EU Declaration of Conformity

MANUFACTURER: **Bio-Rad Laboratories, Inc.**
ADDRESS: 9500 Jeronimo Rd
Irvine, CA 92618
UNITED STATES OF AMERICA

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

PRODUCT(S) NAME(S)
Lyphochek Immunoassay Plus Control

CATALOG NUMBER(S):
370, 371, 372, 373, 370X

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature: 53594

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: Multiple Clinical Chemistry Protein 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

EC CERTIFICATE No.: 19347
Name of Notified Body : **GMED**
Notified Body Identification No.: **0459**
Expiration Date : **26 MAY 2025**

☐ 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*

Signature	Irvine, CA	23-June-22
	Issued in	Date
Vindeep Kohli	Regulatory Affairs Manager	
Name	Function	

Digitally signed by Levința Alexandru
Date: 2023.12.18 11:39:37 EET
Reason: MoldSign Signature
Location: Moldova