

EC-DECLARATION OF CONFORMITY

Document: No. 707.033.6
Product line: **Hemo_Control**
Product description: **Hemo_Control Manager, Hemo_Control and auxiliary equipment and consumables***
*) see annex 1 to declaration of conformity for product line Hemo_Control
Intended Use: In vitro diagnostic fast and exact determination of hemoglobin in blood by professional personnel



We herewith declare that the above mentioned products meet the essential requirements of the European Directives

98/79/EC IVD (essential requirements Annex I)
2004/108/EC Electromagnetic Compatibility (EMC)
2006/95/EC Low Voltage Directive

with the classification:
In-vitro-diagnostic medical equipment for professional use;
not mentioned in 98/79/EC annex II list A and B


proved by complete compliance of the following harmonized standards:

EN 375	EN 591	EN 980
EN 13612	EN 13640	EN 14971
EN 17511	EN 61010	EN 61010-2-101
EN 61326	EN 61326-2-6	EN 62304
EN 62366	NCCLS H15-13	

This declaration certifies the conformity with the mentioned requirements but does not include warranty of attributes.
The safety notes of the delivered product documentation have to be followed.

Quality Certificate: TUEV SUED Product Service GmbH
Certificate-No.: Q1N 09 06 44132 008
Conformity assessment procedure: **own conformity assessment**
Valid from: **2010-02**
Initial issuing in: **2002**
Manufacturer: **EKF-diagnostic GmbH
Ebendorfer Chaussee 3
D-39179 Barleben**
Issuer, title: **B. Walter (General Manager)**

Barleben, 2010-02-24
Place, date of issue


.....
legally binding signature

Anschrift

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Handelsregister

Stendal HRB 101939

Umsatzsteuer-ID-Nr.

DE 139 233 820

Geschäftsführer

Dipl.-Ing. B. Walter

Bankverbindungen

Dresdner Bank MD
BLZ 810 800 00
Konto 319 978 200

Deutsche Bank MD
BLZ 810 700 00
Konto 1 186 253 00

Stadtsparkasse MD
BLZ 810 532 72
Konto 30 970 116

Commerzbank
BLZ 810 400 00
Konto 209 600 600