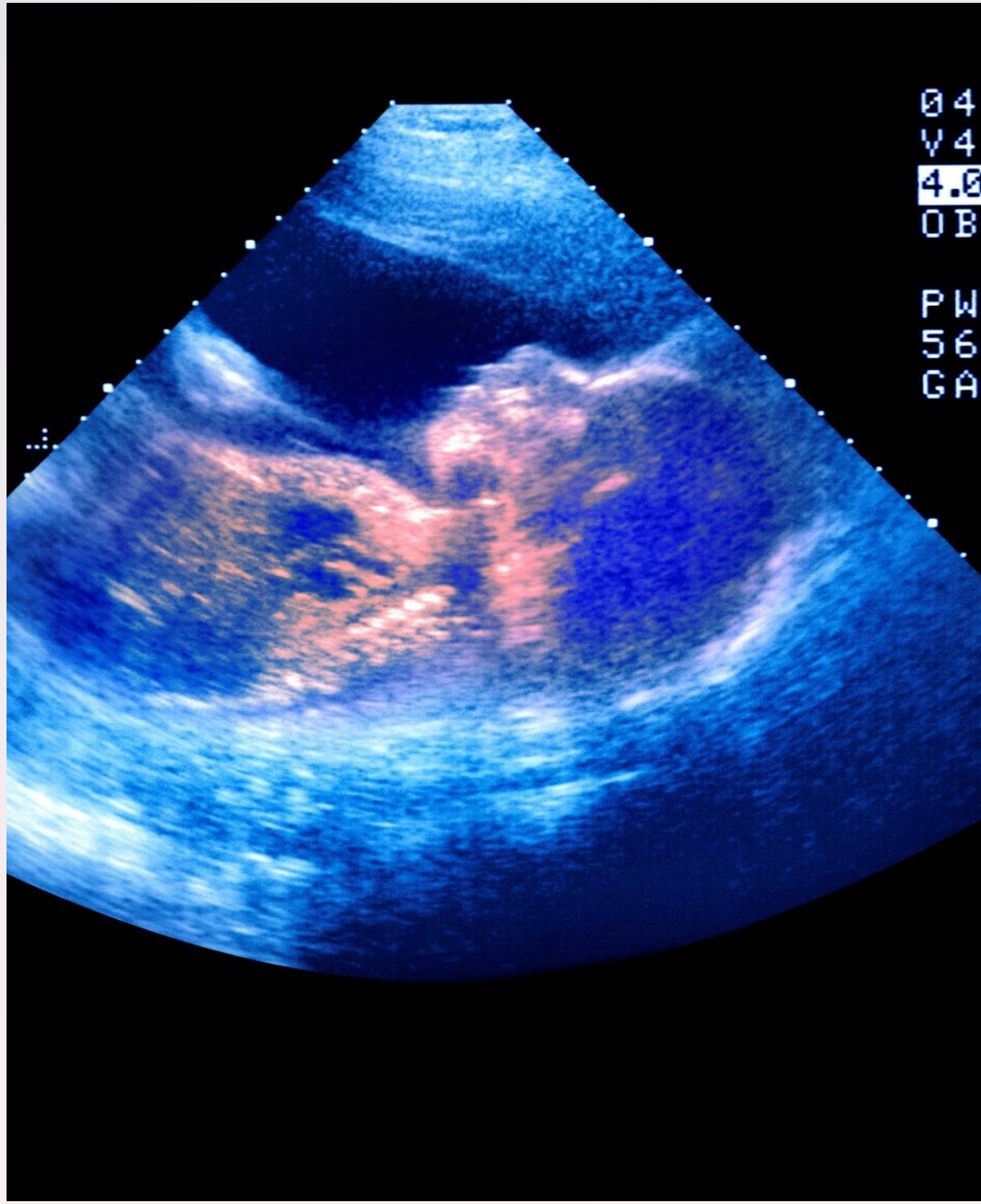
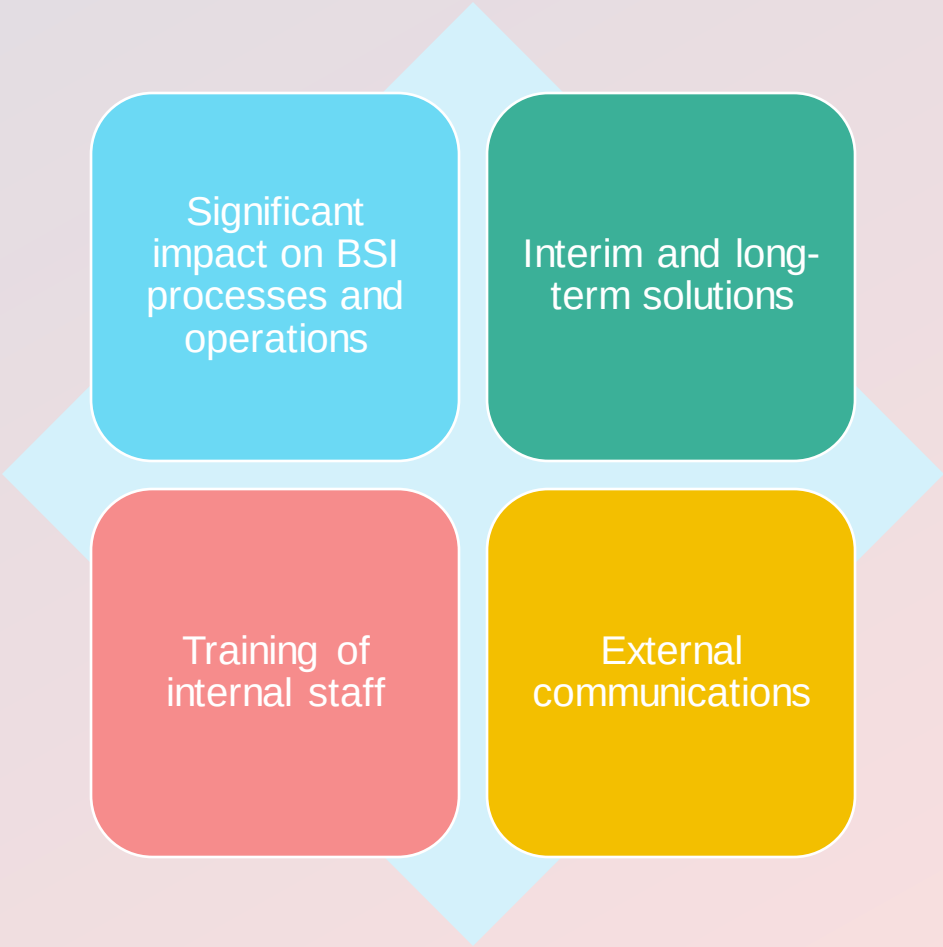
- BSI Implementation Plans



