



Marienfeld * Am Wöllerspfad 4 * 97922 Lauda-Königshofen * Germany

EC Declaration of Conformity

In accordance with the requirements of Directive 98/79/EC for in vitro diagnostic medical devices, Annex I, we declare under our sole responsibility the conformity of the products.

We, the Paul Marienfeld GmbH & Co. KG, are registered as manufacturer respectively marketing authorisation holder of in-vitro diagnostic devices at DIMDI (Deutsches Institut für Medizinische Dokumentation und Information).

We hereby certify that the following in-vitro diagnostic devices comply with the essential requirements of Annex I to the Directive 98/79/EC and are suitable for use in accordance with these regulations.

Product specification	Registration no.
Counting chamber for blood cells	DE/CA 37/IVD/8/11

This registration number covers the products with the following Art.No.

0640010	0640230	0640510	0640730	0650030
0640011	0640231	0640511	0640731	0680010
0640030	0640310	0640530	0640810	0680030
0640031	0640311	0640531	0640811	
0640110	0640330	0640610	0640830	
0640111	0640331	0640611	0640831	
0640130	0640410	0640630	0642010	
0640131	0640411	0640631	0642110	
0640210	0640430	0640710	0642710	
0640211	0640431	0640711	0650010	

The conformity assessment procedure has been carried out in accordance with Annex III without point 6 of Directive 98/78/EC.

The above mentioned in-vitro diagnostic devices are neither covered by Annex II nor intended for self-application.

This declaration is valid until 31st December 2021.

Best regards,

Harry Marienfeld
 Managing Director
 Lauda-Königshofen, 24th October 2019