EC Declaration of Conformity

MANUFACTURER: Bio-Rad Laboratories
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M.S.D.N: 0106619054 - C.T.T.N.H.H - CÔNG TY TNHH THƯƠNG MẠI SIXMURS HTH VIỆT NAM - Q. NAM TỪ LIÊM - TP. HÀ NỘI

PRODUCT(S) NAME(S) and CATALOG NUMBER(S) Liquichek Urinalysis Control
Catalog Numbers: 435, 436, 437, 435X

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.:
Name of Notified Body :
Notified Body Identification No.:
Expiration Date :

☐ ANNEX IV.4 Product Design Examination

☐ 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: 11 50 02 06
GMDN Nomenclature: 30219 – Multiple urine analyte IVD, control

GENERIC DEVICE GROUP TERM (EDMS Nomenclature): Urine 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 ISO 13485:2012	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2012	EN ISO 18113-2:2011	EN ISO 23640:2013
EN ISO 15225:2010	EN ISO 15223-1:2012	EN 13641:2002
EN 980:2008	EN 62366:2008	EN 13975:2003

Signature	Issued in	Date
	Irvine, CA, USA	Feb. 22, 2017

Name	Function
Suzanne Parsons	Regulatory Affairs Manager