



Z vami več kot
With you for over
50 let
years

SIQ Ljubljana

Mašera-Spasičeva ulica 10

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.:

datum / date:

OSV/5361

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./ **MDD-091**
Št. ES certifikata:
Issued to / Meridian Medical d.o.o.
Naziv organizacije: 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
Kategorija proizvoda: Medicinski terapevtski laserski sistem
GMDN: 16947
Classification / IIb
Klasifikacija:
Product name / MR Q SUPINE
Ime proizvoda:
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



**Notified Body Confirmation Letter**

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.

Notified Body Confirmation Letter

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



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-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



Director of SIQ

Igor Likar



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



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



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

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



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

IQNET Members*:

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 **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

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