

# 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

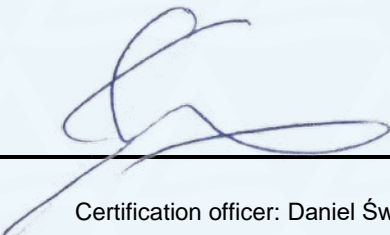
Certification criteria: ISO 13485:2016  
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,  
Schedule 3 Part 4 – Production Quality Assurance Procedure  
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,  
RDC ANVISA n. 67/2009  
Canada Medical Devices Regulations – Part 1 – SOR 98/282  
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.

# Certificate

Certificate No.: MD 1497914-1-3  
Manufacturer: **OPTOPOL TECHNOLOGY Sp. z o.o.**  
ul. Żabia 42  
42-400 Zawiercie  
Poland

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



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