| BIO-RAD | GLOBAL FORM | 04.01.GLB.FRM.00125 |
|---|---|---|
| | EU DECLARATION OF CONFORMITY | |
| Division/Group: RAQA | | Revision: 1 |

**MANUFACTURER:** Bio-Rad
**ADDRESS:** 3 Boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France

**EUROPEAN AUTHORIZED REPRESENTATIVE:** /

**PRODUCT(S) NAME(S) and CATALOG NUMBER(S): Geenius™ HIV 1/ 2 Confirmatory Controls, cat# 72329**

**GENERIC DEVICE GROUP CODE** (GMDN nomenclature): **48456**

**GENERIC DEVICE GROUP TERM** (GMDN Nomenclature): **HIV1 / HIV2 antibody IVD, Control**

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

**CONFORMITY ROUTE**

☐ ANNEX III
☒ ANNEX IV.3 Full Quality System — **EC CERTIFICATE No.: 9150**
Name of Notified Body : G-MED
Notified Body Identification No.: 0459
Expiration Date : May 26th, 2025

☒ ANNEX IV.4 Product Design Examination — **EC CERTIFICATE No.: 24928**
Name of Notified Body :G-MED
Notified Body Identification No.: 0459
Expiration Date : May 26th, 2025

☐ ANNEX V Type Examination

☐ 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:** April 4th, 2013

Digitally signed by Levinta Alexandru
Date: 2025.01.03 11:22:40 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Marnes-la-Coquette — Issued in
May 20, 2022 — Date

Signature

Sylvie FERNEZ
Name

Associate Director Regulatory Affairs
Function


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