Impact on BSI and what do we need to do to prepare for the new amending regulation

- NB confirmation letter – Mechanism for request, process for generation and maintenance
- Process for (limited) QMS document review at the time of application in certain scenarios
- Process for re-activating cancelled or expired directive certificates
- Changes to terms and conditions of contract to handle appropriate surveillance of expired certificates
- Changes to manufacturer submission plans
- Development of the tri-partite agreement for transfer of appropriate surveillance
- Ability to accept other NB certificates and undertake appropriate surveillance of those devices
- Client communications
- Training for all relevant BSI staff



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NB Confirmation Letter

'confirmation letter' issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Such confirmation should clearly identify the devices covered by the extension and certificates concerned. Such confirmation letter could be based on a harmonised template and be issued, in principle, without extra costs.

(extract from Commission Q&A document on EU 2023/607)

Scope of the letter - Limited to confirming receipt of the manufacturer's application and conclusion of a written agreement.

NBs have developed a template – currently under review by EC

BSI process to be finalised in the next 2-4 weeks

Costs for the letter (policy to be determined)

Confirmation Letter anticipated to be updated and re-issued in the future based on any changes to the list of devices under application

BSI Process for issuing the Confirmation Letter

Manufacturers who have already submitted their MDR applications and application/contract review has been completed – Request the letter from your BSI Scheme Manager

New applications for legacy devices between now and 26 Sep 2024 – To be issued as part of the Application/contract review

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Other important considerations for manufacturers

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Can the manufacturer apply the principles within (EU)2023/607 immediately and benefit from longer transition timelines and extended validity of Directive certificates?

Yes, as long as the manufacturer can demonstrate compliance to the conditions from the amending regulation

The NB Confirmation, manufacturer Self-declaration are not legislative requirements, but are aimed at harmonising/simplifying the way evidence can be provided to demonstrate compliance.

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Maintenance of Manufacturer self-declaration (stating compliance to updated MDR Article 120 via (EU)2023/607)

Does the manufacturer have a process for updating/re-issuing the Manufacturer Self-declaration based on the factors/outcomes/data that affect compliance to those specific conditions?

