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
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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

2024-05-17

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

Notified Body Confirmation Letter

Reference: 5361-2024/01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.

This letter confirms that, SIQ Ljubljana, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1304 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	Meridian Medical d.o.o.
Legal address/street	Plemljeva ulica 8
Zip code/town	1210 Ljubljana-Šentvid
Country:	Slovenia
SRN number	SI-MF-000006685, SI-IM-000010125, SI-AR-000010124

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

– 26 May 2026 for Class III custom-made implantable devices;

– 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors);

– 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function;

– 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments).

On behalf of the Notified Body,

Ana Pribaković Borštnik

Product manager MDR

SIQ Ljubljana
Tašera-Spasićeva ulica 10
1000 Ljubljana

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

DEVICE NAME OR BASIC UDI-DI (under MDR Application)	MDR DEVICE CLASSIFICATION (as proposed by the manufacturer and verified at the pre-application stage)	IF THE MDR DEVICE IS A SUBSTITUTE DEVICE, IDENTIFICATION OF THE CORRESPONDING MDD DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
MR Q SUPINE	Class IIb	N/A	MDD-091, NB 1304
MR Q	Class IIb	N/A	MDD-172, NB 1304

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive

DEVICE NAME OR BASIC UDI-DI (under MDR Application)	MDR DEVICE CLASSIFICATION (as proposed by the manufacturer and verified at the pre-application stage)	IF THE MDR DEVICE IS A SUBSTITUTE DEVICE, IDENTIFICATION OF THE CORRESPONDING MDD DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

DATE	NB INTERNAL REFERENCE TRACEABLE TO EACH VERSION OF THE LETTER	ACTION
2024/05/17	5361-2024/01	Initial issue

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

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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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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