Medicines & Healthcare products
Regulatory Agency

Guidance

Registration of certain medical devices which are reusable Class I devices, upclassified Class I devices, and/or reliant on expired/expiring CE certificates

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The EU has extended the validity of certain Directive 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01993L0042-20071011) on medical devices (EU MDD) and Directive 90/385/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01990L0385-20071011) on active implantable medical devices (EU AIMDD) certificates. This guidance sets out what this means for registration and managing registered devices in the MHRA Device Online Registration System (DORS).

EU MDD and EU AIMDD CE certificates that have been extended under the revised EU MDR transitional arrangements.

The EU has revised the timelines for medical devices to comply with the EU Medical Devices Regulation (2017/745) (EU MDR). The EU will now be accepting devices with EU Medical Devices Directive (EU MDD) and EU Active Implantable Medical Devices Directive (EU AIMDD) certificates on the EU market for longer.

The EU MDR transitional arrangements have been amended to extend the validity of EU MDD and EU AIMDD CE certificates, subject to meeting certain conditions. Previously, certificates would remain valid until the end of the period indicated on the certificate and any remaining certificates would become void on 26 May 2024. The validity of certificates has been extended, to:

a) 31 December 2027 for higher risk devices (class III and class IIb implantable devices except certain devices for which the EU MDR provides exemptions, such as screws and sutures (listed in the table in Annex A) given that these devices are considered to be based on well-established technologies). This includes systems and procedure packs that contain such class III and class IIb implantable devices.

b) 31 December 2028 for medium and lower risk devices (other class IIb devices and class IIa, class Im, Is and Ir devices). This includes system and procedure packs that contain such devices and that do not contain class III and class IIb implantable devices that are covered at point (a) above.

The EU MDR now also provides that EU MDD and EU AIMDD CE certificates issued from 25 May 2017 and still valid on 26 May 2021 (that are not withdrawn by a notified body) remain valid for the above devices benefiting from the extended transition period, subject to:

- the length of the extension of the certificate's validity is the length of the applicable extended transition period under Article 120(3a) of the EU MDR (see points a and b above)
- **for certificates that have already expired** before 20 March 2023 (see: EUR-Lex - 32023R0607 - EN - EUR-Lex (europa.eu) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.080.01.0024.01.ENG&toc=OJ%3AL%3A2023%3A080%3ATOC)) the extended validity is subject to the condition that:

- before the date of expiry, the manufacturer has signed a contract with a notified body for the conformity assessment of the device in question, OR
- a competent authority has granted a derogation from the conformity assessment procedures under Article 59 of EU MDR or has given the manufacturer a period of time to carry out conformity assessment in accordance with Article 97 of EU MDR.

Please note that notified bodies are not required to change the date on the individual certificates. See the EU's revisions (EUR-Lex - 32023R0607 - EN - EUR-Lex (europa.eu) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.080.01.0024.01.ENG&toc=OJ%3AL%3A2023%3A080%3ATOC)) for more details. Please see separate guidance regarding the extension that applies to EU IVDD certificates (https://www.gov.uk/government/publications/registration-of-in-vitro-diagnostic-devices-with-expiring-ce-certificates).

Reliance on extended certificates in Great Britain (GB)

CE certificates with extended validity under the extended EU MDR transitional arrangements (Article 120) are valid for placing devices on the GB market for the period in which EU AIMDD and EU MDD CE marked medical devices are accepted on those markets.

We have put in place legislation to extend acceptance of CE marked medical devices on the GB market to support ongoing safe supply of medical devices to GB and ease the transition to the future regulatory framework for medical devices.

We have introduced measures which provide that CE marked medical devices may be placed on the GB market to the following overall timelines:

a) general medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (EU AIMDD) with a valid declaration and CE mark can be placed on the GB market up until the sooner of expiry of certificate or 30 June 2028

b) in vitro diagnostic medical devices (IVDs) compliant with the EU IVD directive (IVDD) can be placed on the GB market up until the sooner of expiry of certificate or 30 June 2030, and

c) general medical devices compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic

medical devices regulation (EU IVDR) can be placed on the GB market up until 30 June 2030.

This enables certain CE marked medical devices to continue to be placed on the GB market for longer. Class I medical devices and general IVDs under the Directives for which the conformity assessment under the EU MDD or EU IVDD did not require a notified body, can only be placed on the GB market if the involvement of a notified body would be required under the EU MDR or EU IVDR (that is, if it is an upclassified device). **Custom-made devices under the EU MDD or EU AIMDD can no longer be placed on the GB market. Please note that you can register your custom-made device under UK MDR Part II or Part III (which is currently consistent with EU medical devices directive requirements) with a suitable accompanying custom-made statement**.

If placing medical devices on the GB market under these transitional measures, manufacturers will not be able to rely on expired certificates (unless such certificates have been otherwise deemed valid by the EU).

This means devices with valid EU AIMDD and EU MDD certificates can be placed on the **GB** market up until the expiry of the certificate or 30 June 2028, whichever is sooner (see the table in Annex A).

If you have an EU MDD or EU AIMDD CE certificate with its validity extended under article 120(2) of the EU MDR that you wish to rely on for placing devices on the GB market, the MHRA encourages you to update the MHRA Device Online Registration system as set out in this guidance below.

We have also put in place strengthened post-market surveillance (PMS) requirements (https://www.gov.uk/government/news/statutory-instrument-laid-in-parliament-sets-out-first-steps-in-delivering-medical-device-regulatory-reform-and-strengthening-patient-safety) for GB.

Reliance on extended certificates in Northern Ireland (NI)

The rules for placing medical devices on the NI market differ from those applicable to GB. The EU MDR has applied in EU Member States and in NI since 26 May 2021. See Regulation of devices in Northern Ireland (https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr).

CE certificates with extended validity under the extended EU MDR transitional arrangements (Article 120) are valid for placing devices on the NI market while EU AIMDD and EU MDD CE marked medical devices are accepted on those markets.

This means provided that the conditions for placing a device on the EU market set out in Article 120(3c) are met, they are valid for placing a medical device on the NI market up until the end of the relevant transition period set out in Article 120(3a) (see the table in Annex A)

If you have an EU MDD or EU AIMDD CE certificate with its validity extended under article 120(2) of the EU MDR that you wish to rely on for placing devices on the NI market, the MHRA encourages you to update the MHRA Device Online Registration System as set out in this guidance below.

Previously expired certificates

If you wish to rely on a previously expired certificate (that was still valid on 26 May 2021 and expired before 20 March 2023), upload a letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Alternatively, instead of a letter issued by a notified body you may upload the template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx) declaring that key conditions for extension of the certificate (under EU MDR Article 120) have been met, namely:

- that the manufacturer has a signed contract with the notified body that pre-dates the original expiry of the certificate OR
- if no such contract was signed at date of expiry, then confirmation that the manufacturer had been granted a derogation from the conformity assessment procedures under Article 59 of EU MDR or that they had been given a period of time to carry out conformity assessment in accordance with Article 97 of EU MDR

Scenario 1 – CE certificate expired prior to 20 March 2023 – Device/s already registered with MHRA

If the medical device that you would like to place on the market reliant on an expired EU AIMDD or EU MDD CE certificate with validity extended under EU MDR is already registered with the MHRA, complete the following steps to make this declaration:

- access your account on the MHRA Device Online Registration System (DORS) and follow the Manage Registered Devices instructions in the

Device Registration Reference Guide (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#reference-guides)

- unlink the expired CE certificate(s)
- upload the appropriate notified body letter or declaration (see the template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx)) that Article 120 extended CE certificate validity applies (indicating that (a) or (b) above apply)
- select the original CE certificate type from the dropdown options
- select the appropriate expiry date for the reliance on the declaration – the new date the CE certificate is valid until (deadlines depending on device type are in the Annex A table below) - note that if your device is being placed on both the GB and NI market you should upload one letter or declaration for both markets and record as the expiry date the sooner applicable validity date
- enter actual CE certificate number in the reference field and append with '_EU MDR Art120 Extension'.
- select the original EU notified body designation – CE- MDD/IVDD/AIMD option
- select the name of the EU notified body currently responsible for the appropriate surveillance in respect of the device(s) concerned (if the notified body is not available in the Device Online Registration system (DORS), email: device.registrations@mhra.gov.uk)
- click 'Upload certificate'

You cannot update the date on which your certificate has expired. If you have a certificate that has expired entered on the system, you will not be able to order Certificates of Free Sale (CFS) and your registered devices on the Public Access Registration Database (PARD) will be appended with 'Conformity Assessment Certificate expired' until you have taken the above action.

Scenario 2 - CE certificate expired prior to 20 March 2023 – device/s not yet registered with the MHRA

If the medical device that you would like to place on the market reliant on an expired AIMDD or MDD CE certificate with validity extended under EU MDR is not already registered with the MHRA, complete the following steps to make this declaration.

Access your account on the MHRA Device Online Registration System (DORS) and follow the Add Devices using GMDN instructions in the Device

Registration Reference Guide (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#reference-guides) On the Conformity Assessment Certificate page:

- upload the expired CE certificate
- select correct certificate type
- enter the appropriate extended CE certificate validity date from Annex A table below in the certificate expiry date field (we recognise this is not the expiry date on the actual certificate)
- enter CE certificate reference number
- select the appropriate EU notified body designation - CE-MDD/IVDD/AIMD option
- select the correct EU notified body name
- click 'Upload certificate'
- follow steps a-g for any additional CE certificates required for the device, then:
- upload the appropriate notified body letter or declaration (see the template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx)) that Article 120 extended CE certificate validity applies (indicating (a) or (b) above apply)
- select the original CE certificate type from the dropdown options
- select the appropriate validity date for the Device Class per below table (Annex A)
- enter actual CE certificate number in the reference field and append with '_EU MDR Art120 Extension'
- select the original EU notified body designation - CE- MDD/IVDD/AIMD option
- select the name of the EU notified body currently responsible for the appropriate surveillance in respect of the device(s) concerned (if the notified body is not available in the Device Online Registration System (DORS), email: device.registrations@mhra.gov.uk)
- click 'Upload certificate'

Certificates expiring on or after 20 March 2023

If you wish to rely on a certificate that was valid on 26 May 2021 and has expired on or after 20 March 2023 or will expire after 20 March 2023, upload a letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written

agreement. Or instead of a letter issued by a notified body you may upload a declaration that the certificate remains valid under EU MDR Article 120.

We have provided a template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx) for this declaration – the above declaration is set out as option c in the template.

Scenario 3 – CE certificate was due to expire on or after 20 March 2023 – device/s already registered with MHRA

To do this, access your account on the MHRA Device Online Registration System (DORS) and follow the Manage Registered Devices instructions in the Device Registration Reference Guide to:

- unlink the expired CE certificate(s)
- upload the appropriate notified body letter or declaration (see the template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx)) Article 120 extended CE certificate validity applies (indicating (c) applies)
- select the original CE certificate type from the dropdown options
- select the appropriate validity date for the Device Class as set out in the Annex A table below - note that if your device is being placed on both the GB and NI market you should upload one letter or declaration for both markets and record as the expiry date the sooner applicable expiry date
- enter actual CE certificate number in the reference field and append with '_EU MDR Art120 Extension'
- select the original EU notified body designation - CE- MDD/IVDD/AIMD option
- select the name of the EU notified body currently responsible for the appropriate surveillance in respect of the device(s) concerned (if the notified body is not available in the Device Online Registration System (DORS), email: device.registrations@mhra.gov.uk)
- click 'Upload certificate'

You cannot update the date on which your certificate has expired. If you have a certificate that has expired entered on the device registration system, you will not be able to order Certificates of Free Sale (CFS) and your registered devices on the Public Access Registrations Database (PARD) (https://pard.mhra.gov.uk/) will be appended with 'Conformity Assessment Certificate expired' until you have taken the above action. We

therefore recommend that you take the above action before the expiry date of your CE certificates/s.

Scenario 4 - CE certificate due to expire on or after 20 March 2023 – NOT yet registered with the MHRA

If the medical device that you would like to place on the market is reliant on an expired AIMDD or MDD CE certificate with validity extended under EU MDR and is NOT already registered with the MHRA, complete the following steps to register your device/s and make this declaration.

Access your account on the MHRA Device Online Registration System (DORS) and follow the Add Devices using GMDN instructions in the Device Registration Reference Guide (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#reference-guides) On the Conformity Assessment Certificate page:

- upload the expired CE certificate
- select correct certificate type
- enter the appropriate extended CE certificate validity date (from Annex A table below) in the certificate expiry date field (we recognise this is not the expiry date on the actual certificate)
- enter CE certificate reference numbers
- select the appropriate EU notified body designation - CE-MDD/IVDD/AIMD option
- select the correct EU notified body name
- click ‘Upload certificate’
- follow steps a-g for any additional CE certificates required for the device, then:
- upload the appropriate notified body letter or declaration (see the template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx)) that Article 120 extended CE certificate validity applies (indicating (c) applies)
- select the original CE certificate type from the dropdown options
- select the appropriate validity date for the Device Class as set out in the Annex A table - note that if your device is being placed on both the GB and NI market you should upload one letter or declaration for both markets and record as the expiry date the sooner applicable validity date
- enter actual CE certificate number in the reference field and append with ‘_EU MDR Art120 Extension’.

- select the original EU notified body designation - CE- MDD/IVDD/AIMD option
- select the name of the EU notified body currently responsible for the appropriate surveillance in respect of the device(s) concerned (if the notified body is not available in the Device Online Registration System (DORS), email: device.registrations@mhra.gov.uk)
- click ‘Upload certificate’

Upclassified Class I medical devices and Class I reusable surgical instruments

EU MDR Article 120(3b) deals with upclassified Class I devices (devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC 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 EU MDR requires the involvement of a notified body).

