CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-16-372

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

CeramOptec GmbH

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

Products: Diode Lasers, Probes for Lasers, Handpieces, Introducer for Probes, Athletic LED

The products defined at the enclosure which is the part of this certificate and contains two pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.
Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III device covered by this certificate.

Report Number:	M.4508.06
Date of first issue:	14 March 2016
Date of last issue:	25 May 2021
Revision Number:	06
Expiry Date:	12 March 2024

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 06

Concerned medical devices;

Product: Diode Lasers
Types:
- Type Ceralas E
- Type Ceralas HPD
- Type Leonardo
- Type Leonardo HPD
- Type Leonardo Mini
- Type Leonardo Bonsai
- Type Leonardo FPS

Product: Probes for Lasers
Types:
- Type Bare Fiber, single-use, sterile
- Type Bare Fiber, reusable, sterile
- Type Endoprobe, single-use, sterile
- Type Gas Liquid Cooled, single-use, sterile
- Type Side Fiber, single-use, sterile
- Type PLDD Bare Fiber, single-use, sterile
- Type Cylindrical diffuser, single-use, sterile
- Type ELVeS Fiber, single-use, sterile
- Type Twister, single-use, sterile
- Type ELVeS Radial, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, reusable, sterile
- X-Ray, single-use, sterile
- CALA, single-use, sterile

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 06

Concerned medical devices;

Product: Handpieces
Type: Type Derma Handpiece; reusable, Loma Handpiece

Product: Introducer for Probes
Type: Type ELVeS Plus Catheter, sterile

Product: Athletic LED

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
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CeramOptec GmbH | Siemensstraße 44 | D-53121 Bonn

CeramOptec GmbH
Siemensstraße 44
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www.ceramoptec.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	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

CeramOptec GmbH
Siemensstraße 44
53121 Bonn
Germany

Notified Body Confirmation Letter

Registration no.: D1486900005

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:

CeramOptec GmbH
Siemensstraße 44
53121 Bonn
Germany
SRN: DE-MF-000005607

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, 2024-11-15

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
Bare Fiber Subgroups: Bare Fiber, single use Bare Fiber, reusable BASIC-UDI-DI: 404905902N2	Class IIa	N/A	1984-MDD-16-372; NB 1984
Cylindrical Diffuser BASIC-UDI-DI: 404905911N3	Class IIa	N/A	1984-MDD-16-372; NB 1984
ELVeS Subgroups: ELVeS Radial ELVeS Bare Fiber X-Ray Fiber ELVeS Plus Catheter BASIC-UDI-DI: 404905901 MY	Class IIa	N/A	1984-MDD-16-372; NB 1984
Proctology Subgroups: FiLaC Fiber LHP Fiber HeLP Fiber BASIC-UDI-DI: 404905910MZ	Class IIa	N/A	1984-MDD-16-372; NB 1984
Endoprobe BASIC-UDI-DI: 404905905N8	Class IIa	N/A	1984-MDD-16-372; NB 1984
Gas-/Liquid Cooled Fiber BASIC-UDI-DI: 404905909NG	Class IIa	N/A	1984-MDD-16-372; NB 1984
PLDD BASIC-UDI-DI: 404905907NC	Class IIa	N/A	1984-MDD-16-372; NB 1984

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
Twister Subgroups: Side Fiber XCAVATOR Fiber Twister Fiber TULA fiber Gynecology Fiber BASIC-UDI-DI: 404905904N6	Class IIa	N/A	1984-MDD-16-372; NB 1984
Ceralas Subgroups: Ceralas E Ceralas HPD BASIC-UDI-DI: 404905947NQ	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Leonardo BASIC-UDI-DI: 404905941NC	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Leonardo Bonsai BASIC-UDI-DI: 404905944NJ	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Leonardo HPD BASIC-UDI-DI: 404905943NG	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Leonardo Mini BASIC-UDI-DI: 404905942NE	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Leonardo FPS BASIC-UDI-DI: 404905946NN	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
beyond RED Pro BASIC-UDI-DI: 404905945NL	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984
Handpieces Dermatology/ Condyloma Accessory Laser BASIC-UDI-DI: 404905912N5	Class IIb excluding Class IIb implantable non-WET	N/A	1984-MDD-16-372; NB 1984

