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 Assay, cat# 72460

GENERIC DEVICE GROUP CODE (GMDN nomenclature): **65847**

GENERIC DEVICE GROUP TERM (GMDN Nomenclature): **HIV1/HIV2 antibody IVD, kit, rapid ICT, clinical**

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.:24927**
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

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

Name	Function
Sylvie FERNEZ	Associate Director Regulatory Affairs

Digitally signed by Levința Alexandru
Date: 2025.01.03 11:24:23 EET
Reason: MoldSign Signature
Location: Moldova
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