EUROPEAN MEDICAL DEVICE REGULATION (MDR)

EXTENSION OF TRANSITION PERIODS IN ACCORDANCE WITH REGULATION (EU) 2023/607

Background

On 20 March 2023, Regulation (EU) 2023/607, amending Regulations (EU) 2017/745 with regards to the transitional provisions for certain medical devices, was published in the Official Journal of the European Union. No changes were made from the original proposal. The amendment immediately entered into force on its publication in the Official Journal.

The central elements of the regulation, as it relates to the MDR, include:

1 Extension of the validity of certificates
Article 1(1)(a)[1] amending MDR Article 120(2)

An extension is directly applicable to devices, which have not been withdrawn by a Notified Body, and which have certificates issued by notified bodies in accordance with Council Directives 93/42/EEC or 90/385/EEC that were valid on the day of the MDR's date of application i.e. 26 May 2021. The length of the extension of the certificate's validity shall be linked to the device's risk classification (refer to Extension of the Transition Period).

2 Extension of the transition period
Article 1(1)(b)[2] amending MDR Article 120(3)

The extension to the transition periods will apply to 'legacy' devices only; specifically, those devices covered by a declaration of conformity / certificate in accordance with Council Directive 93/42/EEC or 90/385/EEC issued before 26 May 2021. The duration of the extension will be based on device classification:

- ***Class III and Class IIB Implantable Devices[2]***
  The transitional provisions under the MDR are to be extended to allow such devices to be placed on the market or put into service until 31 December 2027.
- ***Class Other Class IIB devices and Class I (sterile or measuring function) Devices***
  The transitional provisions under the MDR are to be extended to allow such devices to be placed on the market or put into service until 31 December 2028.
- ***Devices up-classified under MDR*** *(i.e. those not requiring involvement of a notified body under the MDD/AIMD and which now require notified body under MDR)*
  The transitional provisions under the MDR are to be extended to allow such devices to be placed on the market or put into service until 31 December 2028.

These extensions are contingent on several cumulative conditions being met, specifically:

- Devices must continue to comply with Council Directive 93/42/EEC or 90/385/EEC.
- Devices must not undergo significant changes in the design and intended purpose.
- Devices must not present an unacceptable risk to the health or safety of patients, users or other persons.
- Manufacturers must have a Quality Management System (QMS), in accordance with Article 10(9), in place by 26 May 2024. No specific attestation i.e. no self-declaration nor verification of the appropriateness of the QMS by a notified body, is required at this stage.
- Manufacturers/Authorised Representatives must have an application for conformity assessment in accordance with the MDR by 26 May 2024 for which a signed written agreement with the Notified Body must be in place by 26 September 2024.

Manufacturers can self-declare (via issuing a self-declaration) that the conditions for the extension are fulfilled and avail of the extended transition provisions.

Furthermore, as with the existing transitional requirements, the MDR requirements related to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply (in place of the corresponding requirements under Council Directives 93/42/EEC and 90/385/EEC) to devices availing of these extended transition periods.

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1 Proposal: https://health.ec.europa.eu/system/files/2023-01/mdr_proposal.pdf
2 Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

3 Removal of the 'sell-off' deadline

Article 1(1)(c)[2] amending MDR Article 120(4)

Under the existing transitional provision of the MDR, devices availing of the transitional provisions could continue to be made available or put into service until 26 May 2025.

This amendment removes this time restriction such that devices placed on the market, in accordance with Council Directives 93/42/EEC or 90/385/EEC, prior to 26 May 2021 and devices placed on the market from 26 May 2021 which are availing of the extended transitional provisions can continue to be made available or put into service without a legal time restriction.

Impact to UK and Switzerland

Both the MHRA (UK) and SwissMedic (Switzerland) have announced their intent to formally recognize the extension with details below:

The MHRA has announced an extension to UKCA requirements (Press Release). In addition to that, the MHRA (UK) has now stated that the MDR extension provisions are automatically applied in Northern Ireland in accordance with the Northern Ireland protocol. CE certificates that have been extended will also be recognized as valid for placing on the market in Great Britain. The MHRA registration guidance has been revised to reflect this change. Lastly, the MHRA has introduced legislation to state that general medical devices compliant with the EU medical devices directive (EU MDD) with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or 30 June 2028 and general medical devices, compliant with the EU medical devices regulation (EU MDR) can be placed on the Great Britain market up until the 30 June 2030.

An infographic is available to further explain the timelines for placing CE marked medical devices on the Great Britain market.

SwissMedic (Switzerland) has stated that the extension provisions will also apply in Switzerland during the transition period. Amendments to the Switzerland medical device ordinance (MedDO) is planned for autumn 2023. Until then SwissMedic will allow the placing of devices on the Swiss market which are covered by a valid certificate according to the MDR amendment (Regulation (EU) 2023/607).

Impact to West's Legacy Medical Devices

West's legacy devices, within the Administration System product portfolio, which have not yet been certified in accordance with the MDR, are impacted by Regulation (EU) 2023/607. For these devices, proactive internal plans are in place to meet the stated conditions in the regulation now and throughout the extension period. West has actively engaged with our Notified Body and received agreement that West's legacy devices, within the Administration System product portfolio, meet the conditions, as stipulated in Article 120(3c) of the MDR (as revised by Regulation (EU) 2023/607), allowing extension of the CE certificates through to 31 December 2028. Please contact your account manager for specific details regarding the catalog numbers you purchase.