# 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

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|---|---|
| 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.

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| 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



The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM