EU-Declaration of Conformity

EU DECLARATION OF CONFORMITY

	Quo-Test Analyzer
REF	*refer to Annex*
Basic-UDI-DI:	*refer to Annex*
CND / GMDN code	*refer to Annex*

	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).

Risk Class: ☒ A ☐ B ☐ C ☐ D

Conformity Assessment Procedure:

☒ ANNEX I & II+III

Optional:
Common Specifications: n.a.

Valid until: **2024-01-31**

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

Steffen Borlich
CEO

Barleben, **2022-05-23**

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ANNEX TO DECLARATION OF CONFORMITY Quo-Test Analyzer

Reference Number:	Device Description:	Basic-UDI-DI:	GMDN code *CND codes*
0108-0000	Quo-Test Analyzer System	4048534BEAAVB	35968 W0201060101
3123-0010-0240	Quo-Test Analyzer System (CN)	4048534BEAAVB	35968 W0201060101