


EU-Declaration of Conformity

EU DECLARATION OF CONFORMITY

Hemo Control Analyzer	
REF	<i>refer to Annex</i>
Basic-UDI-DI:	<i>refer to Annex</i>
Optional: CND / GMDN code	<i>refer to Annex</i>

	EKF-diagnostic GmbH Ebendorfer Chaussee 3, 39179 Barleben, Germany
SRN:	DE-MF-000006416

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

- Regulation (EU) 2017/746 on in vitro diagnostic medical devices
- Directive 2011/65/EU – Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II)
- Directive 2014/53/EU – Radio equipment


Risk Class: A B C D

Conformity Assessment Procedure:

ANNEX I & II+III

Optional:
Common Specifications: N/A

Valid until: **2027-01-31**


Dr. Olga Suckau
CEO



Barleben, **2024-01-10**

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ANNEX TO DECLARATION OF CONFORMITY Hemo Control Analyzer

Reference Number:	Device Description:	Basic-UDI-DI:	GMDN code CND codes
3040-0010-0218	Hemo Control	4048534AEAAV4	32435 W02010101
3041-0010-0229	Hemo Control Manager	4048534AEAAV4	32435 W02010101
3000-6138	Control Cuvette Set	4048534AHABVM	58049 W0201010185
3000-6232	Cleaner	4048534AHA AVK	63377 W0201010185
3040-7201-0099	Add Pack Hemo Control DM	4048534AHACVP	43472 W0201010182
3040-7021-0463	Printer cable for MCP 1880	4048534AHAGVX	32435 W02010199
3000-7051-0028	Data cable USB interface	4048534AHADVR	32435 W02010199
3005-7011-0039	Data Cable D-Sub 9	4048534AHAEVT	32435 W02010199
3005-7086-0201	3-fold Adapter	4048534AHAGVX	32435 W02010199
3040-7231-0132	Software HemoConnect_HC	4048534AHAHVZ	43472 W0201010182