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
Bare Fiber for Ho:YAG Laser, single-use, sterile	Class IIa	N/A	1984-MDD-16-372; NB 1984
Bare Fiber for Ho:YAG Laser, reusable, sterile	Class IIa	N/A	1984-MDD-16-372; NB 1984
CALA	Class III	N/A	1984-MDD-16-372; NB 1984

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-08-15	D1486900002	Initial
2024-11-15	D1486900005	Rev 01: Revision of the products covered by this letter

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

mdc	**Transfer Agreement for Surveillance of Legacy Devices**	11323 003/08.2023

This agreement specifies the terms of the transfer of the appropriate surveillance activities according to Article 120 (3e) of Regulation (EU) (EU) 2017/745[1] in respect of legacy devices covered by a certificate issued in accordance with Directive 93/42/EEC between the manufacturer

CeramOptec GmbH
Siemensstraße 44
53121 Bonn
Germany

(in the following "CERTIFICATION HOLDER"),

his Notified Body under Directive 93/42/EEC with the identification number **1984**

Kiwa Belgelendirme Hizmetleri A.Ş
ITOSB 9.Cadde No:15 Tepeören
Tuzla - İstanbul
Türkiye

(in the following "OUTGOING NB")

and his Notified Body under Regulation (EU) 2017/745 with the identification number **0483**

mdc medical device certification GmbH
Kriegerstraße 6
70191 Stuttgart
Germany

(in the following "INCOMING NB")

The parties have concluded the following under the TRANSFER DATE effective on **[2024-09-27]**:

§ 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by OUTGOING NB in accordance with Directive 93/42/EEC that is valid or to be considered to be valid by virtue of paragraph 2 of Article 120 Regulation (EU) 2017/745 covering devices which are placed on the market after date of application of the Regulation (EU) 2017/745 until the date set out in paragraph 3a of Article 120 of this Regulation (hereinafter referred to as "legacy device[2]") that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 120 (3e) of Regulation (EU) 2017/745 (hereinafter referred to as "appropriate surveillance"), and intends that this appropriate surveillance in respect of that legacy devices are in future carried out by the INCOMING NB. Appropriate surveillance[3] can include for example documentation review, audits or other kinds of assessments performed by a notified body in respect of a legacy device (see § 6 (1)) as part of CERTIFICATION HOLDER's previous conformity assessment procedure under Directive 93/42/EEC. Certification is a valid confirmation in the form of a certification document, in accordance this Directive, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by OUTGOING NB[4].

2. The legacy devices that the OUTGOING NB issued a certification for and which are subject to transferred appropriate surveillance to the INCOMING NB (hereinafter referred to as "legacy devices subject to transfer of appropriate surveillance"), and the agreed date on which any review activities by the INCOMING NB in accordance with § 4 are to be completed and from which any surveillance activities by the INCOMING NB are to be carried out and the responsibility for the appropriate surveillance assumed by INCOMING NB (hereinafter referred to as "TRANSFER DATE"), are specified in Appendix 1. The TRANSFER DATE shall not exceed 26 September 2024.

3. Appropriate surveillance may be transferred only in respect of a legacy device for as long as it is included in the scope of a certification considered as valid in accordance with Article 120 paragraph 2 or Regulation (EU) 2017/745 and issued by an OUTGOING NB covered with the respective designation/notification valid at the time when this certification was issued.

