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 Diabetes Control

CATALOG NUMBER(S):
740, 740X

Digitally signed by Levința Alexandru
Date: 2023.12.08 11:42:47 EET
Reason: MoldSign Signature
Location: Moldova

GENERIC DEVICE GROUP CODE:
GMDN Nomenclature: 44435

GENERIC DEVICE GROUP TERM:
GMDN Nomenclature: Glycated Haemoglobin (HbA1c) 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
☐ 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	22-Feb-19
	Issued in	Date
Vindeep Kohli	Regulatory Affairs Manager	
Name	Function	

QUALITY ASSURANCE RH DOCUMENT CONTROL