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Transfer of appropriate surveillance (if MDR NB is different to Directive NB)

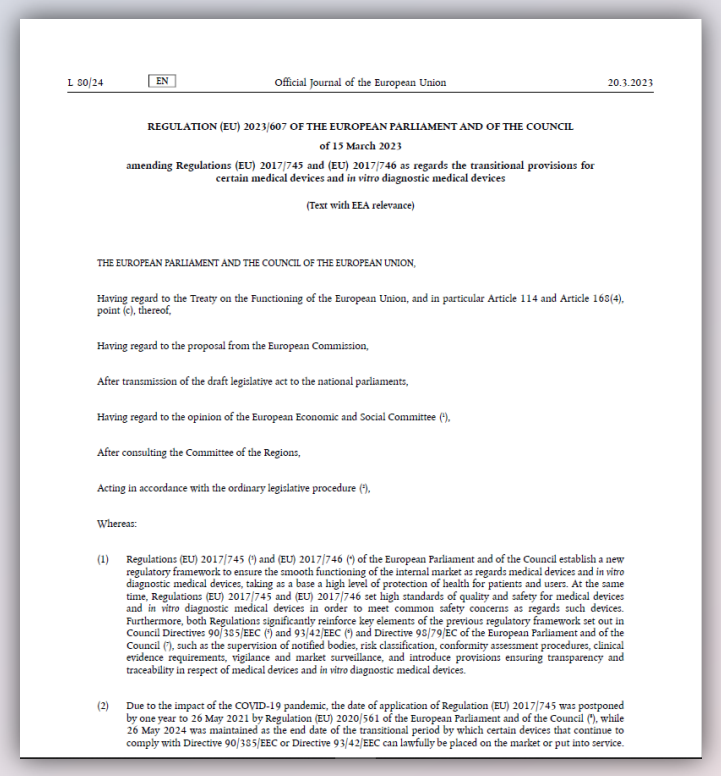
A Tri-partite agreement is required between the manufacturer, Directive NB and MDR NB

If transferred, the MDR NB is anticipated to take full control of appropriate surveillance, and the maintenance of the Directive certificates for the longer transition periods

Manufacturer can continue to use previous NB number on the labelling during the transition period

Manufacturer will be expected to update their procedures, processes etc to submit change notifications, vigilance reports etc to the MDR Notified Body

Summary



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REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Regulations (EU) 2017/745 (3) and (EU) 2017/746 (4) of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC (5) and 93/42/EEC (6) and Directive 98/79/EC of the European Parliament and of the Council (7), such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council (8), while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

- More time now available for MDR transitions, but the additional time comes with strict conditions
- Manufacturers benefit from the amending regulation immediately, but have to be able to demonstrate compliance to the conditions
- Some aspects of the new amending regulation still need clarifications and the interpretations could evolve
- Do not wait until May/Sep 2024 for making new MDR applications for legacy devices
- Do not delay or postpone your MDR submissions – you risk losing market access
- Focus should remain on MDR transitions and compliance to MDR

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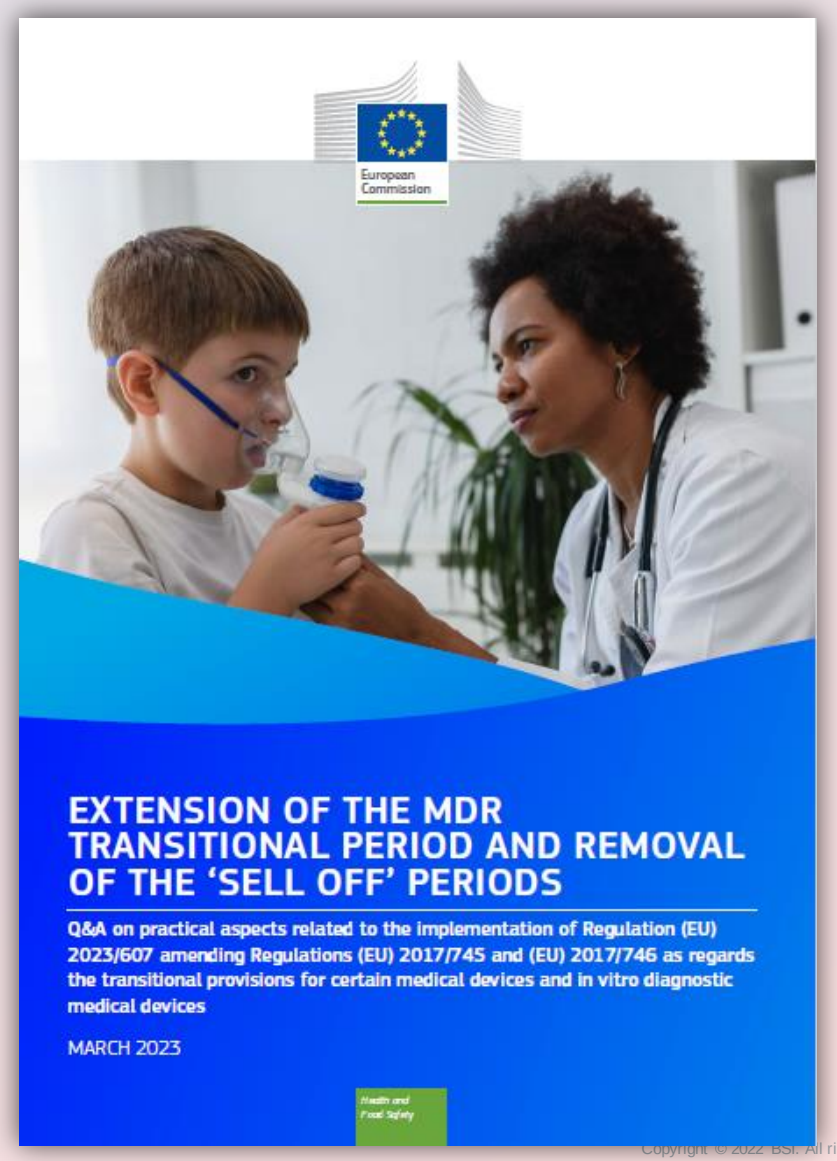
Additional Resources

