



**BIO-RAD LABORATORIES  
CLINICAL DIAGNOSTICS GROUP  
EC DECLARATION OF CONFORMITY**

**MANUFACTURER:**

Bio-Rad Laboratories, QSD

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**EUROPEAN AUTHORIZED  
REPRESENTATIVE:**

**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

*Vasif Vora*

Signature

Vasif Vora

Name

IRVINE CA USA

Issued in

12/2/10

Date

Regulatory Affairs Representative

Function

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