Certifikat / Certificate

za
sistem vodenja

Meridian Medical d.o.o.

Ljubljana, Plemljeva ulica 8, 1210 Ljubljana - Šentvid

Razvoj, proizvodnja, prodaja in servisiranje
medicinskih oftalmoloških laserskih pripomočkov

ima vzpostavljen in ustrezno vzdrževan sistem vodenja,
ki izpolnjuje zahteve standarda

ISO 13485:2016

Certifikat št. / Datum certifikacije
M-128/ 2018-03-16

Izdaja **08 / 2020-12-30** *Velja do:* **2023-12-31**

Direktor SIQ Ljubljana
Igor Likar

SIQ je partner IQNet — THE INTERNATIONAL CERTIFICATION NETWORK

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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

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

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

Meridian Medical d.o.o.

Ljubljana, Plemljeva ulica 8, 1210 Ljubljana - Šentvid, Slovenia

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

R&D, manufacturing, sales and servicing of medical laser devices for ophthalmology

which fulfils the requirements of the following standard:

ISO 13485:2016

First issued on: **2018-03-16**
Issued on: **08 / 2020-12-30** *Expires on:* **2023-12-31**

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-128**

Alex Stoichitoiu
President of IQNet

Igor Likar
Managing Director of SIQ Ljubljana

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

EC Certificate – Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate No. MDD-091

Issued to:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Product category:	Medical therapeutical laser system
GMDN:	16947

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. This certificate is based on

Audit report No.:
OSV 00802/2017, 2017-07-31
OSV 00949/2017, 2017-10-24
OSV 01257/2017, 2017-12-29
OSV 00170/2018, 2018-03-16
OSV 01414/2019, 2020-02-26

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: 2018-03-20

Issue : 4/2020-08-31

Valid until: 2024-05-27

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Director of SIQ
Igor Likar

SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
tel.: +386 1 4778 100 • fax: +386 1 4778 444 • e-mail: info@siq.si • http://www.siq.si

SIQ Ljubljana | Mašera-Spasićeva ulica 10 | SI-1000 Ljubljana | Slovenija
T +386 1 4778 100 | F +386 1 4778 444 | info@siq.si, www.siq.si

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

vaš znak / your ref.:
naš znak / our ref.: OSV/5361
datum / date: 2020-09-02

Mr.
Kristijan Lamot
Meridian Medical d.o.o.
Ljubljana, Plemljeva ulica 8

1210 LJUBLJANA-ŠENTVID

Dear Mr Lamot!

We would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

On the basis of technical documentation audit report (OSV 00802/2017 dated 2017-07-31), technical documentation post-audit report (OSV 00949/2017 dated 2017-10-24), technical documentation post-audit report (OSV 01257/2017 dated 2017-12-29), technical documentation post-audit report (OSV 00170/2018 dated 2018-03-16), re-certification audit report (OSV 01414/2019 dated 2020-02-26) and on the basis of a notification from the organization of a change in the name of the manufacturer and a change in the name of the product dated 21.6.2020, the current edition (03/2020-02-26) of the EC certificate MDD-091 is cancelled and the new edition is issued:

EC certificate No.:	**MDD-091**
Issued to:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Product category:	Medical therapeutical laser system
GMDN:	16947
Standard:	MDD 93/42/EGS
Priloga /Annex:	II
Kategorija proizvoda:	Medicinski terapevtski laserski sistem
GMDN:	16947

Certification date:	2018-03-20
Issue:	04/2020-08-31
Valid until:	2024-05-27

Identification Number of the Notified Body (1304) can be used in conjunction with EC certificate. Details of affixing CE marking are given in Article 17 of Medical Device Directive (93/42/EEC).

The EC certificate (A4 paper format) is granted in English. EC certificate is enclosed in attachment. Also form for possible additional order of certificate is enclosed.

Detailed list of product names, models and types:

EC Certificate No./ Št. ES certifikata:	**MDD-091**
Issued to / Naziv organizacije:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid, Slovenia
Product category / Kategorija proizvoda:	Medical therapeutical laser system Medicinski terapevtski laserski sistem
GMDN:	16947
Classification / Klasifikacija:	IIb
Product name / Ime proizvoda:	MR Q SUPINE
Alternative name / Alternativno ime:	/
Model / Type / Model / Tip:	/

Standard:	MDD 93/42/EEC
Date of issuing the list:	2020-08-31
Valid until:	2024-05-27

For all further information we are available on telephone number 00 386 1 4778 159 and email: marjeta.tusek@siq.si

Management Systems Assessment
MDD Product Manager
Ana Pribaković Borštnik

SIQ Ljubljana
Ažbetova ulica 10
1000 Ljubljana

EC Certificate – Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate No. MDD-172

Issued to:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Product category:	Medical therapeutical laser system
UMDNS:	16947

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. This certificate is based on

Audit report No.:
OSV 01414/2019, 2020-02-26
OSV 00196/2020, 2020-05-29
OSV 00805/2020, 2020-08-28

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: 2020-08-31

Issue : 1/2020-08-31

Valid until: 2024-05-27

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Director of SIQ
Igor Likar

SIQ Ljubljana | Mašera-Spasićeva ulica 10 | SI-1000 Ljubljana | Slovenija | T +386 1 4778 100 | F +386 1 4778 444 | info@siq.si, www.siq.si

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

vaš znak / your ref.:
naš znak / our ref.: OSV/5361
datum / date: 2020-09-02

Mr.
Kristijan Lamot
Meridian Medical d.o.o.
Ljubljana, Plemljeva ulica 8

1210 LJUBLJANA-ŠENTVID

Dear Mr Lamot!

We would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

On the basis of re-certification audit report (OSV 01414/2019 dated 2020-02-26), technical documentation audit report (OSV 00196/2020 dated 2020-05-29) and technical documentation post-audit report (OSV 00805/2020 dated 2020-08-28), the current edition (03/2020-02-26) of the EC certificate MDD-091 is cancelled and the new edition is issued:

EC certificate No.:	**MDD-172**
Issued to:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Product category:	Medical therapeutical laser system
UMDNS:	16947
Standard:	MDD 93/42/EGS
Priloga /Annex:	II

Certification date:	2020-08-31
Issue:	01/2020-08-31
Valid until:	2024-05-27

Identification Number of the Notified Body (1304) can be used in conjunction with EC certificate. Details of affixing CE marking are given in Article 17 of Medical Device Directive (93/42/EEC).

The EC certificate (A4 paper format) is granted in English. EC certificate is enclosed in attachment. Also form for possible additional order of certificate is enclosed.

Detailed list of product names, models and types:

EC Certificate No./ Št. ES certifikata:	**MDD-172**
Issued to / Naziv organizacije:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Place of production:	Meridian Medical d.o.o. Plemljeva 8, 1210 Ljubljana-Šentvid Slovenija
Product category / Kategorija proizvoda:	Medical therapeutical laser system / Medicinski terapevtski laserski sistem
UMDNS:	16947
Classification / Klasifikacija:	IIb
Product name / Ime proizvoda:	MR Q
Alternative name / Alternativno ime:	/
Model / Type / Model / Tip:	/

Standard:	MDD 93/42/EEC
Date of issuing the list:	2020-08-31
Valid until:	2024-05-27

For all further information we are available on telephone number 00 386 1 4778 159 and email: marjeta.tusek@siq.si

Management Systems Assessment
MDD Product Manager
Ana Pribaković Borštnik

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana