

## 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*<sup>1</sup>
- 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	CeramOptec GmbH
Manufacturer address and contact details	Siemensstraße 44, 53121 Bonn, Germany
Single Registration Number (SRN) (if available)	DE-MF-000005607

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

Notified body name (if applicable)	MDD: kiwa Certification Services Inc. MDR: mdc medical device certificate GmbH
------------------------------------	---

<sup>1</sup> 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.

	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	kiwa Certification Services Inc.:1984 mdc medical device certificate GmbH: 0483  <div style="text-align: right;"><input checked="" type="checkbox"/> See attached schedule</div>
Directive Certificate number(s) to which this confirmation is made (if applicable)	1984-MDD-16-372  <div style="text-align: right;"><input checked="" type="checkbox"/> See attached schedule</div>
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	12 March 2024  <div style="text-align: right;"><input checked="" type="checkbox"/> See attached schedule</div>
End date of extended validity/transition period	December 31, 2028, for Class IIb December 31, 2027, for Class III  <div style="text-align: right;"><input checked="" type="checkbox"/> See attached schedule</div>

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*<sup>2</sup>
  - 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:
  - 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)

<sup>2</sup> 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



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

Expired/expires *after* 20 March 2023:

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 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.

➤ **Upclassified 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.
- 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:**

Full Company Name: CeramOptec GmbH

Location & Date: Bonn, 15.01.2024

Signature, Print Name, Title: **Dr. Roland Dreschau**

Contact Details (at least email): [roland.dreschau@biolitec.com](mailto:roland.dreschau@biolitec.com)



**Schedule of Devices**

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

Identification of the device(s) <sup>3</sup> (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)
Bare Fiber, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Bare Fiber, reusable, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Cylindrical Diffusor, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
CALA, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2027	NA
ELVeS Fiber, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
ELVeS Radial, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA

<sup>3</sup> 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)



Endoprobe, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Gas-Liquid Cooled Fiber, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
PLDD Bare Fiber, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Side Fiber, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Twister, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
X-ray, single use sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Ceralas E	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Ceralas HPD	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Leonardo	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Leonardo HPD	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Leonardo Mini	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Leonardo FPS	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Leonardo Bonsai	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA

Athletik-LED	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
Handpieces, Dermatology/Condyloma, Accessory Laser	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA
ELVeS Plus Cathether, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	December 31, 2028	NA