[1] As amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023
[2] As per MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021)
[3] MDCG 2022-4 Rev. 1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR regarding devices covered by certificates according to the MDD or the AIMDD
Examples of surveillance activities (non-exhaustive): QMS audits, focused audits (e.g. sterilization, microbiology, supplier etc.), unannounced audits, for cause audits, change notification assessment, e.g. changes which are considered not to be significant as per Art. 120.3, Vigilance handling, appeals, complaints, authority notes (e.g. CEFs, classification disputes/decisions), certificate actions (withdrawal, suspension, re-instatement, cancellations), notification to national authorities
[4] According MDCG 2020-3 rev 1 section 4.3

Certification, which is suspended or temporarily restricted for the relevant legacy device may not be accepted for transfer of appropriate surveillance in respect of that device, but it is up to the INCOMING NB's decision and subject to the assessment prior to transfer in accordance with § 4.
Certification, which is withdrawn or otherwise invalidated prior to TRANSFER DATE is not subject to transfer of appropriate surveillance in respect of that device.

4. The transition of appropriate surveillance in respect of a legacy device from OUTGOING NB to INCOMING NB by way of transfer means that the INCOMING NB, when assuming these activities, takes into account, according to its procedures, the activities of the OUTGOING NB in respect of that device. The INCOMING NB has to ensure that adequate rights and obligations are agreed with CERTIFICATION HOLDER on a contractual basis to ensure the performance of appropriate surveillance incl. the right to suspend, restrict, withdraw etc. concerned certificates that issued the OUTGOING NB and are subject to this agreement; this includes as well auditing rights e.g. on the premisses of CERTIFICATE HOLDER and his subcontractors etc.

5. The appropriate surveillance subject to transfer performed by OUTGOING NB prior to transfer date is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and OUTGOING NB. Following the transfer, the OUTGOING NB and the manufacturer shall amend or terminate (whatever is applicable) their certification agreements in respect of legacy devices subject to transfer of appropriate surveillance.

6. This Agreement specifies the terms and modalities for the transfer of appropriate surveillance from an OUTGOING NB to an INCOMING NB in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities between the OUTGOING NB and the INCOMING NB in accordance with this Regulation and requirements. The appropriate surveillance should be transferred from OUTGOING NB to INCOMING NB in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

§ 2 Agreement conclusion and amendments

The transfer of appropriate surveillance in accordance with this Agreement shall be accomplished in the following steps:

1. (Step1): The transfer process starts with the conclusion of this Agreement, including Appendix 1. Specification of TRANSFER DATE in Appendix 1 and the complete Appendix 2 are optional in this step and may be provided in Step 2.

   a. CERTIFICATION HOLDER signs the Agreement. The Agreement shall include Appendix 1, and certificates listed in Appendix 1 shall be attached. The Agreement may additionally include Appendix 2. CERTIFICATION HOLDER then forwards the Agreement to INCOMING NB.

   b. INCOMING NB verifies and countersigns the Agreement and returns it to CERTIFICATION HOLDER. At this time, any unclarities in the description of appropriate surveillance subject to transfer shall be resolved between the INCOMING NB and CERTIFICATION HOLDER, and corrections to the Agreement made, as necessary. The CERTIFICATION HOLDER then forwards the Agreement to the OUTGOING NB.

   c. OUTGOING NB verifies and countersigns the Agreement, and forwards it to both CERTIFICATION HOLDER and INCOMING NB.

2. (Step 2): As soon as the INCOMING NB's activities have progressed sufficiently in order to specify the TRANSFER DATE and any other information in Appendices 1 and 2, or if it becomes clear that any of this information is no longer correct, the information in Appendices 1 and 2 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 3 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

If the involvement of the OUTGOING NB in this Agreement is not practicable[5], only in those cases, the Agreement shall be considered valid with only two signatures. In those cases the obligations of the OUTGOING NB in accordance with this Agreement should be fulfilled by CERTIFICATION HOLDER as far as possible.

