# CE EU Declaration of conformity

in accordance with Annex IV of Regulation
(EU) 2017/745 on medical devices (MDR)

## 1. Manufacturer

| | |
|---|---|
| Name: | Deutsche Augenoptik GmbH |
| Adress: | Ziegeleistraße 18-24, 75417 Mühlacker |
| E-Mail: | mail@dao-gmbh.com |
| 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"



EINFACH. BESSER. SEHEN.

**Deutsche Augenoptik GmbH**
Ziegeleistraße 18-24
75417 Mühlacker
Germany

Registered office and
court of registration:
Mannheim, HRB 753980
VAT ID No.: DE 158808088

Managing Director:
Stefan Rüdiger, Verena Burghardt,
Oliver Fischbach, David Upton

Sparkasse Pforzheim Calw
IBAN DE56 6665 0085 0000 7121 40
BIC PZHSDE66XXX

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## 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 |



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