To whom it may concern,

Assendelft, the Netherlands, 17 May 2024,

Subject: Extension of validity CE-certificates of CuraMedical B.V.

An amendment to the EU's Medical Device Regulation (MDR) extended the certificate validity for certain legacy medical devices. The deadline of May 26, 2024, has been postponed to 31 December 2027 for all CuraMedical B.V. device families. This extension period is called the transitional period or Grace Period.

The Notified Body MDC (Medical Device Certification GmbH) of CuraMedical B.V. has provided us with an official extension letter (D1169400035 dated 24-04-2024) that confirms this Grace Period. This means our current CE-certificates remain valid until 31 December 2027, i.e. our products can still be placed on the EU market during this Grace Period.

Please note that Notified Bodies can and will no longer provide new certificates. For that reason, the attached confirmation letter is in place, and should be considered as an extended certificate.

Certain requirements are applicable to this regulation, and these can be found in the attached documents (Notified Body Confirmation Letter and CuraMedical Manufacturer's Declaration).

The following product families are covered by this declaration:

- CuraSpon®
- TenaTac®
- CuraCel® (including CuraCel® Standard, CuraCel® High Density and CuraCel® Fibrillar)
- CuraTamp®
- CuraWax®

Important requirements that are consistently met to maintain the extended validity of the certificates during the transitional period are listed below:

- CuraMedical B.V. and mdc medical device certification have signed a formal written agreement for certification of the whole product range according to Regulation (EU) 2017/745 (MDR)
- CuraMedical B.V. devices continue to comply with Directive 93/42/EEC
- CuraMedical B.V. devices have not undergone or will not undergo significant changes in their design and intended purpose during this transitional period.
- CuraMedical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects to the protection of public health
- CuraMedical B.V. has put in place a quality management system in accordance with Article 10(9) of Regulation (EU) 2017/745.

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In case there are any questions, do not hesitate to contact Patricia Garcia Rodriguez on p.garcia-rodriguez@curamedical.com.

References:

- Regulation (EU) 2017/745
- Regulation (EU) 2023/607
- MDCG 2021-25

Attachments:

- Notified Body Confirmation Letter: D1169400035 dated 24-04-2024.
- CuraMedical Manufacturer's Declaration dated 20-02-2024.

Signed by:	Patricia Garcia Rodriguez
Function:	Manager Quality & Regulatory Affairs & Person Responsible for Regulatory Compliance (PRRC)
Place:	Assendelft, the Netherlands
Date:	17 May 2024
Signature:	

CuraMedical B.V.
Industrieweg 6B
1566 JP Assendelft
Netherlands

Notified Body Confirmation Letter

Registration no.: D1169400035

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

CuraMedical B.V.
Industrieweg 6B
1566 JP Assendelft
Netherlands
SRN: NL-MF000000052

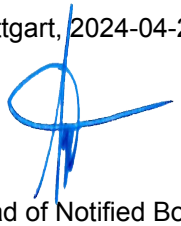
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which a MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Stuttgart, 2024-04-24



Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CuraSpon® **Bloxang®** **Gelaspon®** **Basic UDI-DI: 871790334SPONQB**	Class III Class III Class III	N/A N/A N/A	Certificates D1169400031; NB 0483 (EC Design examination, Annex II Section 4) D1169400028; NB 0483 (Quality System, Annex II, excluding Section 4)
TenaTac® **Basic UDI-DI: 871790334TACQV**	Class III	N/A	Certificates: D1169400033; NB 0483 (EC Design examination, Annex II Section 4) D1169400028; NB 0483 (Quality System, Annex II, excluding Section 4)
CuraCel® **Basic UDI-DI: 871790334CELP6**	Class III	N/A	Certificates: D1169400030; NB 0483 (EC Design examination, Annex II Section 4) D1169400028; NB 0483 (Quality System, Annex II, excluding Section 4)
CuraTamp® **Basic UDI-DI: 871790334TAMPN5**	Class III	N/A	Certificates: D1169400030; NB 0483 (EC Design examination, Annex II Section 4) D1169400028; NB 0483 (Quality System, Annex II, excluding Section 4)
CuraWax® **Basic UDI-DI: 871790334WAXSN**	Class IIb	N/A	Certificate: D1169400028; NB 0483 (Quality System, Annex II, excluding Section 4)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-24	D1169400035	Initial

mdc medical device certification GmbH
Kriegerstraße 6 | 70191 Stuttgart | Germany | www.mdc-ce.de

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	CuraMedical B.V.
Manufacturer address and contact details	Industrieweg 6B 1566 JP Assendelft The Netherlands
Single Registration Number (SRN) (if available)	NL-MF-000000052

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	MDC □ See attached schedule
Notified body number (if applicable)	0483 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	D1169400028 D1169400030 D1169400031 D1169400033 D1169400034 □ 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.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26-May-2024 □ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  X Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] 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

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up classified devices**

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:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- X A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

CuraMedical B.V.

Assendelft, 20-Feb-2024





Patricia Garcia Rodriguez, Manager Quality & Regulatory Affairs (QARC)
p.garcia-rodriguez@curamedical.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CuraSpon, CuraCel Standard, CuraCel Fibrillar, CuraCel High Density, CuraTamp Standard, TenaTac, CuraWax	**D1169400028**	**2024-05-26**	**MDC 0483**	**MDC 0483**	**2027-12-31**	**Not applicable**
CuraCel Standard, CuraCel Fibrillar, CuraCel High Density, CuraTamp Standard	**D1169400030**	**2024-05-26**	**MDC 0483**	**MDC 0483**	**2027-12-31**	**Not applicable**
CuraSpon	**D1169400031**	**2024-05-26**	**MDC 0483**	**MDC 0483**	**2027-12-31**	**Not applicable**
TenaTac	**D1169400033**	**2024-05-26**	**MDC 0483**	**MDC 0483**	**2027-12-31**	**Not applicable**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)