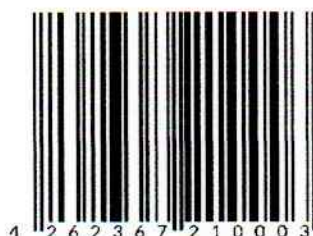


Instruction manual

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

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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:

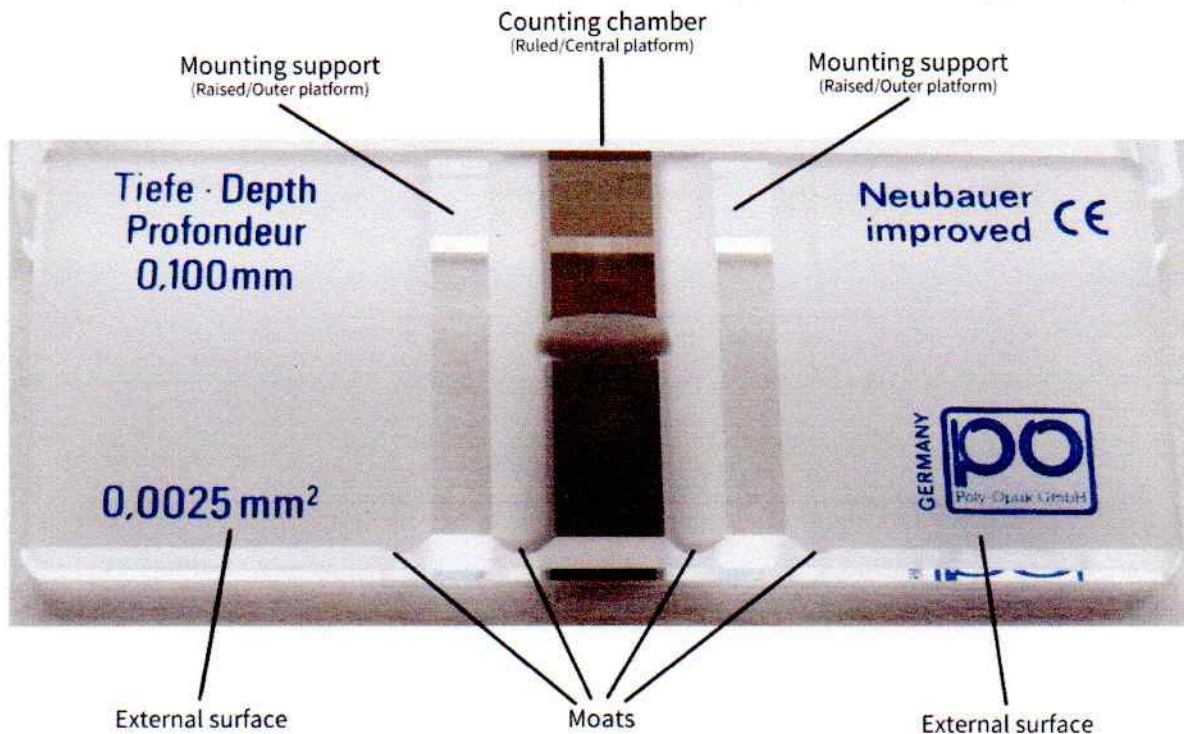
Cell counting chambers are used to determine a number of particles (e.g. leukocytes and erythrocytes in blood, bacteria in a liquid culture). The counting is performed while using a microscope after applying a cover glass to the counting chamber. The corresponding laboratories have trained personnel, so that it is not the manufacturer's task to describe the procedure to be used for filling the chamber and counting the particles, depending on the task. In addition, extensive literature and textbooks exist on this subject, depending on the task.

Examples for literature:

- R.Gräfe, O.Patzelt: Einführung in die Hämatologie
Theodor Steinkopf Dresden und Leipzig 1965, S.155 ff
- R.Mahlberg u.a.: Hämatologie, Theorie und Praxis für medizinische
Assistenzberufe, Wiley-VCH Weinheim 2014, S.171 ff
- A.Störiko u.a.: Methoden der Mikrobiologie
Springer Spektrum Berlin 2020, S.45 ff

Advice for usage:

- The counting chamber and associated cover slip are made of glass. In case of careless handling the user may risk breakage and injury.
- The counting chamber and mounting support (figure below) are polished, therefore mechanical damage to these surfaces must be avoided.
- The ruled grid on the counting chamber is manufactured with a tolerance smaller than 2 microns, thus avoid mechanical damage and temperature shocks.
- For repeated usage of the counting chamber, it must be cleaned in accordance with the aforementioned instructions. Correspondingly, use mild detergents only.



Bad Blankenburg, 12.05.2022

Axel Weidner
Dr. Axel Weidner