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)	Catalog Numbers:
VIROTROL I	00100, 00100A, 00100B, 00100C, 00100E, 00100F, 00100G, 00100H
VIROTROL I	00101, 00101B, 00101C, 00101D, 00101E, 00101F, 00101G
Assayed VIROTROL I-C	00164
Assayed VIROTROL I-E	00166
Assayed VIROTROL I-F	00168

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 — **EC CERTIFICATE No.: 16403** Name of Notified Body : LNE/G-MED Notified Body Identification No.: 0459 Expiration Date: July 11, 2019
☒ ANNEX VII Production Quality System

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

GENERIC DEVICE GROUP CODE:

EDMS Nomenclature: 15 50 01 30

GMDN Nomenclature: 42652 – Multiple blood-borne virus antigen/antibody IVD, control

GENERIC DEVICE GROUP TERM (EDMS Nomenclature): Multiconstituent Controls – Inf.Imm

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 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 13641:2002
EN 980:2008	EN 62366:2008	EN 13975:2003

Signature	Issued in	Date
	Irvine, CA, USA	August 9, 2016

Name	Function
Suzanne S. Parsons	Regulatory Affairs Manager