EU Declaration of Conformity

MANUFACTURER: **Bio-Rad Laboratories, Inc.**

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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 Sedimentation Rate Control

CATALOG NUMBER(S):
514, 514X, 515

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature: 55972

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: Erythrocyte Sedimentation Rate (ESR) 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

Digitally signed by Levinţa Alexandru
Date: 2026.05.19 11:29:25 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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	Issued in	Date
	Irvine, CA	22-Feb-19

Name	Function
Vindeep Kohli	Regulatory Affairs Manager

QUALITY ASSURANCE RH DOCUMENT CONTROL