



Certificate

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative basis mentioned.

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

Scope

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

Normative base

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

Reg. no. 41785

Validity 29.05.2021 – 28.05.2024
Issue 29.05.2021


A. Grisard, President SQS


F. Müller, CEO SQS



sqs.ch



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





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:

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

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

EN ISO 13485:2016

Issued on: 2021-05-29

Expires on: 2024-05-28

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

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

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 January 18, 2021.

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.

Reg. no. 42060

Validity 10.02.2021 – 25.05.2024
Issue 10.02.2021

Approved Medical Responsible
10.02.2021



F. Müller, CEO SQS



D. Taddeo, Medical Responsible

