EU Declaration of Conformity

MANUFACTURER:
ADDRESS:

Bio-Rad Laboratories, Inc.
9500 Jeronimo Rd
Irvine, CA 92618
UNITED STATES OF AMERICA

EUROPEAN AUTHORIZED REPRESENTATIVE:
ADDRESS:

Bio-Rad
3 boulevard Raymond Poincaré
92430 Marnes-la Coquette, France

PRODUCT(S) NAME(S)
Liquichek D-Dimer Control

CATALOG NUMBER(S):
27100, 27101, 27102, 27102X, 27103

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature: 47347

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: D-Dimer IVD, Control

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives
☒Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

CLASSIFICATION:

☐ ANNEX II-A
☐ ANNEX II-B
☐ DEVICE FOR SELF TESTING
☒ OTHER DEVICE

CONFORMITY ROUTE

☒ ANNEX III
☐ ANNEX IV.3 Full Quality System
☐ ANNEX IV.4 Product EC Design Examination
☐ ANNEX V EC Type Examination
☐ ANNEX VII Production Quality System

NEW PRODUCT(S) (Notification according to article 10 point 4) ☐ YES ☒ NO

APPLICABLE HARMONIZED STANDARDS: *Listed in the Bio-Rad QSD Quality Manual Normative References*

Signature	Irvine, CA Issued in	13-Mar-19 Date
Vindeep Kohli Name	Regulatory Affairs Manager Function	

Digitally signed by Levința Alexandru
Date: 2023.12.11 14:34:31 EET
Reason: MoldSign Signature
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QUALITY ASSURANCE RH DOCUMENT CONTROL