

CERTIFICATE

Number: 2231916

The management system of:

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

Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Manufacturer Facility Identifier 407522184

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

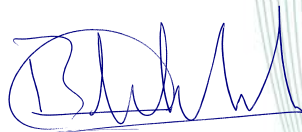
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 665/2022, 551/2021 and and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 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:

Design, development, manufacture, servicing, distribution and installation of surgical instruments, systems, equipment, ocular endotamponades, staining solutions for intraocular use and scleral buckling device for ophthalmic surgery.

Certificate expiry date: 2026-03-01
Certificate effective date: 2023-03-01
Certified since: 2020-03-01

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

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<https://www.dekra-product-safety.com/en/certified-organizations>

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

