EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices
Annex XI Part A

Registration No.:	DZ 1497914-1
Manufacturer:	OPTOPOL TECHNOLOGY Sp. z o.o. ul. Żabia 42 42-400 Zawiercie Poland
EUDAMED Single Registration No.:	PL-MF-000004770
Products:	Products of class IIa: Z12120121 - OPTICAL CONSISTENCY TOMOGRAPHS Z12120182 - OPHTALMOLOGY ASSESSMENTS AND DIAGNOSIS INSTRUMENTS – SOFTWARE ACCESSORIES
Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-10-30

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.
If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	84954728-120
Effective date:	2024-10-30
Expiry date:	2029-10-29
Issue date:	2024-10-30

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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