



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-005

Issued to: OPTOTEK d.o.o.
Tehnološki park 21, 1000 Ljubljana, Slovenia

Place of production: OPTOTEK d.o.o.
Tehnološki park 21, 1000 Ljubljana, Slovenia

Product category: Active therapeutic device intended to exchange or administer energy
GMDN: 35940

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II, including all subsequent amendments. This certificate is based on

Audit report No.:

OSV 00446/2019, 2019-05-16

OSV 00656/2019, 2019-06-14

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2009-09-03

Issue: 05/2019-06-28

Valid until: 2024-05-27



Director of SIQ

Igor Likar



SIQ Ljubljana

Tržaška cesta 2

T +386 1 4778 100

SI-1000 Ljubljana

F +386 1 4778 444

Slovenija

info@siq.si, www.siq.si

vaš znak / your ref.:

naš znak / our ref.:

OSV/1245

datum / date:

2019-06-28

Gospod
Andrej Vrečko
OPTOTEK d.o.o.
Tehnološki park 21

1000 LJUBLJANA

Spoštovani gospod Vrečko!

Obveščamo vas, da je komisija priglašenega organa na svoji zadnji seji sprejela naslednji sklep:

Na podlagi poročila o obnovitveni presoji in presoji tehnične dokumentacije (OSV 00446/2019, z dne 2019-05-16) in poročila o presoji tehnične dokumentacije (OSV 00656/2019, z dne 2019-06-14), se razveljavi sedanja izdaja (Izdaja 04/2017-04-11) certifikata **MDD-005**, in izda nova:

EC certificate No: **MDD-005**

Issued to: OPTOTEK d.o.o.

Tehnološki park 21, 1000 Ljubljana, Slovenia

Place of production: OPTOTEK d.o.o.

Tehnološki park 21, 1000 Ljubljana, Slovenia

Product category: Active therapeutic device intended to exchange or administer energy

GMDN: 35940

Standard/regulation: MDD 93/42/EEC

Annex: II

Certification date: 2009-09-03

Issue: 05/2019-06-28

Valid until: 2024-05-27

Detailed list of products names, models and types/
Podrobni seznam imen, proizvodov, modelov in tipov:

EC certificate No. / **MDD-005**
Št. ES certifikata:
Issued to / OPTOTEK d.o.o.
Naziv organizacije: Tehnološki park 21, 1000 Ljubljana, Slovenia
Place of production/ OPTOTEK d.o.o.
Lokacija proizvodnje: Tehnološki park 21, 1000 Ljubljana, Slovenia
Product category / Active therapeutic device intended to exchange or administer energy /
Kategorija proizvoda: Aktivni terapevtski pripomočki, namenjeni dovajanju ali izmenjavi energije
GMDN: 35940
Classification / IIb
Klasifikacija:
Product name / Medical therapeutic laser device /
Naziv proizvoda: Medicinska terapevtska laserska naprava
Alternative name /
/Alternativno ime:
Model/Type / OptoYag&SLT, OptoYag, OptoSLT,
Model / Tip: OptoYag&SLT M, OptoYag M, OptoSLT M, OptoSLT nano
Standard: MDD 93/42/EGS
Date of issuing the 2019-06-28
list / Datum izdaje
seznama:
Valid until / 2024-05-27
Velja do:

Za dodatna pojasnila v zvezi s sklepom komisije za certificiranje sistemov vodenja smo vam na voljo na telefonski številki 01 4778 159 ali na elektronskem naslovu vesna.rems@siq.si.

Ocenjevanje sistemov vodenja
Medicinski pripomočki – Vodja produkta

Ana Pribaković Borštnik





Certifikat / Certificate

*for
Management System*

OPTOTEK d.o.o.

Tehnološki park 21, 1000 Ljubljana, Slovenia

Design, development, production, sales and service of the therapeutic LASER devices, optical diagnostic devices and articulated arms

*adequately operates and maintains a management system
which meets the requirements of the standard*

ISO 13485:2016

Certificate No. / Certification date

M-003 / 2004-07-19

Issue 12 / 2022-04-25 Valid until: 2025-05-31

*Director of SIQ Ljubljana
Gregor Schoss*



**SLOVENSKA
AKREDITACIJA**
SIST EN ISO/IEC 17021-1
CS-001



SIQ Ljubljana, Mašera-Spasičeva ulica 10, 1000 Ljubljana, Slovenija



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SIQ Ljubljana has issued an IQNet recognized certificate that the organization:

OPTOTEK d.o.o.

