

Certificate

Certificate No.: MD 1497914-1-3

Manufacturer: **OPTOPOL TECHNOLOGY Sp. z o.o.**
ul. Żabia 42
42-400 Zawiercie
Poland

REPs Facility ID: F001076

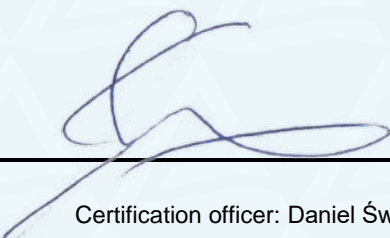
Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 4 – Production Quality Assurance Procedure
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and development, production, distribution and servicing of
spectral optical coherence tomography systems and automatic
perimeters for the area of ophthalmology

TÜV Rheinland

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 84975838-30
Issue Date: 2024-08-20
Effective Date: 2024-08-29
Expiry Date: 2027-08-28



Certification officer: Daniel Światko
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	OPTOPOL Technology Sp. z o.o. ul. Żabia 42 42-400 Zawiercie Poland REPs Facility ID: F001076	Design and development, production, distribution and servicing of spectral optical coherence tomography systems and automatic perimeters for the area of ophthalmology
/02	OPTOPOL Technology Sp. z o.o. ul. Żmigrodzka 81-83/102 51-130 Wrocław Poland REPs Facility ID: F006898	Design and development of spectral optical coherence tomography systems and automatic perimeters for the area of ophthalmology
/03	OPTOPOL Technology Sp. z o. o. ul. Bóźnicza 15/4 61-751 Poznań Poland REPs Facility ID: F006899	Design and development of software for optical coherence tomography systems and automatic perimeters for the area of ophthalmology



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