

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☒ 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 26th, 2025

EC CERTIFICATE No.: 24928

Name of Notified Body : G-MED

Notified Body Identification No.: 0459

Expiration Date : May 26th, 2025

NEW PRODUCT(S) (Notification according to article 10 point 4)

☐ YES☒ NODate of the first issuance of the EU Declaration of Conformity: April 4th, 2013

Signature

Sylvie FERNEZ

Name

Marnes-la-Coquette

Issued in

May 20, 2022

Date

Associate Director Regulatory Affairs

Function

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