

EU declaration of conformity

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**

Declaration: We confirm that the cell counting chambers produced by Poly-Optik GmbH comply with the EU Regulation 2017/746 for in vitro diagnostic medical devices and are manufactured and tested according to DIN 12847.

Our quality management system is certified according to DIN EN ISO 9001:2015.

Poly-Optik GmbH bears the sole responsibility for issuing the declaration of conformity.

The declaration of conformity is valid until product modifications are necessary, but not further than May 12 2027.

Bad Blankenburg, 12.05.2022



Dr. Axel Weidner
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