

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**SRN:** /

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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ANNEX IX Quality Management System

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

ANNEX II+III

Common Specification (CS) : /

Date of the first issuance of the EU Declaration of Conformity: /



Signature	Marnes-la-Coquette	2022-04-27
Sylvie Fernandez	Issued in	Date
Name	Assoc. Director Regulatory Affairs	Function

Annex- Product list

REF	Product name	BUDI-DI	GMDN code & term:
72240	CONCENTRATED WASHING SOLUTION R2 (10X)	361052A003047S	58207 Buffered wash solution IVD, manual
72700	CONCENTRATED WASHING SOLUTION R2 (20X)	361052A003047S	58207 Buffered wash solution IVD, manual
12017178	Platelia anti-SARS-CoV-2 S IgG Quant Sample Diluent (R7)	361052A002998S	58208 Buffered sample diluent IVD, manual
62739	MYCOPLASMA DUO Suspension medium	361052A000177L	58673 Saline suspension medium/diluent IVD