Tehnološki park 21, 1000 Ljubljana, Slovenia

*has implemented and maintains a Medical devices - Quality System
for the following scope:*

Design, development, production, sales and service of the therapeutic LASER devices,
optical diagnostic devices and articulated arms

which fulfils the requirements of the following standard:

ISO 13485:2016

First issued on: 2004-07-19

Issued on: 12 / 2022-04-25 Expires on: 2025-05-31

*This attestation is directly linked to the IQNet Partner's original certificate
and shall not be used as a stand-alone document*

Registration Number: SI – M-003



Alex Stoichitoiu
President of IQNet

Gregor Schoss
Managing Director of SIQ



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



Z vami več kot
With you for over
50 let
years
o o o

SIQ Ljubljana

Mašera-Spasičeva ulica 10
SI-1000 Ljubljana
Slovenija

T +386 1 4778 100
F +386 1 4778 444
info@siq.si, www.siq.si

vaš znak / your ref.:

OSV/1245

naš znak / our ref.:

2021-12-15

datum / date:

Gospa
Vesna Perc
OPTOTEK d.o.o.
Tehnološki park 21

1000 LJUBLJANA

Subject: Statement on the non-significant change regarding transitional provision under Article 120 of the MDR and additional notice to the certificate MDD-005

Slovenian Institute of Quality and Metrology (NB 1304) hereby confirms that the

OPTOTEK d.o.o.
Tehnološki park 21, 1000 LJUBLJANA
Slovenia

informed SIQ Ljubljana on the updated GMDN code for the product name Medical therapeutic laser device / Medicinska terapevtska laserska naprava (Product category: Active therapeutic device intended to exchange or administer energy) and provided all the necessary documentation regarding the change.

Slovenian Institute of Quality and Metrology (NB 1304) conducted the assessment of documentation and hereby confirms that the organization's change is non significant.

SIQ Ljubljana as a certification and Notified body regularly checks whether an EC certificate holder meets the requirements of the Medical Device Directive 93/42/EEC by surveillance audits at least once a year.

On the basis of Notice of change, MDD DN022 (received 2021-11-18) and the review of documentation, SIQ Ljubljana hereby issues an Additional notice to the current Certificate MDD-005 and Detailed list of product names, models, and types annexed to the certificate MDD-005, version 05, issued on 2019-06-28 (valid until 2024-05-27):

Data of the EC certificate:

EC certificate No: **MDD-005**

Issued to: OPTOTEK d.o.o.
Tehnološki park 21, 1000 Ljubljana, Slovenia

Place of production: OPTOTEK d.o.o.
Tehnološki park 21, 1000 Ljubljana, Slovenia

Product category: Active therapeutic device intended to exchange or administer energy

GMDN: 62197

Detailed list of products names, models and types:

EC certificate No. / **MDD-005**
Št. ES certifikata:
Issued to / OPTOTEK d.o.o.
Naziv organizacije: Tehnološki park 21, 1000 Ljubljana, Slovenia
Place of production/ OPTOTEK d.o.o.
Lokacija proizvodnje: Tehnološki park 21, 1000 Ljubljana, Slovenia
Product category / Active therapeutic device intended to exchange or administer energy /
Kategorija proizvoda: Aktivni terapevtski pripomočki, namenjeni dovajanju ali izmenjavi energije
GMDN: 62197
Classification / IIb
Klasifikacija:
Product name / Medical therapeutic laser device /
Naziv proizvoda: Medicinska terapevtska laserska naprava
Alternative name /
/Alternativno ime:
Model/Type / OptoYag&SLT, OptoYag, OptoSLT,
Model / Tip: OptoYag&SLT M, OptoYag M, OptoSLT M, OptoSLT nano

For any further information, we are available by phone at 00 386 1 4778 106 and by email at kristina.holesek@siq.si.

Management Systems Assessment
MDD Product Manager
Ana Pribaković Borštnik



EC DECLARATION OF CONFORMITY

Declaration No.: 01-2021

Manufacturer: OPTOTEK d.o.o.
Tehnološki park 21
1000 Ljubljana, Slovenia

Product Name: Medical therapeutic laser device

Model/Type: OptoYag M, Opto SLT M, OptoYag&SLT M

Classification: IIb (Annex IX, Rule 9)

GMDN Code: 62197

OPTOTEK d.o.o. HEREBY STATES THAT THE ABOVE-MENTIONED PRODUCTS COMPLY WITH THE ESSENTIAL REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC, FOR MEDICAL DEVICES.

OPTOTEK d.o.o. HEREBY STATES THAT THE ABOVE-MENTIONED PRODUCTS ARE IN CONFORMITY WITH DIRECTIVE (EU) 2015/863 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 31 MARCH 2015 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT.

The product was a subject of conformity assessment procedure described in Annex II (Full Quality Assurance System), excluding Section 4.

Standards Applied: EN 60601-1:2006/A1:2013/A12:2014
EN 60601-1-2:2015
EN 60601-2-22:2013
EN 62304:2006/A1:2015
EN 60825-1:2014
EN 62366-1:2015
EN ISO 15004-1:2009; EN ISO 15004-2:2007
EN ISO 15223-1:2016
EN ISO 10939:2017
EN ISO 14971:2019
EN ISO 10993-1:2009/AC:2010

Notified Body: SIQ, Slovenian Institute of Quality and Metrology
Tržaška cesta 2
1000 Ljubljana, Slovenia
Notified Body No. 1304

EC Certificate: No: MDD-005
Issued: 05/2019-06-28
Valid until: 2024-05-27

Name: Iztok Dvoraček
Position: Optotek CEO&CFO

Signature:



OPTOTEK
medical
Optotek d.o.o. Tehnološki park 21 Ljubljana, Slovenija

Place and Date: Ljubljana, 29.12.2021