CeramOptec

EG-Konformitätserklärung
EC Declaration of Conformity

gemäß EG-Richtlinie 93/42/EWG inkl. der Änderung 2007/47/EG
according to EC directive 93/42/EEC incl. Amendment 2007/47/EC

Produkt *Product*	**Gas-, Liquid Cooled Fiber, single-use, steril, siehe Anhang "Produkte"** **Gas-, Liquid Cooled Fiber, single-use, sterile, see Appendix „Products"**
Klassifizierung *Classification*	IIb gemäß EG-Richtlinie 93/42/EWG Anhang IX; Regel 9. *IIb according to EC directive 93/42/EC Annex IX, rule 9.*
UMDNS-Nummer UMDNS-No	17-807
GMDN-Nummer GMDN-No	62600
Hersteller **Manufacturer**	CeramOptec GmbH Siemensstraße 44 53121 Bonn Germany

Hiermit erklären wir die Konformität der im Anhang „Produkte" gelisteten Produkte gemäß EG-Richtlinie 93/42/EWG Anhang I, (mit den anwendbaren harmonisierten Normen) sowie Anhang II (ohne Abschnitt 4).
We hereby declare the conformity of products listed in appendix „Products" according to EC directive 93/42/EC Annex I (including all applicable harmonized standards) and Annex II (w/o section 4).

Benannte Stelle Notified Body	**Kiwa Certification Services Inc.** (Kennnummer 1984) İTOSB 9. Cad. No:15 Tepeören Tuzla İstanbul Türkiye
EG-Zertifikat EC-Certificate	1984-MDD-16-372 gültig bis 12.03.2024 1984-MDD-16-372 valid until 12.03.2024
Gültigkeit dieser EG-Konformitätserklärung *Expiring date of this Declaration of Conformity*	12.03.2024

Bonn, 06.12.2019

Ceramoptec

Anhang PRODUKTE
Appendix PRODUCTS

REF	Produktname / Product name
500200525	GLC 180 Gas-, Liquid Cooled Fiber
500201903-1	Gas Cooled Fiber GLC-0180 SH Sharplan connector
500201903	GLC 180 Gas-, Liquid Cooled Fiber, Sharplan connector
500201938	Ceralas GLC-0210 DL length: 4m
501200520	GLC 180 Gas-, Liquid Cooled Fiber, Broncho, ID 3x3h
501200525-1	GLC 180 Gas-, Liquid Cooled Fiber, ID 1x6h, TESL
501200525	GLC 180 Gas-, Liquid Cooled Fiber, ID 1x6h
501200550	GLC 180 Gas-Liquid Cooled Fiber, 3.5m, ID 1x6h
503200520	GLC 180 Gas-, Liquid Cooled Fiber, Broncho, IC 3x3h
503200525	GLC 180 Gas-, Liquid Cooled Fiber, IC 1x6h
503200550	GLC 180 Gas-Liquid Cooled Fiber, 3.5m, IC 1x6h
FV 600	Fibre 600 m — OH^- - vent.-L:3,00m-Dia1,8mm
FV600L	Fibre 600 m vent. - L:3,00 m Dia 1,8 mm

CeramOptec GmbH | Siemensstraße 44 | D-53121 Bonn

CeramOptec GmbH
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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	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

[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.

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

  ☐ 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)

[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

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

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)
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

[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)

Endoprobe, single use, sterile	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 31, 2028	NA
Leonardo	1984-MDD-16-372	12 March 2024	kiwa Certification Services Inc. Nr.: 1984	mdc medical device certificate GmbH Nr.: 0483	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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	Decembe r 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

Kiwa Belgelendirme Hizmetleri A.Ş.
İ.T.O.S.B 9. Cadde No: 15
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Tuzla İstanbul
Türkiye

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Notified Body Confirmation Letter

Subject/*Konu*: Continuation of Surveillance Audits in the Context of MDD Certificate Extension
MDD Sertifikasının Uzatılması Bağlamında Gözetim Denetimlerinin Devamı

Date/*Tarih*: 20.11.2023

Reference No/*Referans Numarası*: MY-23-002695

To whom it may concern,
Sayın Yetkili,

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.
AB) 2017/745 sayılı ve (AB) 2017/746 sayılı Tüzükleri belirli Tıbbi cihazların ve in vitro tanı amaçlı Tıbbi cihazların geçiş hükümlerini tadil eden 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü" Sayılı Yönetmelik çerçevesinde, resmi bir başvurunun durumunun onaylanması, yazılı anlaşma ve uygun gözetim.

