

CERTIFICATE

Berlin Cert

Prüf- und Zertifizierstelle für Medizinprodukte GmbH



hereby certifies that

Meridian AG

Biergutstrasse 7, 3608 Thun, Schweiz

and further locations

Biergutstrasse 1a, 3608 Thun, Schweiz

has implemented and uses a quality management system for the following scope of application

Import, Development, manufacturing, distribution, installation and maintenance of medical laser and imaging systems

Distribution, installation and maintenance of third party diagnostic and therapeutic medical devices

The audit report no. B-23-019-S-RZ provided confirmation that the requirements in the standard

DIN EN ISO 13485:2016

Medical devices - Quality management systems requirements for regulatory purposes

have been fulfilled.

Issued: 07.06.2023

Valid from: 07.06.2023

Valid until: 26.05.2024

BERLIN CERT
AFNOR Group
Dr.-Ing. Martin Fetteke
Signature of authorised representative



EC-Certificate**Directive 93/42/EEC, Annex II excluding (4)****Full Quality Assurance System**

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-207.15.04

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Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that

Meridian AG

Bierigutstrasse 7, 3608 Thun, Switzerland

and further locations

Bierigutstrasse 1a, 3608 Thun, Switzerland

has implemented and uses a quality assurance system for the following scope of application:

Design, production, final inspection of medical ophthalmic laser devices (see appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. B-19-151-S-EZ) provided confirmation that the requirements of Annex II of MDD 93/42/EEC have been fulfilled. The Manufacturer has to be inspected periodically by the notified body according the requirements of Annex II, Article 5 of MDD 93/42/EEC. The manufacturer is allowed to use this certification in his process for the declaration of conformity.

The manufacturer is allowed to place the CE-mark on the above-mentioned products in combination with the identification No. **0633**.

issued on: **19.05.2021**valid from: **19.05.2021**valid to: **26.05.2024**


BERLIN CERT
AFNOR Group
Dr. N. Eschweiler
Signature of authorized representative
Prüf- und Zertifizierstelle für Medizinprodukte GmbH



Appendix to certificate Z-19-151-S-R II-E-N1

from 19.05.2021

product/product category	UMDNS	Classification
Merilas 532alpha	17-446	IIb
Merilas 532 shortpulse	17-446	IIb
Merilas 577 shortpulse	17-446	IIb
Merilas 810 shortpulse	17-446	IIb
Merilas Cooling System	17-446	IIb
Merilas SLA-BMBQ	17-446	IIb
Merilas SLA-UNI	17-446	IIb
Merilas UPF passive	17-446	IIb
Merilas UPF active	17-446	IIb
Merilas UPF semiactive	17-446	IIb


Dr. N. Eschweiler
Signature of authorized representative

