BIO-RAD	GLOBAL FORM	04.01.GLB.FRM.00289
	EU DECLARATION OF CONFORMITY	
Division/Group: RAQA		Revision: 1

IH-500

REF 001500

BUDI-DI : 361052A002437X

DiaMed GmbH
Pra Rond 23, 1785 Cressier, Switzerland
SRN : CH-MF-000020826

EC REP

Bio-Rad
3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
SRN : FR-AR-000006264

Real Manufacturing Site

Bio-Rad Singapore
1 Kaki Bukit View
#05-01 Techview
415941 Republic of Singapore

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):

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Regulation EU 2017/746 on *in vitro* Diagnostic medical devices

Risk CLASS:

☒ A ☐ B ☐ C ☐ D

CONFORMITY ROUTE

☒ ANNEX I & II+III

Common Specification (CS) : Not Applicable

Digitally signed by Levința Alexandru
Date: 2024.07.29 11:47:24 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Date of the first issuance of the EU Declaration of Conformity: 04-05-2022

Place, Date:	Cressier, 03.10.2023
Signed by:	Jérémy Poropane
Function:	Associate Director, Regulatory Affairs, Bio-Rad CDG
Signature: