

Certificate

Quality Management System EN ISO 13485:2016

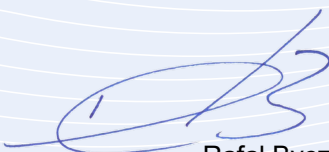
Registration No.: SX 2541411-1
Certificate Holder: Medlight S.A.
Chemin des Larges-Pièces 6
1024 Ecublens
Switzerland

Scope: Design and development, manufacture and distribution
of sterile optical instruments for medical application.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 73086271-100
Effective date: 2024-02-19
Expiry date: 2027-02-18
Issue date: 2024-02-19

This certificate can be validated on <https://www.certipedia.com>


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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

