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 | 0680410 |
| 0640110 | 0640330 | 0640610 | 0640830 | 0680430 |
| 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

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