BIO-RAD EC Declaration of Conformity

MANUFACTURER: Bio-Rad Laboratories
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EUROPEAN AUTHORIZED REPRESENTATIVE: Bio-Rad
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M.S.D.N: 0106619054 - C.T.T.N.H.H - CÔNG TY TNHH THƯƠNG MẠI SIXMURS HTH VIỆT NAM - Q. NAM TỪ LIÊM - TP. HÀ NỘI

PRODUCT(S) NAME(S) and CATALOG NUMBER(S): Liquichek Hematology-16 Control
Catalog no. 760, 761, 762, 763, 760X

CLASSIFICATION:

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

CONFORMITY ROUTE

☒ ANNEX III
☐ ANNEX IV.3 Full Quality System

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
Expiration Date:

☐ ANNEX IV.4 Product Design Examination

☐ ANNEX V Type Examination

☐ ANNEX VII Production Quality System

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

GENERIC DEVICE GROUP CODE:

EDMS Nomenclature: 13 01 50 03
GMDN Nomenclature: 55866

GENERIC DEVICE GROUP TERM (EDMS Nomenclature): Blood Multilevel Controls

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives

APPLICABLE DIRECTIVE:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic Medical Devices

APPLICABLE HARMONIZED STANDARDS:

EN ISO 13485:2012	EN ISO 18113-1:2011	EN ISO 13612:2002
EN ISO 14971:2012	EN ISO 18113-2:2011	EN ISO 23640:2013
EN ISO 15225:2010	EN ISO 15223-1:2012	EN ISO 13641:2002
EN ISO 980:2008	EN ISO 62366:2008	EN ISO 13975:2003

Signature	Issued in	Date
	Irvine, CA	5th December 2016

Name	Function
Suzanne Parsons	Regulatory Affairs Manager