

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



12014330, 12014335, 12016687, 12014349

BUDI-DI: 361052A003107M



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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 II+III

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

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DocuSigned by:

Jackie Buckley

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Signature

Hercules,
CA

1-20-23

Issued in

Date

Jackie Buckley

Name

Regulatory Affairs Manager

Function

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 Cyclers, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12014335	CFX Opus 384 Dx	361052A003107M	48031- Thermal Cyclers, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12014349	CFX Maestro Dx SE Software	361052A003107M	48031- Thermal Cyclers, Nucleic Acid Amplification Analyzer IVD, Automated	16 May 22
12016687	CFX Opus Deepwell Dx	361052A003107M	48031- Thermal Cyclers, Nucleic Acid Amplification Analyzer IVD, Automated	20 Jan 23

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