BIO-RAD	GLOBAL FORM	04.01.GLB.FRM.00125

EU DECLARATION OF CONFORMITY

Division/Group: RAQA	Revision: 1

MANUFACTURER: Bio-Rad Laboratories, Inc.
ADDRESS: 4000 Alfred Nobel Drive, Hercules, CA 94547, United States

EUROPEAN AUTHORIZED REPRESENTATIVE: Bio-Rad
ADDRESS: 3 Boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France

PRODUCT(S) NAME(S) and CATALOG NUMBER(S):
12000949 – D-10™ Hemoglobin A1c Program
220-0110 – D-10™ Hemoglobin A1c Program Elution Buffer 1
220-0111 – D-10™ Hemoglobin A1c Program Elution Buffer 2
220-0112- D-10™ Wash/Diluent Solution
12005707- D-10™ Hemoglobin A1c Program Analytical Cartridge
12005706 – D-10™ Hemoglobin A1c Program Calibrator/Diluent Set
220-0148- Whole Blood Primer
12002716 – D-10™ Hemoglobin A1c Program Floppy Diskette
12002715 – D-10™ Hemoglobin A1c Program CD-ROM
220-0109 - D-10™Hemoglobin A1c Supplemental Reagent Pack

GENERIC DEVICE GROUP CODE (GMDN nomenclature):
53315, 53316, 53313

GENERIC DEVICE GROUP TERM (GMDN Nomenclature):

Glycated hemoglobin (HbA1c) IVD, Calibrator
Glycated hemoglobin (HbA1c) IVD, reagent
Glycated hemoglobin (HbA1c) IVD kit, liquid chromatography

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives

■ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

CLASSIFICATION:

☐ ANNEX II-A
☐ ANNEX II-B
☐ DEVICE FOR SELF TESTING
☒ OTHER DEVICE

Digitally signed by Levința Alexandru
Date: 2023.12.08 11:42:21 EET
Reason: MoldSign Signature
Location: Moldova

CONFORMITY ROUTE

☒ ANNEX III
☐ ANNEX IV.3 Full Quality System
☐ ANNEX IV.4 Product Design Examination

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
Expiration Date :

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☐ ANNEX V Type Examination

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
Expiration Date:

☐ ANNEX VII Production Quality System

NEW PRODUCT(S) (Notification according to article 10 point 4) ☐ YES ☒ NO

Date of the first issuance of the EU Declaration of Conformity: 07/25/2017, Current revision 5

APPLICABLE HARMONIZED STANDARDS:

ISO 13485:2016, ISO 14971:2012, EN 23640 :2015, EN 13641:2002, EN ISO 17511:2003, EN ISO 18113-2:2011, EN ISO 15223-1:2016, IEC 62366-1: 2015

Jackie Buckley — Signature

Hercules, CA — Issued in

1-28-2019 — Date

Jackie Buckley — Name

RA Manager — Function