EU Declaration of Conformity

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

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

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

PRODUCT(S) NAME(S)
VIROTROL II

CATALOG NUMBER(S):
00104A , 00104B

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature: 42652

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: Multiple Blood-borne Virus Antigen/Antibody 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
EC CERTIFICATE No.: 15874
Name of Notified Body : **GMED**
Notified Body Identification No.: **0459**
Expiration Date: **02 APRIL 2024**

☒ ANNEX VII Production Quality System
EC CERTIFICATE No.: 18255
Name of Notified Body : **GMED**
Notified Body Identification No.: **0459**
Expiration Date: **27 NOV 2022**

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	13-Nov-19
	Issued in	Date
Vindeep Kohli	Regulatory Affairs Manager	
Name	Function	

QUALITY ASSURANCE RH DOCUMENT CONTROL