Commission Q&A document on interpretation of (EU) 2023/607

Q&A document available on Commission website

https://health.ec.europa.eu/medical-devices-sector/new-regulations_en



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UK guidance – Acceptance of extended Directive certificates

EU Directive Certificates that will be recognised as valid until the end of 2027 or end of 2028 due to the amending regulation (EU) 2023/607 will also be recognised as valid for placing CE marked devices on the Great Britain market.

(The amending regulation applied automatically in the Northern Ireland due to the NI protocol)

https://www.gov.uk/government/news/extension-of-ce-certificates

News story

Extension of CE certificates

The EU has taken steps to give manufacturers more time to get certain medical devices certified under the EU Medical Devices Regulation (EU MDR).

From: Medicines and Healthcare products Regulatory Agency

Published 28 March 2023

The EU has taken steps to give manufacturers more time to get certain medical devices certified under the EU Medical Devices Regulation (EU MDR). The new arrangements recognise the challenges in capacity across notified bodies.

This is an update to our previous announcement in February 2023.

Key changes include:

- Extension of the transitional period for higher-risk devices (class III and

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BSI client communication and webpage

https://www.bsigroup.com/en-GB/medical-devices/our-services/MDR-Revision/

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Client communication: MDR Transition Timelines Extended

20 March 2023

Dear Client,

On 20 March 2023, the Regulation (EU) 2023/607 amending the MDR and IVDR was published in the Official Journal of the European Union (OJEU) with immediate effect. The objective of the amending Regulation is to address the projected imminent risks of shortages of medical devices in EU due to the slower than anticipated transition from the medical device Directives to MDR and IVDR.

The new amending Regulation extends the MDR transition timelines while also recognising as valid previously issued MDD, AIMDD Certificates for the duration of those longer transition timelines. This allows manufacturers to continue placing their devices on the market based on compliance to the Directives while they continue the transition of their devices to the MDR. However, it is important to note that the longer transition timelines apply only to devices that are transitioning to MDR and meet other specific conditions set out in the Regulation. These conditions are aimed at ensuring that the manufacturer has taken steps to transition to the MDR. A summary of the salient points from the new amending Regulation is outlined below.

Key elements of the new amending Regulation

Medical Device Regulation (MDR)

Trending Services Devices Resources News

Medical Device Regulation

The European Medical Device Regulation (MDR) replaced the MDD and the AIMDD and entered into force on 25 May 2017 with 26 May 2021 as date of application.

To access legacy devices' extended timelines, by May 2024 manufacturers must have implemented an MDR compliant QMS and have applied to a Notified Body for a Conformity Assessment. By September 2024, the Notified Body and the manufacturer must have signed a formal written agreement. Depending on legacy devices classification, MDR transition deadline is May 2026 for Class III custom-made implantable devices, December 2027 for Class III and Class IIb implantable devices (non-WET) and December 2028 for other Class IIb, Class IIa, Class Is and class Im devices. On the same date, up-classified legacy devices (whose Declaration of Conformity was signed by 26 May 2021) now requiring Notified Body involvement must be MDR certified. All legacy devices must be MDR compliant by the end of December 2028.

The sell-off period for medical devices already placed on the market under MDD and AIMDD has been removed. These devices can be made further available on the market without legal time restrictions.

For detailed information and conditions of applicability of transitional provisions, please refer to the Regulation amending (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices published in March 2023.

**Please note, for the MDR timeline, these changes can be considered effective only once published on the Official Journal.*

Download the MDR timeline

MDR transition guide FAQ

Find answers to most frequently asked questions on the Medical Device Regulation transition and associated topics.

Download FAQs

Issued on 20th March 2023
Includes a link to some frequently asked questions

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Questions & Answers