Konformitätserklärung
Declaration of Conformity

Wir / We

EKF-diagnostic GmbH
Ebendorfer Chaussee 3, 39179 Barleben, Deutschland

erklären in alleiniger Verantwortung, dass das die Medizinprodukte zur In-vitro-Diagnostik
declare under sole responsibility that the in vitro diagnostic medical devices

der Produktfamilie / of the product family

Hemo Control

Produktmodelle / Product models

Hemo_Control Hemoglobin Microcuvettes*

Hb-con*

den Anforderungen der *Richtlinie 98/79/EG des europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika* entsprechen.

comply with the requirements of the *Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices*.

Konformitätsbewertungsverfahren Conformity assessment procedure	Anhang III Annex III	(EG-Richtlinie 98/79/EG) (Council Directive 98/79/EC)
Klassifizierung Classification	IVD ; Sonstige IVD/ Andere, nicht für Eigenanwendung ; (EG-Richtlinie 98/79/EG) IVD ; General IVD/ Others, not for self-testing ; (Council Directive 98/79/EC)	
Gültig bis Valid until	25.05.2026	

Barleben, 09.05.2022

Steffen Borlich
Geschäftsführer / CEO

EKF-diagnostic GmbH HRB 101939 CIC 287282 DIAGNOSTIC www.EKF-diagnostic.com Ebendorfer Chaussee 3 · 39179 Barleben · Germany

*** siehe Anhang zur Konformitäterklärung** / see annex to Declaration of Conformity Hemo Control Consumables

Die EKF-diagnostic GmbH ist zertifiziert gemäß EN ISO 13485.
EKF-diagnostic GmbH is certified according to EN ISO 13485.

Anhang zur Konformitätserklärung: *Hemo Control – Consumables*

Annex to Declaration of Conformity:

Reference Number	Device Description	GMDN Code *CND codes*	EDMA Code
3000-3012-0765	Hemo_Control Hemoglobin Microcuvettes 50 pcs	61032 *W0103010601*	13.01.70.01
3000-3013-0278	Hemo_Control Hemoglobin Microcuvettes 50 x1 single packed	61032 *W0103010601*	13.01.70.01
3000-6121	Hb-con low, Control solution, 1mL in dropper bottle	57272 *W0103010504*	13.01.20.04
3000-6128	Hb-con Set 2, Control solution (Set of 2 dropper bottles 1 ml with 1x Hb-con norm, 1x Hb-con high)	57272 *W0103010504*	13.01.20.04

Manufacturer's Declaration

EKF-diagnostic GmbH
Ebendorfer Chaussee 3, 39179 Barleben, Deutschland

Manufacturer's Declaration in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 as regards the transitional provisions for in vitro diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body and
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Declaration(s) of Conformity to which this confirmation is made	DoC Hemo Control consumables+Annex de-en 2_5_exp.20260525 DoC supplement Hemo Control consumables+Annex de-en 2_5
Original expiry date as indicated on the Declaration(s) of Conformity prior to the extension of the validity	25.05.2026
End date of the extended transition period	31.12.2029

We, as the manufacturer declare under our sole responsibility that for the device(s) covered in the above listed Declaration(s) of Conformity the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met and that the device(s) and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

- Signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) covered in the above listed Declaration(s) of Conformity or its/their substitutes.
- QMS in accordance with Article 10(8) IVDR is in place
- The device(s) continue to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:
Barleben, 24.06.2025

i.V. K. Riemer

i.V. Kerstin Riemer
Head of Regulatory Affairs / PRRC
EKF-diagnostic GmbH

EKF-diagnostic GmbH HRB 101939 CIC 287282 EKF DIAGNOSTIC www.EKF-diagnostic.com Ebendorfer Chaussee 3 · 39179 Barleben · Germany