BIO-RAD	GLOBAL FORM	04.01.GLB.FRM.00289

EU DECLARATION OF CONFORMITY

Division/Group: RAQA	Revision: 1

CFX Opus 96 Dx, CFX Opus 384 Dx, CFX Opus Deepwell Dx, CFX Maestro Dx SE Software

REF **12014330, 12014335, 12016687, 12014349**

BUDI-DI : 361052A003107M

Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Dr.
Hercules, CA 94547 USA
SRN : US-MF-000020713

EC REP

Bio-Rad
3 Boulevard Raymond Poincaré
92430 Marnes-La-Coquette, France

SRN : FR-AR-000006264

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 8June2011 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 II+III

Date of the first issuance of the EU Declaration of Conformity: 16May2022, current Revision 3

EU DECLARATION OF CONFORMITY

Division/Group: RAQA	Revision: 1

DocuSigned by:
Jackie Buckley
08A07A91ED5848B...

Signature	Issued in	Date
	Hercules, CA	1-20-23

Name	Function
Jackie Buckley	Regulatory Affairs Manager

Product List

REF	Product Name	BUDI-DI	GMDN Code and term	Date of first issuance of Declaration of Conformity
12014330	CFX Opus 96 Dx	361052A003107M	**48031-** Thermal Cycler, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12014335	CFX Opus 384 Dx	361052A003107M	**48031-** Thermal Cycler, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12014349	CFX Maestro Dx SE Software	361052A003107M	**48031-** Thermal Cycler, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12016687	CFX Opus Deepwell Dx	361052A003107M	**48031-** Thermal Cycler, Nucleic Acid Amplification Analyzer IVD, Automated	20 Jan 23