


EU-Declaration of Conformity

EU DECLARATION OF CONFORMITY

Glucose/Lactate System Solution Glucose/Lactate hemolyzing solution	
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

Risk Class: A B C D

Conformity Assessment Procedure:

ANNEX I & II+III

**Optional:
Common Specifications: n.a.**

Valid until: *[Signature]* **2024-01-31**

Steffen Borlich
CEO



Barleben, 2022-12-01

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ANNEX TO DECLARATION OF CONFORMITY **Glucose/Lactate System Solution**
Glucose/Lactate hemolyzing solution

Reference Number:	Device Description:	Basic-UDI-DI:	GMDN code CND codes
0201-0002-025	Glucose/Lactate System Solution bottle of 500 ml	4048534BFDAVR	58236 W0101070303
0201-0002-024	Glucose/Lactate System Solution canister of 2.500 ml	4048534BFDAVR	58236 W0101070303
0201-0002-026	Glucose/Lactate System Solution canister of 5.000 ml	4048534BFDAVR	58236 W0101070303
0209-0100-005	Glucose/Lactate hemolyzing solution with 10 µL end-to-end glass capillaries (Sodium [Na+] heparinized), 1.000x 0.5 mL in micro test tube colourless with 10x 100 capillaries	4048534BFEAVU	58208 W0101070303
0209-0100-012	Glucose/Lactate hemolyzing solution with 20 µL end-to-end plastic capillaries (Sodium [Na+] heparinized), 1.000x 1 mL in micro test tube colourless with 10x 100 capillaries	4048534BFEAVU	58208 W0101070303
0209-0100-013	Glucose/Lactate hemolyzing solution with 20 µL end-to-end plastic capillaries (Sodium [Na+] heparinized), 200x 1 mL in micro test tube colourless with 2x 100 capillaries	4048534BFEAVU	58208 W0101070303
0209-0100-014	Glucose/Lactate hemolyzing solution with 20 µL end-to-end plastic capillaries (Sodium [Na+] heparinized), 5x (200x 1 mL) in micro test tube colourless with 2x 100 capillaries	4048534BFEAVU	58208 W0101070303
0209-0100-122	Glucose/Lactate hemolyzing solution 1.000x 1 mL in micro test tube colourless	4048534BFEAVU	58208 W0101070303