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): Genscreen™ Ultra HIV Ag-Ab – cat# 72386-72388

GENERIC DEVICE GROUP CODE (GMDN nomenclature): 48445

GENERIC DEVICE GROUP TERM (GMDN Nomenclature): HIV1/HIV2 antigen/antibody, kit, enzyme immunoassay (EIA)

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directive

■ 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 : **GMED**
Notified Body Identification No.: 0459
Expiration Date: May 26th, 2025

☒ ANNEX IV.4 Product Design Examination — **EC CERTIFICATE No.: 8977**
Name of Notified Body : **GMED**
Notified Body Identification No.: 0459
Expiration Date : May 26th 2024

☐ 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: July 22, 2004

Digitally sign
Date: 2023.05
Reason: Mold
Location: Mo

Signature	Issued in	Date
	Marnes-la-Coquette	May 23, 2022

Name	Function
Sylvie Fernez	Associate Director Regulatory Affairs