



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)
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*

Vindeep Kohli
Name

Irvine, CA
Issued in

23-June-22
Date

Regulatory Affairs Manager
Function

