



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 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☐ DEVICE FOR SELF TESTING☐ ANNEX II-B☒ 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

Vindeep Kohli

Name

Irvine, CA

Issued in

22-Feb-19

Date

Regulatory Affairs Manager

Function

