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: /
ADDRESS:

PRODUCT(S) NAME(S) and CATALOG NUMBER(S): MONOLISA™ HBs Ag ULTRA Confirmatory, cat# 72408

GENERIC DEVICE GROUP CODE (GMDN nomenclature): **48319**

GENERIC DEVICE GROUP TERM (GMDN Nomenclature): **Hepatitis B virus surface antigen IVD 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.: 9927**
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: August, 20th ,2006

Signature	Marnes-la-coquette	May 23, 2022
	Issued in	Date
Sylvie FERNEZ	Associate Director Regulatory Affairs	
Name	Function	

Digitally signed by Levința Alexandru
Date: 2022.05.23 20:42:24 EEST
Reason: MoldSign Signature
Location: Moldova