R-Biopharm AG • An der neuen Bergstraße 17 • 64297 Darmstadt

EC-Declaration of Conformity according to Annex III, EC Directive 98/79/EC

Product: **RIDA®QUICK Helicobacter (Item code: N2303)**

Manufacturer: R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt
Germany

Classification according to Annex II, IVDD: Self declare

We herewith declare that the above mentioned product meets the provisions of the council directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained by the manufacturer and is in accordance with the Annex III (EC Declaration of Conformity) of the IVDD.

Standards applied:

DIN EN ISO 13485:2016	Medical devices – Quality Management for regulatory purposes
DIN EN ISO 14971:2013	Medical devices – Application of risk management to medical devices
DIN EN ISO 18113-1:2013	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
DIN EN ISO 15223-1:2017	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements

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Darmstadt,

Date: 03. Mai 2019

i. A. Thaens
Head of Quality Management / Regulatory Affairs

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