


BIO-RAD		GLOBAL FORM		04.01.GLB.FRM.00289	
EU declaration of conformity					
Division/Group: RAQA				Revision: 1en	

see Product list in annex REF see product list in annex BUDI-DI: see product list in annex GMDN code & term: see product list in annex			
 Bio-Rad 3 Boulevard Raymond Poincaré, Marnes-la-Coquette, 92430 France SRN: FR-MF-000006261			
<table border="1" style="display: inline-table;"> <tr> <td>EC</td> <td>REP</td> </tr> </table> : / SRN : /		EC	REP
EC	REP		


We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s) / Directive(s):

- Regulation EU 2017/746 on *in vitro* Diagnostic medical devices

Risk CLASS:

☐ A
 ☐ B
 ☒ C
 ☐ D

CONFORMITY ROUTE

- ☐ ANNEX IX Technical Documentation Examination
 EC CERTIFICATE No.:
 Name of Notified Body :
 Notified Body Identification No.:
 Expiration Date :

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BIO-RAD**GLOBAL FORM****04.01.GLB.FRM.00289****EU declaration of conformity****Division/Group:** RAQA**Revision:** 1en☒ ANNEX IX Quality Management System**EC CERTIFICATE No.: 38909**

Name of Notified Body : GMED

Notified Body Identification No.: 0459

 Expiration Date: April 3, 2027☐ ANNEX II+III**Common Specification (CS) :** /**Date of the first issuance of the EU Declaration of Conformity:** see product list in annex

Signature

Marnes-la-Coquette

Issued in

2024-03-19

Date

Sylvie Fernez

Name

Assoc. Director Regulatory Affairs

Function

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Revision: 1en
Annex - Product list

REF	Product name	BUDI-DI	GMDN code & term:	Date of the first issuance of the EU Declaration of Conformity
61607	Pastorex Meningitis	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61608	Pastorex Meningitis meningitidis A	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61610	Pastorex Meningitis meningitidis C	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61611	Pastorex Meningitis N.meningitidis B/E.coli K1	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61613	Pastorex Meningitis Streptococcus B	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61614	Pastorex Meningitis pneumoniae	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61616	Pastorex Meningitis influenzae b	361052A000157G	50399 Multiple meningitis-associated bacteria antigen IVD, kit, agglutination	April 28, 2022
61618	Pastorex Meningitis Control	361052A000157G	50401 Multiple meningitis-associated bacteria antigen IVD, control	April 28, 2022
62783	Platelia Aspergillus IgG	361052A000197Q	52002 Aspergillus fumigatus Immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	April 28, 2022
62784	Platelia Candida Ag Plus	361052A0002079	52027 Candida species mannan antigen IVD, reagent	April 28, 2022
62785	Platelia Candida Ab Plus	361052A000217B	52039 Multiple Candida species immunoglobulin A (IgA)/IgG/IgM antibody IVD, reagent	April 28, 2022
62786	Platelia Aspergillus IgG-Negative and Positive Controls	361052A000227D	52004 Aspergillus fumigatus immunoglobulin G (IgG) antibody IVD, control	April 28, 2022
62787	Platelia Candida Ab plus - negative and positive controls	361052A000237F	52038 Multiple Candida species immunoglobulin A (IgA)/IgG/IgM antibody IVD, control	April 28, 2022
62794	Platelia Aspergillus Ag	361052A000247H	51988 Multiple Aspergillus species antigen IVD, kit, enzyme immunoassay (EIA)	April 28, 2022
72830	Platelia Dengue NS1 Ag	361052A000447P	48907 Dengue virus antigen IVD, kit, enzyme immunoassay (EIA)	April 28, 2022
3551180	Platelia Rabies II	361052A000477V	50190 Rabies virus envelope glycoprotein neutralizing antibody IVD, kit, enzyme immunoassay (EIA)	April 28, 2022
72840	Platelia Toxo IgG	361052A001537V	52436 Toxoplasma gondii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	September 29, 2023
72841	Platelia Toxo IgM	361052A001547X	52440 Toxoplasma gondii immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	September 29, 2023

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REF	Product name	BUDI-DI	GMDN code & term:	Date of the first issuance of the EU Declaration of Conformity
72842	Platelia Toxo IgG Avidity	361052A001557Z	52436 Toxoplasma gondii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	September 29, 2023
72850	Platelia Rubella IgG	361052A0015683	50265 Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	September 29, 2023
72851	Platelia Rubella IgM	361052A0015785	50268 Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	September 29, 2023

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