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 – 72346/72348

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.: 9003
Name of Notified Body: GMED
Notified Body Identification No.: 0459
Expiration Date: June, 29th 2025

Digitally signed by Alexandru
Date: 2022.07.18 10:18:43 EEST
Reason: MoldSign Signature
Location: Moldova

☐ 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 7, 2003

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