

**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  DEVICE FOR SELF TESTING
- ANNEX II-B  OTHER DEVICE

**CONFORMITY ROUTE**

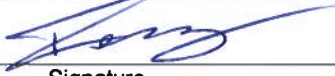
- ANNEX III
- ANNEX IV.3 Full Quality System
- ANNEX IV.4 Product Design Examination
- ANNEX V Type Examination
- ANNEX VII Production Quality System

**EC CERTIFICATE No.: 9150**  
 Name of Notified Body : G-MED  
 Notified Body Identification No.: 0459  
 Expiration Date : May 26<sup>th</sup>, 2025

**EC CERTIFICATE No.: 24928**  
 Name of Notified Body :G-MED  
 Notified Body Identification No.: 0459  
 Expiration Date : May 26<sup>th</sup>, 2025

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

**Date of the first issuance of the EU Declaration of Conformity:** April 4<sup>th</sup>, 2013

 Signature	Marnes-la-Coquette Issued in	May 20, 2022 Date
Sylvie FERNEZ Name	Associate Director Regulatory Affairs Function	