



EU Quality Management Certificate



This is to certify that the company

SMT Swiss Microtechnology AG

Allmendstrasse 11
2562 Port
Switzerland

SRN: CH-MF-000025016

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	066412 MDR2017Q
Certificate ID	1000169470
Effective date	2024-04-11
Expiry date	2027-12-14
Frankfurt am Main,	2024-04-11



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)





Annex to EU Quality Management Certificate

SRN of Manufacturer: CH-MF-000025016

Certificate ID: 1000169470

Authorised Representative of the company:

Ziemer Ophthalmology (Deutschland) GmbH

Kronenstr. 38
79211 Denzlingen
Germany

SRN: DE-AR-000005638

Device categories and variants covered by this certificate:

Device category: **MDA 0302 - Active non-implantable devices utilising non-ionizing radiation**
Product name: AQUARIUZ corneal ablation laser
Risk classification: IIb
Basic-UDI-DI: 764016775ABLXXXFZ
Intended purpose: Abtragung von Hornhautgewebe einer vorderen Hornhautoberfläche

Examinations and tests performed:

066412_A209785MED_01 dated 2022-07-08
066412_A209785MED_02 dated 2022-10-07

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-12-15	170779961	Change of Certificate Template