



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 Tumor Marker Plus Control

CATALOG NUMBER(S):

367, 368, 369, 368X

GENERIC DEVICE GROUP CODE:

GMDN Nomenclature: 38220

GENERIC DEVICE GROUP TERM:

GMDN Nomenclature: Multiple Tissue-Associated Protein / Tumour Marker 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

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

Vindeep Kohli

Name

Irvine, CA

Issued in

23-June-22

Date

Regulatory Affairs Manager

Function

