BIO-RAD LABORATORIES
CLINICAL DIAGNOSTICS GROUP
EC DECLARATION OF CONFORMITY

MANUFACTURER: **Bio-Rad Laboratories, QSD**

ADDRESS: **Bio-Rad Laboratories, QSD**
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Irvine CA 92618

EUROPEAN AUTHORIZED REPRESENTATIVE: **Bio-Rad**
3, Boulevard Raymond Poincare
Marnes-la-Coquette, France 92430

PRODUCT(S) NAME(S) and CATALOG NUMBER(S):
Lyphochek® Immunoassay Plus Control **Catalog Number: 370, 371, 372, 373, 370X**

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 Design Examination — **EC CERTIFICATE No.: 19347-1**, Name of Notified Body : **LNE/G-MED**, Notified Body Identification No.: **0459**, Expiration Date : **27.11.2013**
☐ ANNEX V Type Examination — **EC CERTIFICATE No.:**, Name of Notified Body :, Notified Body Identification No.:, Expiration Date:
☐ ANNEX VII Production Quality System

NEW PRODUCT(S) (Notification according to article 10 point 4) ☐ YES ☒ NO

GENERIC DEVICE GROUP CODE:

EDMS Nomenclature: **12-50-01-30**
GMDN Nomenclature: **None**

GENERIC DEVICE GROUP TERM (EDMS Nomenclature): Multi Constituents Immunochemistry Controls

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives

APPLICABLE DIRECTIVE:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

APPLICABLE HARMONIZED STANDARDS:

EN 13641:2002
EN ISO 14971: 2007
EN ISO 15225:2000
EN 375:2001
EN 980: 2008
EN 13485:2003
EN 13612:2002
EN 13640:2002

Signature	Issued in	Date
	IRVINE CA USA	12/9/10

Name	Function
Vasif Vora	Regulatory Affairs Representative