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): Genie™ Fast HIV 1/2 , cat # 72327-72330-72347

GENERIC DEVICE GROUP CODE (GMDN nomenclature):
48454

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

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 — **EC CERTIFICATE No.: 20857**
Name of Notified Body : GMED
Notified Body Identification No.: 0459
Expiration Date: 26/05/2025
☒ ANNEX VII Production Quality System — **EC CERTIFICATE No.:8323**
Name of Notified Body : GMED
Notified Body Identification No.: 0459
Expiration Date : 26/05/2025

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

Date of the first issuance of the EU Declaration of Conformity: 08-2018 (cat # 72347) and 03-2011 (cat # 72327-72330

Signature	Marnes-La-Coquette,	May, 24th ,2022
	Issued in	Date
S.Fernez	Assoc. Dir. Regulatory Affairs	
Name	Function	

Digitally
Date: 20
Reason:
Location