



Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.

Medlight SA
Chemin des Larges-Pièces B
1024 Ecublens VD
Switzerland

Scope of certification

Whole Company

Field of activity

Design, manufacturing and marketing of optical instruments for medical and industrial applications

Normative base

EN ISO 13485:2016 **Medical devices –**
Quality Management System

Validity 13.07.2018–28.05.2021
Issue 13.07.2018

Reg. no. 41785

X. Edelmann, President SQS

F. Müller, CEO SQS



sqs.ch



Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland



Swiss Made



SQS as a conformity assessment body identification number 1250 herewith certifies the company

Medlight SA
Chemin des Grandes-Pièces B
1024 Ecublens VD
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated June 4, 2018.

The scope of validity covers the products

Class IIb

- Frontal Light Distributor, Model FD (UMDNS 17193)**
- Cylindrical Light Diffuser, Model RD-ML (UMDNS 17193)**
- Cylindrical Light Diffuser, Model RD (UMDNS 17193)**
- Spherical Light Distributor, Model SD (UMDNS 17193)**
- Isotropic Probe, Model IP (UMDNS 17193)**

The following CE label can be applied to these products

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 27.07.2018–26.07.2021
 Issue 27.07.2018

Reg. no. 42060
 Approved Medical Responsible
 18.07.2018



F. Müller, CEO SQS



J. Jäkle, Medical Responsible





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SQS has issued an IQNet recognized certificate that the organization:

Medlight SA
Chemin des Larges-Pièces B
1024 Ecublens VD
Switzerland

has implemented and maintains a

Management System

for the following scope(s):

3, 19

which fulfills the requirements of the following standard(s):

EN ISO 13485:2016 Medical devices – Quality Management System

Issued on: 2018-07-13

Expires on: 2021-05-28

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

Registration Number: CH-41785



Alex Stoichitoiu
President of IQNet

Felix Müller
CEO SQS



IQNet Partners*:

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
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IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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