



# biolitec® laser systems

CERALAS® HPD  
combined with smoke  
evacuation system



## LEONARDO® DUAL 100 and Ceralas® HPD

REF	Product
SL980+1470nm100W	Laser Set LEONARDO® DUAL 100
SL980+1470nm45W	Laser Set LEONARDO® DUAL 45
SH1350nm60W400u	Laser Set Ceralas® HPD 1350nm 60W

All laser sets incl. 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case. 1350 nm for Thoracic Surgery / Pneumology / General Surgery

## Fibers

### Bare Fibers Flat Tip

REF	Product	Length [m]	Core ø [µm] / [Fr]	OD ø [µm] / [Fr]
501200745	Bare Fiber 600 µm, Flat Tip, Adj. Luer, ID (1 × 6 h)	3	565 / 1.7	860 / 2.6
503200745	Bare Fiber 600 µm, Flat Tip, Adj. Luer, IC (1 × 6 h)	3	565 / 1.7	860 / 2.6
501300415	Bare Fiber 1000 µm, Flat Tip, Adj. Luer, ID (1 × 6 h)	2.6	945 / 2.9	1400 / 4
503300415	Bare Fiber 1000 µm, Flat Tip, Adj. Luer, IC (1 × 6 h)	2.6	945 / 2.9	1400 / 4

### Gas Liquid Cooled Fibers

501200525	GLC 180 Gas-, Liquid Cooled fiber, ID (1 × 6 h)	3	565 / 1.7	1800 / 5.4
503200525	GLC 180 Gas-, Liquid Cooled fiber, IC (1 × 6 h)	3	565 / 1.7	1800 / 5.4

### Special Fibers

501200990	Jumper for LFHP, ID (1 × 6 h)	3	565 / 1.7	1800 / 5.4
503200990	Jumper for LFHP, IC (1 × 6 h)	3	565 / 1.7	1800 / 5.4

## Handpieces and instruments

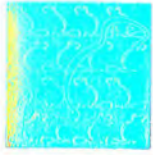
501200985	Laser Focus Handpiece
500400370	Instrument for Thoracoscopy, with smoke suction adapter, for 600 – 1000 µm fibers
400100100	Universal Dual Luer Handpiece, for 600 – 1000 µm fibers

## Accessories

AB2570	Mobile Table for HPD Laser
LA5199	Laser safety goggles 950 – 110 L4 + 1470 L2 (FULL), type: ear piece
LA1371	Laser safety goggles DIR 804 – 1755 L3 (FULL), type: basket, clear
LA5165	Sticker Laser warning 20 × 20 cm
400100115	Medi Strip 0.7/1.2 BF 600 µm, autoclavable – Fiber stripper for BF 600 µm
400100120	Medi Strip 1.0/1.5 BF 1000 µm, autoclavable – Fiber stripper for BF 1000 µm
400100130	Ceramic Fiber Cleaver, autoclavable
AB1908	Touhy Borst Adapter
AB2519	Luer Lock Adapter Female – Female Adapter for GLC fibers
AB2594	Biopsy needle 14 G, 6 cm with cm markings, sterile

## Smoke evacuation

MP0016	ATMOSAFE mobile smoke evacuation inclusive autoclavable hose system
MP0017	ATMOS Main filter (ULPA)
MP0018	ATMOS Prefilter (HEPA)
MP0019	ATMOS Air hose, ø 22 mm, L = 2.10 m, single use
MP0020	ATMOS Air hose, ø 22 mm, L = 2.10 m, reusable
MP0021	ATMOS Hose connector straight ø 22 mm to ø 10 mm



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

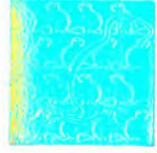
The products defined at the enclosure which is the part of this certificate and contains two pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

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



# 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

25 May 2021, Istanbul, Turkey

Muhtesem Gökhan Yücel  
Head of Notified Body



**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

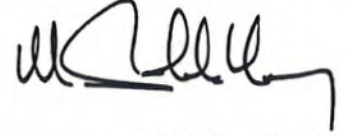
**Type:** Type Derma Handpiece; reusable, Loma Handpiece

**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



## 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'nin**, 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,

**Kiwa Belgelendirme Hizmetleri A.Ş.**  
İ.T.O.S.B 9. Cadde No: 15  
Tepeören Mevkii PK 34959  
Tuzla İstanbul  
Türkiye

Tel. +90 216 593 25 75  
Faks +90 216 593 25 74  
[posta@kiwa.com.tr](mailto:posta@kiwa.com.tr)  
[www.kiwa.com](http://www.kiwa.com)  
[www.1kiwa.com](http://www.1kiwa.com)

 1/2

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 verdiği dair kanıt sunulmuştur; veya
- Bir AB üye devletinin yetkili makamının, MDR'nin 97(1) maddesine uygun olarak geçerli uygunluk değerlendirme prosedüründen muafiyet verdiği 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 bulunmuş 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-21-372/1984-MDD-21-745	12.03.2024	93/42/AT

Kind Regards,  
Saygılarımla,  
Debut General Menager  
Genel Müdür Yardımcısı

Mehmet Fevzi Gülünay

**KIWA**  
**BELGELENDİRME HİZMETLERİ A.Ş.**  
Eski Ankara A.Ş. Eski Bulvarı, Eski Org. San. Bölge,  
9. Cad. No: 15, 06050 ÇAYIROVA/İSTANBUL/ TÜRKİYE  
Tic. Sic. No: 270907, Mersis No: 365270  
Muh. Sic. No: 270907, Tic. Sic. No: 270907

## 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
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<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