



**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 Hematology – 16T Control

**CATALOG NUMBER(S):**  
144, 144X

**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*

*Vindeep Kohli*  
Signature

Vindeep Kohli  
Name

Irvine, CA  
Issued in

27-Feb-19  
Date

Regulatory Affairs Manager  
Function

