# Technical documentation

for in vitro diagnostic medical devices according to Regulation (EU) 2017/746


Manufacturer: Poly-Optik GmbH
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Signed by: Dr. Axel Weidner, Managing director and regulatory compliance officer

UDI: 4262367210003

Name of product: Cell counting chamber according to DIN 12847

Classification: Class A in vitro diagnostic

Marking: CE

General information:

Cell counting chambers were originally developed for the examination of human blood. This applies to both the external shape of the counting chambers and the used counting grid (cf. Verso: "Some Nineteenth-Century Pioneers of Haematology", Cambridge Journal of Medical History, 15,1971,55).
Counting chambers found early applications in other fields besides haematology (cf. Reumuth,Loske: "Küvettenmikroskopie in Biologie und Technik", Mikroskopie, 17,1962,149).
**These days, standardized types of counting chambers are manufactured. A normation according to DIN 12847 "Cell counting chambers" took place, which is valid since 1984.**

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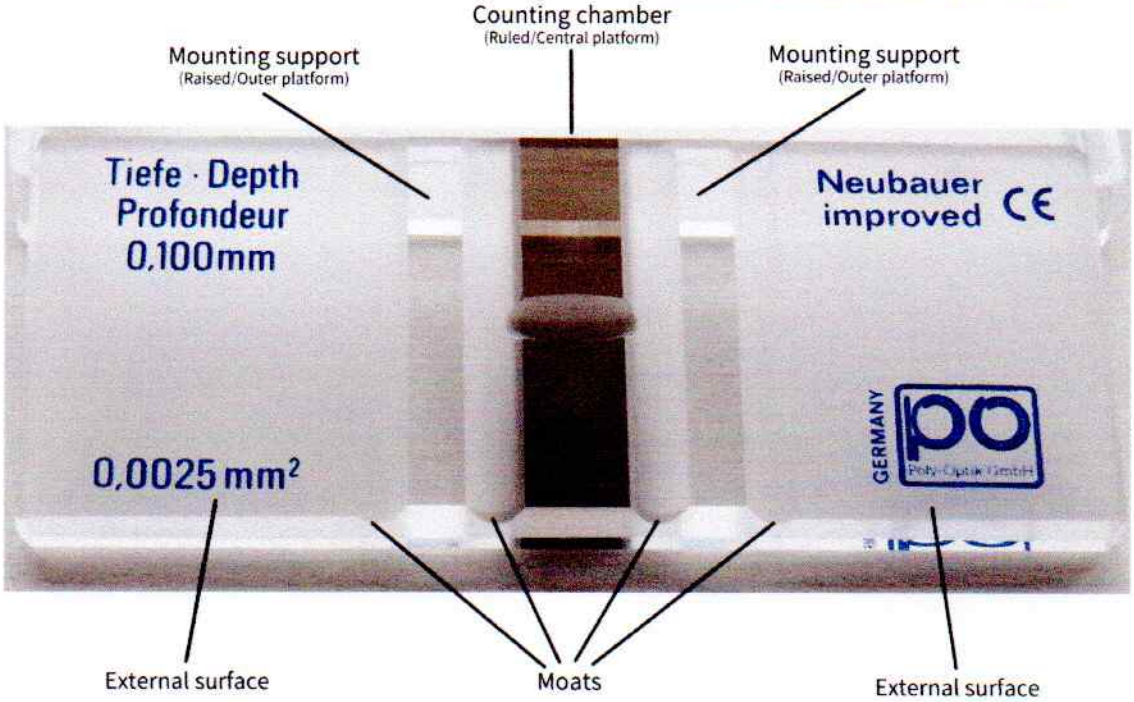
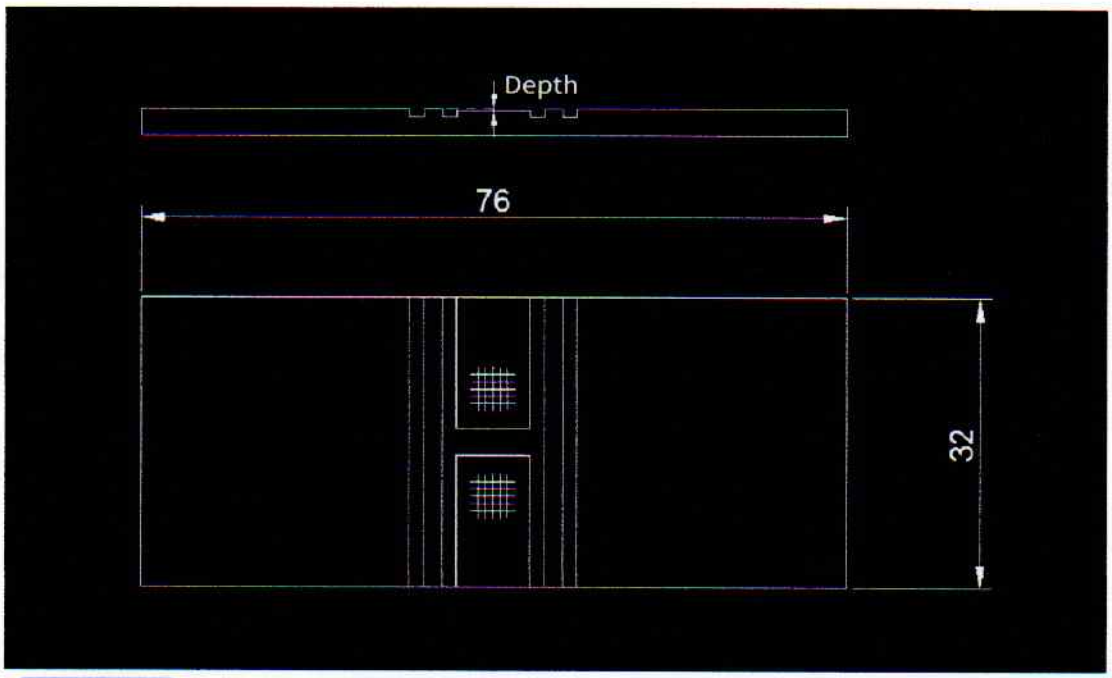
Terminology:

