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

RUMEX INTERNATIONAL LTD

311 Shoreham Street, Sheffield, Yorkshire S24FA, United Kingdom

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

manufacturing, distribution, storage, quality control, sales and delivery of ophthalmic devices

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

Registered under

Valid until

571-18-627

Z/18/04338E

November 14th, 2021

Valid as of: November 15th, 2018

Certification Body