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

vaš znak / your ref.:
naš znak / our ref.: OSV/5361
datum / date: 2024-09-06

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:

Due to an administrative error in issuing the certificate, the current edition MDR-0015/01 of the Certificate, Detailed list of product names, models and types and Detailed list of relevant common specifications and standards, MDR-0015/01 is cancelled and a new edition is issued:

| | |
|---|---|
| EU certificate No.: | **MDR-0015** |
| Issued to: | Meridian Medical d.o.o.<br>Plemljeva ulica 8, 1210 Ljubljana-Šentvid<br>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: | Laser photocoagulators |
| EMDN: | Z12120202 |
| Intended purpose: | The devices of the Merilas family are intended for use in the treatment of ocular pathology in both segments (posterior and anterior) of eye.<br>The intended procedures are:<br>• retinal photocoagulation (Merilas 532 alpha, Merilas 532/577/810 shortpulse), to treat retinopathies,<br>• transscleral cyclophotocoagulation (Merilas 810 shortpulse), to treat glaucoma,<br>• transpupillary thermotherapy (Merilas 810 shortpulse), to treat tumors. |
| Classification: | IIb |

Certification date: 2024-08-09
Issue: 02/2024-09-06
Valid until: 2029-08-08
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-0015** |
| Issued to: | Meridian Medical d.o.o.<br>Plemljeva ulica 8, 1210 Ljubljana-Šentvid<br>Slovenija |
| SRN of manufacturer: | SI-MF-000006685 |
| Place of production: | Meridian Medical d.o.o.<br>Plemljeva ulica 8, 1210 Ljubljana-Šentvid<br>Slovenija (Subsidiary company) |
| Place of production: | Meridian AG<br>Bierigutstrasse 1A & Bierigutstrasse 7, 3608 Thun<br>Switzerland (Parent company) |
| Authorised representative: | Not applicable |
| SRN of authorised representative: | Not applicable |
| Device: | Laser photocoagulators |
| EMDN: | Z12120202 |
| Intended purpose: | The devices of the Merilas family are intended for use in the treatment of ocular pathology in both segments (posterior and anterior) of eye.<br><br>The intended procedures are:<br>• retinal photocoagulation (Merilas 532 alpha, Merilas 532/577/810 shortpulse), to treat retinopathies,<br>• transscleral cyclophotocoagulation (Merilas 810 shortpulse), to treat glaucoma,<br>• transpupillary thermotherapy (Merilas 810 shortpulse), to treat tumors. |
| Basic UDI-DI: | 383007498LPMFXX1ST |
| MDR code: | MDA 0302 |
| Classification: | IIb |
| Device name: | Merilas |
| Model/Type and/or Reference/ Catalogue number: | 100491 Merilas 532 alpha<br>100490 Merilas 532 alpha 1500 mW<br>100557 Merilas 532 shortpulse<br>100555 Merilas 577 shortpulse<br>100580 Merilas 810 shortpulse |
| Legislative act/requirements: | Regulation (EU) 2017/745 |
| Annex: | IX |
| Date of issuing the list: | 2024-09-06 |
| Valid until: | 2029-08-08 |

Detailed list of relevant common specifications and standards

| | |
|---|---|
| EU certificate No.: | **MDR-0015** |
| Issued to: | Meridian Medical d.o.o.<br>Plemljeva ulica 8, 1210 Ljubljana-Šentvid<br>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)<br>EN 60601-1-2:2015/A1:2021 (IEC 60601-1-2:2014/A1:2020)<br>EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020)<br>EN 60825-1:2014/A11:2021 (IEC 60825-1:2014)<br>EN 62304:2006/A1:2015 (IEC 62304:2006/A1:2015)<br>EN ISO 14971:2019/A11:2021<br>EN ISO 13485:2016/A11:2021<br>EN 62366-1:2015/A1:2020 (IEC 62366-1:2015/A1:2020)<br>EN ISO 15004-2:2007<br>EN ISO 10993-1:2020 (ISO 10993-1:2018)<br>EN ISO 15223-1:2021<br>EN 20417:2021<br><br>Regulation (EU) 2017/745<br>RoHS Directive 2011/65/EU<br>WEEE Directive 2012/19/EU |
| Device: | Laser photocoagulators |
| EMDN: | Z12120202 |
| Basic UDI-DI: | 383007498LPMFXX1ST |
| Legislative act/requirements: | Regulation (EU) 2017/745 |
| Annex: | IX |
| Date of issuing the list: | 2024-09-06 |
| Valid until: | 2029-08-08 |

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
Ašker-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-0015

| | |
|---|---|
| Issued to: | Meridian Medical d.o.o.<br>Plemljeva ulica 8, 1210 Ljubljana-Šentvid<br>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 00369A/2024, 2024-05-09
OSV 00598/2024, 2024-05-21
OSV 00830/2024, 2024-08-09
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: MDR-0015/01**

| | |
|---|---|
| Certification date: | 2024-08-09 |
| Issue: | 02/2024-09-06 |
| Valid until: | 2029-08-08 |

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ
Gregor Schoss


SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
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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-0015**

| | |
|---|---|
| Device: | Laser photocoagulators |
| EMDN: | Z12120202 |
| Intended purpose: | The devices of the Merilas family are intended for use in the treatment of ocular pathology in both segments (posterior and anterior) of eye.<br>The intended procedures are:<br>• retinal photocoagulation (Merilas 532 alpha, Merilas 532/577/810 shortpulse), to treat retinopathies,<br>• transscleral cyclophotocoagulation (Merilas 810 shortpulse), to treat glaucoma,<br>• transpupillary thermotherapy (Merilas 810 shortpulse), to treat tumors. |
| Classification: | IIb |
| Specific conditions for or provisions or limitations to the validity of certificate: | / |

| | |
|---|---|
| Certification date: | 2024-08-09 |
| Issue: | 02/2024-09-06 |
| Valid until: | 2029-08-08 |

SIQ Ljubljana
SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ

Gregor Schoss



SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
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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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SIST EN ISO/IEC 17021-1
CS-001

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

IQNET

Building trust together.

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