

# 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 - OPHTHALMOLOGY 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

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

  
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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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