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: 2023-03-23

Mr.
Kristijan Lamot
Meridian Medical d.o.o.
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 certification audit report (OSV 01133/2022 dated 2022-09-30), technical documentation audit report and technical documentation post audit report (OSV 01548/2022 dated 2022-12-30) and technical documentation post-audit report and post audit report (OSV 00316A/2023 dated 2023-03-23), a decision on granting the EU certificate was adopted:

EU certificate No.:	**MDR-001**
Issued to:	Meridian Medical d.o.o. Plemljeva ulica 8, 1210 Ljubljana-Šentvid Slovenija
SRN of manufacturer:	SI-MF-000006685
Authorised representative:	Not applicable
SRN of authorised representative:	Not applicable
Legislative act/requirements:	Regulation (EU) 2017/745
Annex:	IX
Device:	Neodymium surgical laser
EMDN:	Z12011017
Intended purpose:	MR Q SLT is an ophthalmic medical device that provides the ability to treat patients in a sitting position using Nd:YAG laser source with 1064 nm nanosecond pulsed output (YAG mode) or with 532 nm (KTP frequency-doubled) nanosecond pulsed output (SLT mode) regarding to selected treatment.
Classification:	IIb
Certification date:	2023-03-23
Issue:	01/2023-03-23
Valid until:	2028-03-22

Specific conditions or provisions or limitations and validity of certificate: /

Identification Number of the Notified Body (1304) can be used in conjunction with EU certificate. Details of affixing CE marking are given in Article 20 of Regulation (EU) 2017/745 on medical devices.

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

Detailed list of product names, models and types:

EU certificate No.:	**MDR-001**
Issued to:	Meridian Medical d.o.o. Plemljeva ulica 8, 1210 Ljubljana-Šentvid Slovenija
SRN of manufacturer:	SI-MF-000006685
Place of production:	Meridian Medical d.o.o. Plemljeva ulica 8, 1210 Ljubljana-Šentvid Slovenija
Authorised representative:	Not applicable
SRN of authorised representative:	Not applicable
Device:	Neodymium surgical laser
EMDN:	Z12011017
Intended purpose:	MR Q SLT is an ophthalmic medical device that provides the ability to treat patients in a sitting position using Nd:YAG laser source with 1064 nm nanosecond pulsed output (YAG mode) or with 532 nm (KTP frequency-doubled) nanosecond pulsed output (SLT mode) regarding to selected treatment.
Basic UDI-DI:	383007498MTLSXX1XG
MDR code:	MDA 0302
Classification:	IIb
Product name:	MR Q SLT
Model/Type and/or Reference/ Catalogue number:	MR Q SLT s, MR Q SLT c
Legislative act/requirements:	Regulation (EU) 2017/745
Date of issuing the list:	2023-03-23
Valid until:	2028-03-22

Detailed list of relevant common specifications and standards

EU certificate No.:	**MDR-001**
Issued to:	Meridian Medical d.o.o. Plemljeva ulica 8, 1210 Ljubljana-Šentvid Slovenija
SRN of manufacturer:	SI-MF-000006685
Authorised representative:	Not applicable
SRN of authorised representative:	Not applicable
List of relevant common specifications and standards:	EN 60601-1:2006/A2:2021 (IEC 60601-1:2005/A2:2020) EN 60601-1-2:2015/A1:2021 (IEC 60601-1-2:2014/A1:2020) EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020) EN 60601-1-9:2008+A1+A2:2020 (IEC 60601-1-9:2007/A2:2020 (Rev 1)) EN IEC 60601-2-22:2020 (IEC 60601-2-22:2019) EN 60825-1:2014/A11:2021 (IEC 60825-1:2014) EN 62304:2006/A1:2015 (IEC 62304:2006/A1:2015) EN ISO 14971:2019/A11:2021 EN ISO 13485:2016/A11:2021 EN 62366-1:2015/A1:2020 (IEC 62366-1:2015/A1:2020) EN ISO 15004-2:2007 EN ISO 10993-1:2020 (ISO 10993-1:2018) EN ISO 15223-1:2021 EN 207:2017
Device:	Neodymium surgical laser
EMDN:	Z12011017
Basic UDI-DI:	383007498MTLSXX1XG
Legislative act/requirements:	Regulation (EU) 2017/745
Date of issuing the list:	2023-03-23
Valid until:	2028-03-22

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

Management Systems Assessment
MDR Product Manager
Ana Pribaković Borštnik

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-001

Issued to:	Meridian Medical d.o.o. Plemljeva ulica 8, 1210 Ljubljana-Šentvid Slovenija
SRN of the manufacturer:	SI-MF-000006685
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.
This certificate is based on

Audit report No.:
OSV 01133/2022, 2022-09-30
OSV 01548/2022, 2022-12-30
OSV 00316A/2023, 2023-03-23
See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: /

Certification date:	2023-03-23
Issue:	01/2023-03-23
Valid until:	2028-03-22

Managing Director of SIQ
Gregor Schoss

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana
8

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EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-001

Device:	Neodymium surgical laser
EMDN:	Z12011017
Intended purpose:	MR Q SLT is an ophthalmic medical device that provides the ability to treat patients in a sitting position using Nd:YAG laser source with 1064 nm nanosecond pulsed output (YAG mode) or with 532 nm (KTP frequency-doubled) nanosecond pulsed output (SLT mode) regarding to selected treatment.
Classification:	IIb

Specific conditions for or provisions or limitations to the validity of certificate:	/

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SIQ

Certifikat / Certificate

for
Management System

Meridian Medical d.o.o.

Plemljeva ulica 8, 1210 Ljubljana-Šentvid, Slovenia

Development, production, sales and servicing
of medical ophthalmic devices at locations:

Meridian Medical d.o.o., Plemljeva ulica 8, 1210 Ljubljana-Šentvid, Slovenia

Meridian AG, Bierigutstrasse 7, 3608 Thun, Switzerland

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

ISO 13485:2016

Certificate no. / Certification date
M-128 / 2018-03-16

Issue **11 / 2024-06-07** *Valid until:* **2026-12-31**

Director of SIQ Ljubljana
Gregor Schoss

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CS-001

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

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Certificate

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

Meridian Medical d.o.o.
Plemljeva ulica 8, 1210 Ljubljana-Šentvid, Slovenia

has implemented and maintains a
Medical devices - Quality System

for the following scope:

Development, production, sales and servicing of medical ophthalmic devices

at locations: Meridian Medical d.o.o., Plemljeva ulica 8, 1210 Ljubljana-Šentvid, Slovenia

Meridian AG, Bierigutstrasse 7, 3608 Thun, Switzerland

which fulfils the requirements of the following **standard:**

ISO 13485:2016

Issued on:	**2024-06-07**
First issued on:	**2018-03-16**
Expires on:	**2026-12-31**

Registration Number: **SI - M-128**

Alex Stoichitoiu
President of IQNET

Gregor Schoss
Managing director of SIQ Ljubljana

SIQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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