[5] Q&A on practical aspects related to the implementation 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 (March 2023)

In this case, it is the responsibility of the INCOMING NB to decide whether the transition of appropriate surveillance by way of transfer is appropriate, what additional assessment activities are needed prior to assuming the responsibility for the appropriate surveillance, and whether they are sufficient to maintain the appropriate surveillance in the way to keep the certification valid in the meaning of § 3 (1).

§ 3 Validity of certification and notified body surveillance activities for the legacy devices subject to transfer of appropriate surveillance

1. CERTIFICATION HOLDER shall comply with the requirements of Article 120 of Regulation (EU) 2017/745 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.

2. OUTGOING NB shall not suspend or withdraw the CERTIFICATION HOLDER's certification, in respect of legacy devices subject to transfer of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the CERTIFICATION HOLDER is transferring the appropriate surveillance to the INCOMING NB. The rights of the OUTGOING NB to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected until the date of transfer. Followed by the transfer, contractual agreements shall be amended respectively or terminated (whatever is applicable) (see § 1 (5)).

3. Appropriate surveillance, performed by OUTGOING NB, will be fully transferred in respect of the legacy devices specified in Appendix 1, i.e. equivalent appropriate surveillance will be commenced by the INCOMING NB, on the TRANSFER DATE.

4. CERTIFICATION HOLDER shall continue to apply the notified body identification number of the OUTGOING NB to legacy devices subject to transfer of appropriate surveillance, if not otherwise agreed as per Appendix 2.

5. If agreed as per Appendix 2, the change of notified body identification number from OUTGOING NB to INCOMING NB number shall be documented for devices in the scope of certification the legacy devices subject to transfer of appropriate surveillance on a product-by-product basis during the agreed TRANSITION SELL-OFF PERIOD. The change of notified body number for each device (catalogue number) shall be documented and fixed to a specific serial number or lot number. CERTIFICATION HOLDER commits to document this change for each device (catalogue number) in Appendix 2 and make this information available upon the request of the INCOMING NB.

6. CERTIFICATION HOLDER commits to inform the OUTGOING NB and INCOMING NB in writing of the dates when the placing on the market of the legacy devices subject to transfer of appropriate surveillance under the notified body surveillance activities of the OUTGOING NB has been discontinued within 30 days after discontinuation.

§ 4 Assessment prior to transfer

INCOMING NB has the full responsibility and authority for the decision, based on information provided by CERTIFICATION HOLDER, OUTGOING NB, and publicly available information, regarding the extent of its assessment prior to TRANSFER DATE. In all cases, prior to transferring the appropriate surveillance on the agreed TRANSFER DATE, INCOMING NB shall ensure that there is an overview of all required assessment activities and their individual status of completion. Any identified unresolved concerns, findings, non-conformities, surveillance notes, etc. shall be addressed based on their criticality in the scheduling/planning of the consecutive appropriate surveillance activities by the INCOMING NB.

§ 5 Confidentiality and obligation to provide information

In order to allow the INCOMING NB to complete the assessment prior to transfer according to § 4 and to perform the appropriate surveillance after the TRANSFER DATE (see § 1):

1. CERTIFICATION HOLDER commits to provide on request to the INCOMING NB any relevant information relating to the assessment and certification of a legacy device subject to transfer of appropriate

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Question 14, Answer: *In the third subparagraph of Article 120(3e) MDR, the limitation that requires the notified body that issued the relevant certificate under the MDD/AIMDD to sign the arrangement for the transfer of the appropriate surveillance where practicable takes into account that there might be cases when this notified body could be unable to sign the contract, e.g. termination of business. In any case, it is required to have in place a written agreement between the manufacturer and the MDR notified body to specify the arrangements concerning the appropriate surveillance to be performed by the latter even if the notified body that issued the MDD/AIMDD certificates cannot be involved.*

➔ "Practicable" means that the outgoing NB cannot be reached any longer.

surveillance. Such a request may include valid certificate(s) for the legacy device concerned by the transfer of appropriate surveillance, assessment reports, consultation reports issued by authorities, non-conformities, corrective actions, complaint records, vigilance records and any other relevant records or information of OUTGOING NB or even another previous notified body.

2. CERTIFICATION HOLDER approves that OUTGOING NB may disclose, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1), related to the assessment and certification of the legacy devices subject to transfer of appropriate surveillance, to INCOMING NB, to enable any direct communication between OUTGOING NB and INCOMING NB that may be required.

3. CERTIFICATION HOLDER understands that INCOMING NB will contact OUTGOING NB to request information relating to the legacy devices subject to transfer of appropriate surveillance.

4. OUTGOING NB understands and approves that CERTIFICATION HOLDER may disclose to INCOMING NB, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1.) related to the legacy device subject to transfer of appropriate surveillance.

5. CERTIFICATION HOLDER commits to submit copies of the written confirmation of the transferred appropriate surveillance issued by INCOMING NB to OUTGOING NB without undue delay, at the latest within 30 calendar days of the TRANSFER DATE.

6. CERTIFICATION HOLDER confirms, for each legacy device subject to modification of the labelling by changing the number of the OUTGOING NB to the number of the INCOMING NB, the last serial number or lot number under the notified body appropriate surveillance of the OUTGOING NB, in accordance with Appendix 2. If this information is not yet known on the date when this Agreement comes into force, or changes occur after the date when this Agreement comes into force, CERTIFICATION HOLDER shall submit to OUTGOING NB and INCOMING NB the last serial number or lot number under the notified body oversight of the OUTGOING NB within 30 calendar days of it becoming known or changed. Together with the actual transfer date, this will allow traceability of devices, and responsibilities regarding appropriate surveillance.

7. The CERTIFICATION HOLDER and the INCOMING NB take care that the OUTGOING NB is informed about the following issues with respect to devices placed on the market with the identification number of the OUTGOING NB:
   a. Vigilance cases (reportable incidents and Field Safety Corrective Actions)
   b. Inspections, inquiries and other activities by Competent Authorities
   c. Misuse of certificates or CE mark
   d. Obstacles encountered regarding performance of adequate surveillance

   The INCOMING NB may inform the OUTGOING NB about additional issues in case there is a justified reason.

§ 6 Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the notified body appropriate surveillance activities[6] for the legacy device subject to transferred appropriate surveillance, including
   a. any continuing conformity assessment activities
   b. surveillance activities
   c. post-certification monitoring and the assessment of the CERTIFICATION HOLDER's vigilance system with respect to the legacy device manufactured which is under the transferred appropriate surveillance, including NB's involvement in vigilance case assessments
   d. communication with authorities in respect of the legacy device
   e. continued assessment of changes to the device
   f. continued assessment of changes for the related quality management system

[6] General applicable document MDCG 2022-4, Rev. 1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

g. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device7 including restriction, suspension and withdrawal of the validity of certification for the legacy device.

2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about transfer of surveillance to INCOMING NB.

3. Changes on the device list as per Appendix 1 of this Agreement: based on MDCG 2020-3, rev. 1, section 4.3.2.3, the following changes are considered as "non-significant change" towards MDR, Art. 120(3c):
Change in Specification/Labelling:
   - change within the currently certified range (more narrow or detailed information), new article inside certified worst case or accepted bracket validations such as:
     - new screw variant within current range of lengths and diameter;
     - new catheter variant, with length and diameter within current range and worst case in sterilisation performance;
     - new stent lengths which are intermediate between the previously certified stent lengths.

