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

EC Declaration of Conformity

according to Directive 98/79/EC for In-vitro Diagnostic Devices

We, 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, Cologne).

We hereby certify that the following in-vitro diagnostic devices meet the essential requirements of Annex I of the Directive 98/79/EC and are appropriate for application according to these regulations.

The application at DIMDI was confirmed by the Regierungspräsidium Stuttgart (government presidency) with the following registration numbers:

Product specification	**Registration no.**
Micro slides for blood smears	DE/CA37/IVD/8/1
Micro slides for tissue sections	DE/CA 37/IVD/8/2
Capillary tubes for microhematocrits	DE/CA37/IVD/8/3
Capillary tubes for blood gas	DE/CA37/IVD/8/4
Micro pipettes 'end-to-end' for taking capillary blood	DE/CA37/IVD/8/5
Micro pipettes with ringmark for taking capillary blood	DE/CA37/IVD/8/6
Blood sedimentation pipettes acc. to Westergren	DE/CA37/IVD/8/7
Blood diluting pipettes	DE/CA37/IVD/8/8
Hemoglobin pipettes acc. to Sahli	DE/CA37/IVD/8/9
Cover glasses for blood cell counting chambers	DE/CA37/IVD/8/10
Counting chamber for blood cells	DE/CA37/IVD/8/11
Cover glasses for blood and tissue sections	DE/CA37/IVD/8/12
Hydrometers acc. to Vogel, for specific weights between 1,0 and 1,06	DE/CA37/IVD/8/13
Embedding cassettes for tissue investigation (histology)	DE/CA37/IVD/8/14
Easy Pap One Step Stain, cytology stain combining OG and EA steps	DE/CA37/IVD/8/15
OG-6 Cytology Stain	DE/CA37/IVD/8/16
EA-65 Cytology Stain	DE/CA37/IVD/8/17
EA-50 Cytology Stain	DE/CA37/IVD/8/18
EA-36 Cytology Stain	DE/CA37/IVD/8/19
Acid Rinse	DE/CA37/IVD/8/20
Bluing Reagent Prestige	DE/CA37/IVD/8/21
Bluing Reagent Ultra	DE/CA37/IVD/8/22
Eosin Prestige	DE/CA37/IVD/8/23
Eosin Ultra	DE/CA37/IVD/8/24
Hematoxylin Prestige	DE/CA37/IVD/8/25
Hematoxylin Ultra	DE/CA37/IVD/8/26

The above mentioned in-vitro diagnostic devices are neither covered by Annex II nor intended for self-testing. They are manufactured according to the implemented Quality System fulfilling the essential requirements of DIN EN ISO 9001:2008 and Annex I of Directive 98/79/EC.

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The Notified Body, DEKRA ITS Certifications Services GmbH, performed an audit of our quality systems and the application of our quality system is subject to surveillance by the Notified Body.

Applied Laws and regulations:

- Medical Devices Law (Medizinprodukte Gesetz)
- Applicable GMP Rules of the WHO

Please do not hesitate to contact us should you require any further information. We will be pleased to assist you and look forward to hearing from you.

Best regards,

Harry F. Marienfeld
Lauda-Königshofen, January 2012