

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

(see appendix for different versions of Marienfeld-Superior-chambers)

Classification: Class A in vitro diagnostic

Marking:



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

Appendix Marienfeld-Superior-chambers

Art.No.	GTIN (Smallest-Sales-Unit)	SSU	GTIN (Multi-Pack)	Multi-Pack
0640010	4262367210010	1	4262367210027	10
0640011	4262367210034	1	4262367210041	10
0640030	4262367210058	1	4262367210065	10
0640031	4262367210072	1	4262367210089	10
0640110	4262367210096	1	4262367210102	10
0640111	4262367210119	1	4262367210126	10
0640130	4262367210133	1	4262367210140	10
0640131	4262367210157	1	4262367210164	10
0640210	4262367210171	1	4262367210188	10
0640211	4262367210195	1	4262367210201	10
0640230	4262367210218	1	4262367210225	10
0640231	4262367210232	1	4262367210249	10
0640310	4262367210256	1	4262367210263	10
0640311	4262367210270	1	4262367210287	10
0640330	4262367210294	1	4262367210300	10
0640331	4262367210317	1	4262367210324	10
0640410	4262367210331	1	4262367210348	10
0640411	4262367210355	1	4262367210362	10
0640430	4262367210379	1	4262367210386	10
0640431	4262367210393	1	4262367210409	10
0640510	4262367210416	1	4262367210423	10
0640511	4262367210430	1	4262367210447	10
0640530	4262367210454	1	4262367210461	10
0640531	4262367210478	1	4262367210485	10
0640610	4262367210492	1	4262367210508	10
0640611	4262367210515	1	4262367210522	10
0640630	4262367210539	1	4262367210546	10
0640631	4262367210553	1	4262367210560	10
0640710	4262367210577	1	4262367210584	10
0640711	4262367210591	1	4262367210607	10
0640730	4262367210614	1	4262367210621	10
0640731	4262367210638	1	4262367210645	10
0640810	4262367210652	1	4262367210669	10
0640811	4262367210676	1	4262367210683	10
0640830	4262367210690	1	4262367210706	10
0640831	4262367210713	1	4262367210720	10
0642010	4262367210737	1	4262367210744	10
0642011	4262367210751	1	4262367210768	10
0642110	4262367210775	1	4262367210782	10
0642111	4262367210799	1	4262367210805	10
0642710	4262367210812	1	4262367210829	10
0650010	4262367210836	1	4262367210843	10
0650030	4262367210850	1	4262367210867	10
0650430	4262367210874	1	4262367210881	10
0649910391	4262367210898	1	4262367210904	10
0649910392	4262367210911	1	4262367210928	10
06499103927	4262367210935	1	4262367210942	10
06499103928	4262367210959	1	4262367210966	10
06499113923	4262367210973	1	4262367210980	10
0650110	04262367210997	1	04262367211000	10
0650130	04262367211017	1	04262367211024	10
0650210	04262367211031	1	04262367211048	10
0650230	04262367211055	1	04262367211062	10
0650310	04262367211079	1	04262367211086	10
0650330	04262367211093	1	04262367211109	10
0650410	04262367211116	1	04262367211123	10
0650610	04262367211154	1	04262367211161	10
0650630	04262367211178	1	04262367211185	10
0650710	04262367211192	1	04262367211208	10
0650730	04262367211215	1	04262367211222	10
0650810	04262367211239	1	04262367211246	10
0650830	04262367211253	1	04262367211260	10
0652010	04262367211277	1	04262367211284	10
0652110	04262367211291	1	04262367211307	10
0652710	04262367211314	1	04262367211321	10

Axel Peters

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süd Thüringen

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