In respect of this agreement, it means that after the TRANSFER DATE additional devices might be added under the scope of the MDD certificate without acknowledgement by the OUTGOING NB initially issued the certificate.
The addition of such additional devices is considered only possible if for the same devices or its substitute device[8] a formal application has been lodged with the MDR Notified Body and written agreement for the MDR conformity assessment conducted.
The responsibility and liability towards the initial certification of the certified range and accepted bracket validations lies with the OUTGOING NB.
The responsibility and liability towards the assessment of the appropriateness of the change under Art. 120, and further appropriate surveillance including individual device traceability along the new conditions lies with the INCOMING NB.
In terms of CExxxx marking, the CERTIFICATION HOLDER and INCOMING NB may decide to agree on the labelling of these specific "legacy devices" indicating the number of the MDR Notified Body, instead of the original MDD certificate issuing OUTGOING NB.

§ 7 Settlement and property rights

1. If not agreed otherwise, CERTIFICATION HOLDER shall settle, in respect of the legacy device subject to transfer of appropriate surveillance, all outstanding invoices with OUTGOING NB and, as applicable, any affiliate of OUTGOING NB supplying notified body certification services under the control of OUTGOING NB. Furthermore, the CERTIFICATION HOLDER agrees that all services related to this transfer performed by the OUTGOING NB are invoiced by the OUTGOING NB to the CERTIFICATION HOLDER according to the existing or previous contractual arrangements regarding certification under Directive 93/42/EEC independently from any termination.

2. All documents provided by OUTGOING NB and all documents (assessment reports, certificates, etc.) which were generated by OUTGOING NB for the execution of certification, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the OUTGOING NB.

3. All documents provided by INCOMING NB and all documents (assessment reports, etc.) which were generated by INCOMMING NB for the performance of appropriate surveillance, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the INCOMING NB.

§ 8 Miscellaneous

1. (Severability). Should any individual provision of this Agreement or any part of any provision be or become void and/or unenforceable, the validity of the other provisions of the Agreement shall in no way be affected. In such case, the CERTIFICATION HOLDER, OUTGOING NB an INCOMING NB shall replace, by way of an amendment or change to this Agreement, the void and/or unenforceable provisions with permissible provisions that fulfil the original intent of the void and/or unenforceable provision to the closest possible extent.

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[7] MDCG 2020-3 Rev.1, Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD - **Section 4.3**
[8] Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Question 10. What is the meaning of "device intended to substitute that device"

2. (Written form). Any amendments or changes to this Agreement shall be made in writing. This applies especially to any change to an agreed TRANSFER DATE, which shall be agreed-upon in writing, by way of an addendum to this Agreement, between the involved parties prior to the respective previously agreed TRANSFER DATE. The form provided in Appendix 3 should be used for such addendum.

3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially INCOMING NB shall assume full responsibility for contracted surveillance activities, incl. the assessment of the CERTIFICATION HOLDER's vigilance system with respect to all devices included in the scope of certification subject to transferred surveillance. However, according to Art. 120 (3e) subparagraph 3 MDR the INCOMMING NB shall not be responsible for conformity assessment activities incl. previous surveillance activities carried out by OUTGOING NB as the notified body that issued the certificate(s).
   Especially OUTGOING NB shall assume full responsibility for the certification subject to transferred surveillance, including all conformity assessment activities incl. previous surveillance activities prior to TRANSFER DATE.
   In particular, the OUTGOING NB recognises its responsibility for any act or omission accomplished prior to TRANSFER DATE. The CERTIFICATION HOLDER commits not to hold the INCOMING NB responsible for these acts or omissions.

4. (Jurisdiction). Unless otherwise agreed, this Agreement shall be governed by, and interpreted in accordance with the substantive laws of the country of INCOMING NB exclusive of any rules with respect to conflicts of laws.

5. (Disputes). Disputes arising in connection with this Agreement shall be settled as follows:

   a. Disputes between CERTIFICATION HOLDER and INCOMING NB shall be settled by CERTIFICATION HOLDER and INCOMING NB under the provisions of their certification agreement.

   b. Disputes between CERTIFICATION HOLDER and OUTGOING NB shall be settled by CERTIFICATION HOLDER and OUTGOING NB under the provisions with regard to appeals of their certification agreement.

