

EU DECLARATION OF CONFORMITY

Division/Group: RAQA

Revision: 1

CFX96 Deep Well Dx ORM, CFX96 Dx ORM, C1000 Dx Thermal Cycler

**1844095-IVD, 1845097-IVD, 1841000-IVD,**
BUDI-DI : 361052A003107MBio-Rad Laboratories, Inc.
5731 W Las Positas Blvd,
Pleasanton CA 94588 USA

SRN : US-MF-000017515

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 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

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

DocuSigned by:

Jackie Buckley

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Hercules CA

Issued in

3/13/23

Date

Jackie Buckley

Name

Regulatory Affairs Manager

Function

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