Blank: B270 plate glass; Measures 76mm x 32mm x 4.5mm
External surfaces, moats, mounting support, counting chamber: figure below




The external surfaces and moats have been ground.
Both the mounting support for the cover slip and counting chamber are polished.
The counting grid was engraved into the counting chamber, which lies slightly below the platform surface of the mounting support. This difference in height is referred to as the depth of the counting chamber.

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Specification:

According to DIN 12847, the counting chambers must comply with the following tolerances:

- Chamber depth in the area of the counting grid: ± 2% of the nominal distance
- Distances < 0.4mm between any grid lines: ± 0.002 mm
- Distances ≥ 0.4mm between any grid lines: ± 5% of the nominal distance
- Angle between grid lines: ± 1%
- Flatness of the counting chamber in the area of the counting grid: 0.002 mm
- Flatness of the mounting support surface in the area of the counting grid: 0.002 mm

In order to maintain these values in the course of production, our quality management system (certified according to DIN EN ISO 9001:2015) includes the following instructions:

**AA-8.5 Zählkammerfertigung**

as well as

**AA-7.1 Prüfmittelanwendung und –überwachung**,

which ensures compliance with the tolerances according to DIN 12847 in the manufacturing process and during final inspection.

Bad Blankenburg, 12.05.2022

Poly-Optik GmbH
aus Thüringen

Dr. Axel Weidner

Poly-Optik GmbH
aus Thüringen

Anlage:

TÜV PROFI CERT

TÜV HESSEN

# CERTIFICATE

for a management system as per

## DIN EN ISO 9001:2015

Evidence of conformity has been furnished.

Poly-Optik GmbH
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Poly-Optik GmbH
Obere Marktstraße 3
07422 Bad Blankenburg / Germany

scope:

Manufacture of and trade with optical parts and assemblies

| | |
|---|---|
| Certificate registration No. **73 100 7768** | Certificate valid from 2022-03-29 to **2025-03-28** |
| Audit report No. 4395 3226 | First certification 2022-03-29 |

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-14137-01-00

Darmstadt, 2022-03-29
Certification body of TÜV Hessen
Head of Certification body

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This certification confirms the introduction and maintenance of the Management system specified above and is monitored regularly.
The current validity is verifiable at www.profi-cert.com. Original certificates contain a glued hologram.
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