6. (Coming into force) This Agreement comes into force on the date the last of the three involved parties, INCOMING NB, OUTGOING NB, and CERTIFICATION HOLDER has signed this Agreement (also see § 6.3).

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Legally Binding Signature CERTIFICATION HOLDER	Legally Binding Signature INCOMING NB	Legally Binding Signature OUTGOING NB
[place, date] Bonn, 10.09.2024	**[place, date]** Stuttgart 23. SEP. 2024	**[place, date]** 26.09.2024/İstanbul
[name] Dr. Roland Dreschau	**[name]** Dr. Klaus Hogh-Janovsky	**[name]** Mustafa Selçuk Sevinç
[position] Managing Director	**[position]** Dep. General Manager	**[position]** Manager

KİWA BELGELENDİRME HİZMETLERİ A.Ş. Eski Ankara Asfalti İstanbul Tuzla Org. San. Bölg. 9. Cad. No:15 Tepeören/ Tuzla/ ISTANBUL/ TÜRKİYE Tuzla V.D. 620 053 0464 Tic. Sic. No:365270 Mersis No: 0620007475700019

Attachments

- ☒ Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- ☒ Copies of certificates specified in Appendix 1 (mandatory)
- ☐ Appendix 2 – Transition provisions (optional)
- ☐ Appendix 3 – Addendum form to specify or amend Appendices 1 and 2 (optional)

Overview of provisions covered or taken into consideration in this Agreement:

1. Articles 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC., as amended by Regulation (EU) 2023/607.
2. MDCG 2020-3 Rev.1, Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
3. MDCG 2022-4 Rev.1, Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD
4. MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021)
5. European Commission, Q&A on practical aspects related to the implementation 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 (July 2023)

Appendix 1 – Legacy devices subject to transfer of appropriate surveillance

Devices covered by this agreement and for which the INCOMING NB is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive

MDD Device name or REF	MDD Certificate Reference of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Bare Fiber, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Bare Fiber, reusable, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Cylindrical Diffuser, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
CALA, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2027 ☐ 31 December 2028		
ELVeS Fiber, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
ELVeS Radial, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
X-ray, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

ELVeS Plus Catheter, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Endoprobe, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Gas-Liquid Cooled Fiber, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
PLDD Bare Fiber, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Side Fiber, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Twister, single-use, sterile	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ceralas E	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ceralas HPD	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Leonardo	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Leonardo HPD	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Leonardo Mini	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Leonardo FPS	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Leonardo Bonsai	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Athletik LED	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Derma Handpiece; reusable, Loma Handpiece	1984-MDD-16-372 Rev.6	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Appendix 2 – Traceability table - identification number of the OUTGOING NB to the number of the INCOMING NB

Legacy device subject to transfer of appropriate surveillance	**The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))**	**Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is six (6) months from the TRANSFER DATE.**
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified

[Sample for information only – Not to be used for initial agreement]

Appendix 3 – Addendum form to specify or amend Appendices 1 and 2

ADDENDUM No. <x> to the TRANSFER AGREEMENT coming into force on <date>

between

[Manufacturer]
[Address]
(in the following "CERTIFICATION HOLDER"),

[Name of outgoing Notified Body]
[Address]
(in the following "OUTGOING NB")

[Name of future Notified Body]
[Address]
(in the following "INCOMING NB")

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 2 (2) and/or § 8 (2):

1. The table in Appendix 1 (Legacy devices subject to transfer of appropriate surveillance) is replaced with the following table:

MDD Device name or REF	MDD Certificate Reference(s) of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Device 1	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		
Device 2	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		

2. **The table in Appendix 2 (Transition provisions) is replaced with the following table:**

