EU Declaration of Conformity

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)
VIROTROL HIV-1 Ag

CATALOG NUMBER(S):
00108A, 00108B

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature : 52846

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: HIV1 Antigen 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
☐ ANNEX II-B
☐ DEVICE FOR SELF TESTING
☐ 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.: 19443
Name of Notified Body : **GMED**
Notified Body Identification No.: **0459**
Expiration Date : **26 MAY 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	1-May-20
	Issued in	Date
Vindeep Kohli	Regulatory Affairs Manager	
Name	Function	