

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

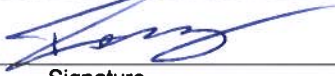
EC CERTIFICATE No.: 9150
 Name of Notified Body : G-MED
 Notified Body Identification No.: 0459
 Expiration Date : May 26th, 2025

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

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