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is [Months] months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Legally Binding Signature CERTIFICATION HOLDER	Legally Binding Signature INCOMING NB:	Legally Binding Signature OUTGOING NB:
[place, date]	**[place, date]**	**[place, date]**
Bonn, 10.09.2024	Stuttgart, 23. SEP. 2024	İstanbul /26.09.2024
	Dr. Klaus Hogh-Janovsky	KİWA BELGELENDİRME HİZMETLERİ A.Ş. Eski Ankara Asfalt İstanbul Tuzla Cad. San. Bölg. 9. Cad. No: 19 Tepeören/ Tuzla/ İSTANBUL/ TÜRKİYE Tuzla V.D. 520 053 0464 Tic. Sic. No:365270 Mersis No: 0520053046400019
	Dep. General Manager	Mustafa Serkan Soran Medical Devices Division Manager
[name]	**[name]**	**[name]**
[position]	**[position]**	**[position]**
Dr. Roland Dreschau Managing Director		

CeramOptec GmbH
Siemensstraße 44, 53121 Bonn
Telefon 0228/97967-0 Fax 97967-99
e-mail: info@ceramoptec.de

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-16-372

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

CeramOptec GmbH

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

Products: Diode Lasers, Probes for Lasers, Handpieces, Introducer for Probes, Athletic LED

The products defined at the enclosure which is the part of this certificate and contains two pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.
Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III device covered by this certificate.

Report Number:	M.4508.06
Date of first issue:	14 March 2016
Date of last issue:	25 May 2021
Revision Number:	06
Expiry Date:	12 March 2024

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 06

Concerned medical devices;

Product: Diode Lasers
Types:
- Type Ceralas E
- Type Ceralas HPD
- Type Leonardo
- Type Leonardo HPD
- Type Leonardo Mini
- Type Leonardo Bonsai
- Type Leonardo FPS

Product: Probes for Lasers
Types:
- Type Bare Fiber, single-use, sterile
- Type Bare Fiber, reusable, sterile
- Type Endoprobe, single-use, sterile
- Type Gas Liquid Cooled, single-use, sterile
- Type Side Fiber, single-use, sterile
- Type PLDD Bare Fiber, single-use, sterile
- Type Cylindrical diffuser, single-use, sterile
- Type ELVeS Fiber, single-use, sterile
- Type Twister, single-use, sterile
- Type ELVeS Radial, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, reusable, sterile
- X-Ray, single-use, sterile
- CALA, single-use, sterile

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 06

Concerned medical devices;

Product: Handpieces
Type: Type Derma Handpiece; reusable, Loma Handpiece

Product: Introducer for Probes
Type: Type ELVeS Plus Catheter, sterile

Product: Athletic LED

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

CeramOptec GmbH
Siemensstr. 44
53121 Bonn
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Design, development, manufacturing and distribution of fiber optic delivery systems and laser systems with accessories and service of laser systems with accessories

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2024-09-04	Registration No.	D1486900003
Valid until	2027-04-24	Report No.	P23-01348-280994

Stuttgart, 2024-09-04

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

Sites included in the certification:

Location	Scope
CeramOptec GmbH Siemensstr. 44, 53121 Bonn Germany	Headquarters
CeramOptec GmbH Brühlerstraße 30, 53119 Bonn Germany	Design, development, manufacturing and distribution of fiber optic delivery systems and laser systems with accessories and service of laser systems with accessories

Stuttgart, 2024-09-04

Certification Body

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

CeramOptec GmbH
Siemensstr. 44
53121 Bonn
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 9001

in the scope

Manufacturing, distribution and service of optical preforms, optical fibers and fiber optic delivery systems

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015
Quality management systems – Requirements

Valid from	2024-09-04	Registration No.	D1486900004
Valid until	2027-04-24	Report No.	P23-01348-280996

Stuttgart, 2024-09-04

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

Sites included in the certification:

Location	Scope
CeramOptec GmbH Siemensstr. 44, 53121 Bonn Germany	Headquarters
CeramOptec GmbH Brühlerstraße 30, 53119 Bonn Germany	Manufacturing, distribution and service of optical preforms, optical fibers and fiber optic delivery systems

Stuttgart, 2024-09-04

Certification Body