

CERTIFICATE

Number: 2231908

The management system of:

Sensimed SA

Route en Rambuz 17
1037 Etagnières
Switzerland

Manufacturer Facility Identifier F003340

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

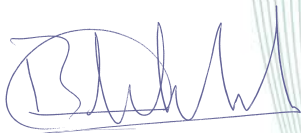
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, Development, Manufacture and Distribution of Sterile intraocular pressure monitoring Medical Devices for continuous intraocular pressure monitoring

Certificate expiry date: 2026-02-01
Certificate effective date: 2023-02-01
Certified since: 2020-02-24

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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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.

