

1. Manufacturer

Name: Deutsche Augenoptik GmbH
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Phone: +49 741/884-105

Registration number (SRN): DE-MF-000007188

2. Product Identification

Name of product: Polakop2
Model/Type: Models see annex
Basic UDI-DI: 426009859PS2JR
Risk category: Category I - non-sterile, no measuring function
Directions for use: Polaskop2 is a digital visual acuity system for determining visual performance during the refraction of refractive errors using various vision tests.

3. Declaration

The manufacturer hereby declares under its sole responsibility that the medical device described above complies with all relevant provisions of **Regulation (EU) 2017/745 (MDR)** on medical devices.

4. Applied EU legislation and standards

5.1 EU legislation

Regulation (EU) 2017/745 (MDR)
on medical devices

Regulation (EC) No 1907/2006
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Directive 2011/65/EU (RoHS)
Restriction of Hazardous Substances (RoHS) Directive

5.2 Harmonised standards

DIN EN ISO 10938:2016
Ophthalmic optics – Chart displays for visual acuity measurement – Printed, projected and electronic

DIN EN ISO 14971:2021
Medical devices – Application of risk management to medical devices

DIN EN ISO 15004-1:2020
Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments

DIN EN ISO 15223-1:2021
Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements"

5. Quality management system

Manufacturing and documentation are carried out in accordance with
DIN EN ISO 13485:2016 + AC:2018 + A11:2021

6. Conformity Assessment Procedure

The conformity assessment procedure has been carried out in accordance with **Article 52(7) of Regulation (EU) 2017/745**.

No notified body was involved.

7. Validity

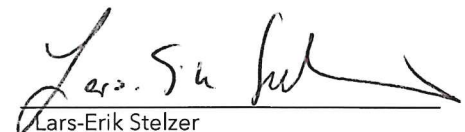
This declaration of conformity is valid from 2025-03-24 for devices with serial number **00157** or higher.

This declaration of conformity has a limit of validity of 5 years.

Mühlacker, 2026-01-15


Stefan Rüdiger
CEO


Verena Burghardt
CEO


Lars-Erik Stelzer
MDR Responsible person (PRRC)

Annex

Model/Type	Size
Polaskop2 Day&Night	24" FHD
Polaskop2 Day	24" FHD