CERTIFICATE

Digitally signed by Antonova Anna
Date: 2021.07.23 16:24:43 EEST
Reason: MoldSign Signature
Location: Moldova

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

EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-745

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

CeramOptec GmbH

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

Product: CALA, Single Use, Sterile
Type: Cala Fiber

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.4508.06
Expiry Date: 12 March 2024

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

15 March 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

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

CERTIFICATE

kiwa

Ceramoptec

CeramOptec GmbH

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

with a scope of

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

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "

" None "

ISO 9001:2015

Certificate No	: M 10351
Initial Certification Date	: 14 March 2016
Certification Date	: 28 February 2019
Expiration Date	: 27 February 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.

Last Modified: 28 February 2019 - R 02

TÜRKAK
Quality Management System
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-CFC6-6520

CERTIFICATE

kiwa

Ceramoptec

CeramOptec GmbH

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

with a scope of

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

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.9.2.2"

EN ISO 13485:2016

Certificate No	: M 10352
Initial Certification Date	: 14 March 2016
Certification Date	: 28 February 2019
Expiration Date	: 27 February 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q M S
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-9247-79FB

Last Modified: 28 February 2019 - R 02