



# EU Declaration of Conformity



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

**EUROPEAN AUTHORIZED REPRESENTATIVE:** Bio-Rad  
**ADDRESS:** 3 boulevard Raymond Poincaré  
 92430 Marnes-la Coquette, France

**PRODUCT(S) NAME(S)** Liquichek Hematology Control (A)  
**CATALOG NUMBER(S):** 865, 866, 867, 868, 865X

**GENERIC DEVICE GROUP CODE:**  
 GMDN Nomenclature: 55866

**GENERIC DEVICE GROUP TERM:**  
 GMDN Nomenclature: Full Blood Count 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:**

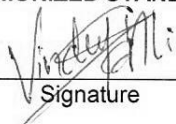
- ANNEX II-A  DEVICE FOR SELF TESTING
- ANNEX II-B  OTHER DEVICE

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

