

Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.



Through an audit performed on behalf of

IOLUTION GmbH

Ruhrstraße 13, 22761 Hamburg, Germany

it could be demonstrated that a quality management system

according to

DIN EN ISO 13485:2016

"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the

development, manufacture and distribution of ophthalmic medical devices and medical device components, services and processes

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report mentioned hereafter.

Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report number

217-22-0309

Registered under

Z/22/04804E

Valid until

31 March 2025

Valid as of: 01 April 2022


Certification body