EU Declaration of Conformity

in accordance with Article 17 and Annex IV of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Wir,

Waldeck GmbH & Co. KG
Havixbecker Straße 62
48161 Münster

Deutschland

Single registration number (SRN):	DE-MF-000029874
Basis-UDI-DI (BLR474 and BLR474K)):	42511373BLR47454
Basis-UDI-DI (BLR174):	42511373BLR1744M
EMDN Code:	W0104010805

hereby declare under our sole responsibility in our role as manufacturer that the devices listed in Appendix 1 comply with the conformity assessment procedure for Class A IVDs referred to in Article 48 (10).

All applicable essential safety and performance requirements of Annex I have been met and technical documentation has been prepared in accordance with Annexes II and III of the same Regulation.

The classification of the products listed above was carried out in accordance with Annex VIII of the above-mentioned Regulation. Classification rule 5 a) was determined to be applicable.

We declare that the product covered by this declaration is in conformity with Regulation (EU) 2017/746 and, where applicable, other relevant Union legislation providing for the drawing up of an EU declaration of conformity.

This declaration is valid for products placed on the market from the date of issue.

This document is valid until 31.12.2025

16.10.2023, Münster

i. A. Dr. Schräder

Dr. W. Schräder
(legally binding signature)

WALDECK

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Appendix 1:

Product name	Description	Item number	GTIN (UDI-DI)
BLR 174	Dilution agent	BLR174.9010	4251137300549
BLR 474	Phosphate buffered saline	BLR474.9010	4251137300587
BLR 474	Phosphate buffered saline	BLR474.5000	4251137300570
BLR 474	Phosphate buffered saline	BLR474.0005	4251137321742
BLR 474K	Phosphate buffered saline, concentrate - 10 fold	BLR474K.0001	4251137330188
BLR 474K	Phosphate buffered saline, concentrate - 10 fold	BLR474K.1000	4251137330171