The EU MDR also sets our requirements for devices which are Class I reusable surgical instruments.

If you wish to rely on a declaration of conformity under EU MDD (for an upclassified device or a device that is a Class I reusable surgical instrument under EU MDR) that was issued before 26 May 2021 to place a device on the NI market, the manufacturer would need to have met the relevant conditions (including the conditions for continued reliance on the aforementioned declaration of conformity (under EU MDR Article 120(3c)), namely:

- those devices continue to comply with Directive 93/42/EEC, as applicable
- there are no significant changes in the design and intended purpose
- 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

In addition, you will need to have completed the following steps below:

- by 26 May 2024, you will need to provide evidence that you have put in place a quality management system in accordance with EU MDR Article 10(9)
- by 26 May 2024 you will need to provide evidence that you or your authorised representative have lodged a formal application with a notified body

- by 26 September 2024, you will need to provide evidence that the notified body and the manufacturer have signed a written agreement

Scenario 5 – EU MDD Class I medical devices that have been upclassified under EU MDR or are a device that is a Class I reusable surgical instrument under EU MDR and require notified body involvement pursuant to EU MDR – Devices already registered with MHRA with a self-declaration under EU MDD

Until the dates set out in the table below, no further action is required in the registration system at this time to maintain reliance on your self-declaration under EU MDD for a device which is Class I medical device under EU MDD that is upclassified under EU MDR or is a device which is a Class I reusable surgical instrument under EU MDD that, under EU MDR, will require Notified Body involvement in its assessment. Please sign up to receive updates via the MHRA registration guidance page (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market) fo (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market)r updates on any future registration requirements related to upclassified medical devices.

Scenario 6 - EU MDD Class I medical devices that have been upclassified under EU MDR, or are a Class I reusable surgical instrument and require notified body involvement pursuant to EU MDR – Device/s NOT yet registered with MHRA

You can register a device with the MHRA which is a non-sterile, non-measuring Class I medical device under EU MDD that is upclassified under EU MDR with an EU MDD self-declaration until the dates set out in the table below.

You can also register a device with the MHRA which is a non-sterile, non-measuring Class I reusable surgical instrument under EU MDD that under EU MDR requires Notified Body involvement in its assessment with an EU MDD self-declaration until the dates set out in the table below.

To register your device with the MHRA in this scenario, access your account on the MHRA Device Online Registration System (DORS) and follow the

instructions to Add Devices using GMDN in the Device Registration Reference Guide (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#reference-guides)

Annex A: extended validity dates

Device Class (general medical devices)	NI market Extended certificate validity end date under EU MDR	GB market Extended certificate validity end date
Class III Class IIb implantables (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) This will apply to system and procedure packs if they contain a device in the above classes.	31 December 2027	31 December 2027
Class IIb (non-implantable) and sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors Class IIa Class Is and Im This will include system and procedure packs that contain such devices unless they also include a Class III or Class IIb implantable device (in which case the validity date will be 31 December 2027 for NI and 30 June 2028 for GB).	31 December 2028	30 June 2028 Note that although the certificate validity will be extended to 31 December 2028 under the EU MDR, these devices can only be placed on the GB market until 30 June 2028. Therefore, for devices being registered for the GB market, the new expiry date should be entered as ’30 June 2028’.

Device Class (general medical devices)	NI market Extended certificate validity end date under EU MDR	GB market Extended certificate validity end date
Upclassified Class I devices (that newly require involvement of a notified body under EU MDR)	The EU MDD Declaration of Conformity will be valid until **31 December 2028**	The EU MDD Declaration of Conformity will be valid until **30 June 2028**

The above dates are subject to any relevant conditions under EU MDR Article 120(3c) being met. Please note, if your device is being placed on both the GB and NI markets you should upload one declaration that Article 120 extended CE certificate validity applies for placement on both the GB and NI markets combined.

Where reliance on such a certificate is possible for longer in NI than in GB, the expiry date of the declaration should be the earlier end date – 30 June 2028. To continue to rely on such a certificate for placement on the NI market alone after that time, the system will need to be updated, and a further declaration uploaded relating to placement on the NI market alone. To update your registration please follow the Update Registered Devices and Products instructions in the MHRA Device Registration Reference Guide (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#reference-guides) to update the product status from 'On the GB & NI market' to 'On the NI market'. Then unlink the EU MDR Article 120 extension confirmation that expires on 30 June 2028 by following the Manage Registered devices instructions and upload a new EU MDR Article 120 extension confirmation for the NI market only, that expires on 31 December 2028.