

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

Meridian Medical OyElannontie 5, FI-01510 Vantaa
Finland

Eurofins Expert Services has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016.
This certificate covers the following functions/services:

**Design, production, sales and servicing of
medical laser equipment and systems**

Issued:

28th February, 2022

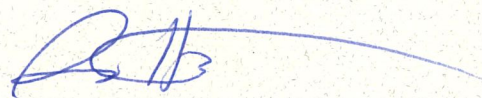
Valid until:

28th February, 2025

First issued:

12th December, 2011

Aliina Nieminen
Certifier
Eurofins Expert Services



Rami Haulisto
Lead Auditor
Eurofins Expert Services



Certificate nr.
EUFI29-22000056-S



Certification body:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Meridian Medical Oy
Elannontie 5
FI-01510 Vantaa
FINLAND


Coverage of Certificate: Design, manufacture and final inspection

Product category: Ophthalmic laser photocoagulation systems

Valid until: 27th May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 29th January 2021



Satu Rajala

Certificate no.
C-01-1158-756-21



Mikko Soikkeli

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1158-756-21

Manufacturer:	Meridian Medical Oy Elannontie 5, FI-01510 Vantaa Finland																
Activity and product category:	Design, manufacture and final inspection of ophthalmic laser photocoagulation systems GMDN code: 44731																
Products:	<p>The certificate covers the following products:</p> <table border="1"> <thead> <tr> <th><i>Name</i></th> <th><i>Brand name</i></th> <th><i>Model</i></th> <th><i>Class</i></th> </tr> </thead> <tbody> <tr> <td>Ophthalmic laser coagulation system</td> <td>Valon Lasers</td> <td>VALON TT</td> <td>Iib</td> </tr> <tr> <td>Ophthalmic laser coagulation system</td> <td>Valon Lasers</td> <td>VALON TT 577</td> <td>Iib</td> </tr> <tr> <td>Ophthalmic laser coagulation system</td> <td>Valon Lasers</td> <td>VALON 5G</td> <td>Iib</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>	Ophthalmic laser coagulation system	Valon Lasers	VALON TT	Iib	Ophthalmic laser coagulation system	Valon Lasers	VALON TT 577	Iib	Ophthalmic laser coagulation system	Valon Lasers	VALON 5G	Iib
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Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.