This letter confirms that, **MDC MEDICAL DEVICE CERTIFICATION GMB** 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 **(Customer No: D14869)** in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer
*Bu mektup, (AB) 2017/745 Sayılı Yönetmelik (MDR) kapsamında atanan ve NANDO'da **0483** numarası ile tanımlanan bir Bildirilmiş Kuruluş (NB) olan **MDC MEDICAL DEVICE CERTIFICATION GMB**'nın, MDR'nin Ek VII'nin 4.3. maddesi birinci alt paragrafına uygun olarak alınan resmi bir başvuruyu ve MDR'nin Ek VII'nin 4.3. maddesi ikinci alt paragrafına uygun olarak imzalanan **(Customer No:D14869)** yazılı anlaşmayı aşağıdaki üretici ile gerçekleştirdiğini teyit etmektedir.*

Ceramoptec GmbH
Siemensstrasse 44, 53121 Bonn, Germany
Facility: Brühler Strasse 30, 53119 Bonn, Germany

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 with-drawn, 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 in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

90/385/EEC Sayılı Direktif (AIMDD) veya 93/42/EEC Sayılı Direktif (MDD) kapsamında düzenlenen ve 26 Mayıs 2021 tarihinden sonra ve 20 Mart 2023 tarihinden önce süresi dolan ve geri çekilmemiş sertifikalı cihazlar durumunda, bu mektup ayrıca şunları da teyit etmektedir:

-Üretici, MDD/AIMDD sertifikasının süresi dolmadan önce MDR kapsamında yazılı anlaşmayı imzalamıştır; veya
-Bir AB üye devletinin yetkili makamının, MDR'nin 59(1) maddesine uygun olarak bir muafiyet verdiğine dair kanıt sunulmuştur; veya
-Bir AB üye devletinin yetkili makamının, MDR'nin 97(1) maddesine uygun olarak geçerli uygunluk değerlendirme prosedüründen muafiyet verdiğine dair kanıt sunulmuştur.

On **16.11.2023**, an application was submitted to our organization for MDD surveillance audits of the products specified in **Annex-I**, and the contract with Reference Number **QUO-189677-C1V0D5** was signed on **16.11.2023**. In this context, the company's audits will be continued by Kiwa Certification Services Inc. until **26.09.2024**.

***16.11.2023** tarihinde, **Ek-I'de** belirtilen ürünlerin MDD denetim denetimleri için kuruluşumuza başvuruda bulunulmuş ve **16.11.2023** tarihinde **QUO-189677-C1V0D5** referans numaralı sözleşme imzalanmıştır. Bu bağlamda, şirketin denetimleri Kiwa Belgelendirme Hizmetleri A.Ş. tarafından **26.09.2024** tarihine kadar devam ettirilecektir.*

Annex-I: Certificate Information
Ek-I: Sertifika bilgileri

Notified Body/*Onaylı Kuruluş*	Products */Cihazlar*	Certificate Number/*Sertifika Numarası*	Valid Date/ *Geçerlilik Tarihi*	Regulation */Yönetmelik*
Kiwa Belgelendirme Hizmetleri A.Ş.	-Diode Lasers -Probes for Lasers -Handpieces -Introducer for Probes -Athletic LED -CALA, Single Use, Sterile	1984-MDD-16-372/1984-MDD-21-745	12.03.2024	93/42/AT

Kind Regards,
Saygılarımla,
Debut General Menager
Genel Müfür Yardımcısı

Mehmet Fevzi Gülünay

KİWA BELGELENDİRME HİZMETLERİ A.Ş.
Eski Ankara Asfalt Yanyol Tuzla Org. San. Bölg.
9. Cad. No: 13 Tepeören/ Tuzla/ İSTANBUL/ TÜRKİYE
Tuzla V.D. 6280054464 Ticaret Sic. No:365270
Mersis No: 0628007475700019