CERTIFICATE

Number: 2231916

The management system of:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

Scheijdelveweg 2
3214 VN Zuidland
Netherlands

Manufacturer Facility Identifier F003786

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada:	Medical Devices Regulations - Part 1 - SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
The design and development, manufacture, and distribution of ocular endotamponades, intraocular staining solutions, and surgical instruments for the area of ophthalmology. The design and development, manufacture, installation, servicing, and distribution of ophthalmic surgical systems and ophthalmic surgical equipment for the area of ophthalmology

Certificate expiry date: 2029-03-01
Certificate effective date: 2026-03-01
Certified since: 2020-03-01

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Certification Manager

The validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-checkme.com/org

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP Medical Device Single Audit Program