

EU DECLARATION OF CONFORMITY

Division/Group: RAQA

Revision: 1

D-10 Hemoglobin Testing System**REF**

D-10 Hemoglobin Testing System, PN 12010405, 220-0220

D-10 Hemoglobin Testing System, PN 12010405RECON, 220-0220RM

D-10 Rack Loader Accessory Box, PN 220-0600

BUDI-DI : 361052A003037Q



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EC**REP**

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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

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EU DECLARATION OF CONFORMITY**Division/Group:** RAQA**Revision:** 1**Date of the first issuance of the EU Declaration of Conformity:** 18May2022; Current revision 3

DocuSigned by:

Jackie Buckley

Signer Name: Jackie Buckley

Signing Reason: I approve this document

Signing Time: 21-Sep-2022 | 5:06:16 PM PDT

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Hercules, CA

21-Sep-2022

Signature

Issued in

Date

Jackie Buckley

Regulatory Affairs Manager

Name

Function

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