

EU DECLARATION OF CONFORMITY

Division/Group: RAQA

Revision: 1

MANUFACTURER: Bio-Rad
 ADDRESS: 3 Boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France

EUROPEAN AUTHORIZED REPRESENTATIVE: /
 ADDRESS: /

PRODUCT(S) NAME(S) and CATALOG NUMBER(S): See Annex

GENERIC DEVICE GROUP CODE (GMDN nomenclature):
 51513

GENERIC DEVICE GROUP TERM (GMDN Nomenclature):
 Multiple Salmonella species culture isolate antigen IVD, kit, agglutination

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
 ANNEX IV.4 Product Design Examination

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

- 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

Date of the first issuance of the EU Declaration of Conformity: September 12th, 2003


Signature

Marnes-La-Coquette

Issued in

October 18, 2018

Date

Sylvie Femez

Name

Regulatory Affairs Manager

Function

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Annex:

Device name	Cat #
Antiserum Salmonella MONOVALENT O:4,5	59021
Antiserum Salmonella MONOVALENT O:1,2	59031
Antiserum Salmonella MONOVALENT O:6,7,8	59062
Antiserum Salmonella MONOVALENT O:7	59081
Antiserum Salmonella MONOVALENT O:8	59091
Antiserum Salmonella MONOVALENT O:9	59101
Antiserum Salmonella MONOVALENT O:3,10,15	59112
Antiserum Salmonella MONOVALENT O:15	59127
Antiserum Salmonella MONOVALENT O:1,3,19	59131
Antiserum Salmonella MONOVALENT O:11	59141
Antiserum Salmonella MONOVALENT O:13,22,23	59162
Antiserum Salmonella MONOVALENT O:6,14,24	59171
Antiserum Salmonella MONOVALENT H:a	60111
Antiserum Salmonella MONOVALENT H:b	60121
Antiserum Salmonella MONOVALENT H:c	60131
Antiserum Salmonella MONOVALENT H:d	60141
Antiserum Salmonella MONOVALENT H:i	60161
Antiserum Salmonella MONOVALENT H:k	60171
Antiserum Salmonella MONOVALENT H:r	60201
Antiserum Salmonella MONOVALENT H:y	60211
Antiserum Salmonella MONOVALENT H:z	60221
Antiserum Salmonella MONOVALENT H:z10	60241
Antiserum Salmonella POLYVALENT HE	60391
Antiserum Salmonella POLYVALENT H1	60401
Antiserum Salmonella POLYVALENT HL	60411
Antiserum Salmonella POLYVALENT HZ4	60431
Antiserum Salmonella POLYVALENT HG	60441
Antiserum Salmonella POLYVALENT HMA	60451
Antiserum Salmonella POLYVALENT HMB	60461
Antiserum Salmonella POLYVALENT HMC	60471
Antiserum Salmonella POLYVALENT HMD	60481
Antiserum Salmonella POLYVALENT HMIII	60493
Antiserum Salmonella OMNIVALENT Omni-O (A-60)	60781
Antiserum Salmonella POLYVALENT OMA	60801

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Device name	Cat #
Antiserum Salmonella POLYVALENT OMB	60811
Antiserum Salmonella POLYVALENT OMC	60821
Antiserum Salmonella POLYVALENT OMD	60831
Antiserum Salmonella POLYVALENT OME	60841
Antiserum Salmonella POLYVALENT OMF	60851
Antiserum Salmonella POLYVALENT OMG	60861
Antiserum Salmonella MONOVALENT Vi	60951
Antiserum Salmonella SG1	61011
Antiserum Salmonella SG2	61021
Antiserum Salmonella SG3	61031
Antiserum Salmonella SG4	61041
Antiserum Salmonella SG5	61051
Antiserum Salmonella SG6	61061
Antiserum Salmonella MONOVALENT H:2	61111
Antiserum Salmonella MONOVALENT H:5	61112
Antiserum Salmonella MONOVALENT H:6	61113
Antiserum Salmonella MONOVALENT H:7	61114
Antiserum Salmonella MONOVALENT H:v	61115
Antiserum Salmonella MONOVALENT H:w	61116
Antiserum Salmonella MONOVALENT H:m	61117
Antiserum Salmonella MONOVALENT H:p	61118
Antiserum Salmonella MONOVALENT H:h	61119
Antiserum Salmonella MONOVALENT H:z15	61120
Antiserum Salmonella MONOVALENT H:g,m	61121
Antiserum Salmonella MONOVALENT H:g,p	61122
Antiserum Salmonella MONOVALENT H:x	61123
Antiserum Salmonella POLYVALENT T, A, B, C, Vi	61261

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