Bio-Rad Laboratories

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate)
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	Bio-Rad
Manufacturer address and contact details	3 Boulevard Raymond Poincaré 92430 Marnes-la-Coquette
Single Registration Number (SRN)	FR-MF-00006261

Notified body name	GMED
Notified body number	0459
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificates prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	31 December 2027

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificates** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met
- the **devices** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed in the attached schedule

Digitally signed by Levința Alexandru
Date: 2025.09.10 08:58:57 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

- Directive Certificates covering the devices listed in the attached schedule were issued after 25 May 2017, were valid on 26 May 2022 and have not been withdrawn afterwards.

  Original expiry date *before 9 July 2024*:

  Before the original date of expiry as indicated on the Directive Certificates, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessments in respect of the devices covered by the expired certificates

  Original expiry date *after 9 July 2024*:

  Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment have been lodged by us to a notified body for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR.

➢ **Quality Management System (QMS)**

QMS in accordance with Article 10(8) IVDR is in place.

Notified body has issued the certificates 38909 and 38917 for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule**

- The devices continue to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Marnes-la-Coquette, 2025-01-06

Signed by:
Sylvie Fernez
6D105B9DEAB04A6...

Sylvie Fernez,

Associate Director Regulatory Affairs

Bio-Rad

Bio-Rad Laboratories

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Notified Body that issued the Directive certificates and where the IVDR application was lodged is GMED 0459

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)
NEW LAV BLOT I Cat# 72251	2027-12-31	8306 - rev.5 8323 - rev.14	2023-07-08 2025-05-26
NEW LAV BLOT II Cat# 72252	2027-12-31	8974 - rev.5 8323 - rev.14	2023-07-08 2025-05-26
Monolisa anti-HBc Plus Cat# 72315-72316	2027-12-31	8998 - rev.9 9150 - rev.15	2023-06-15 2025-05-26
Monolisa Anti-HCV PLUS Version 3 Cat# 72340-72341	2027-12-31	26475 - rev.2 9150 - rev.15	2023-11-26 2025-05-26
Monolisa HBs Ag ULTRA Cat# 72346-72348	2027-12-31	9003 - rev.7 9150 - rev.15	2023-06-29 2025-05-26
Genscreen ULTRA HIV Ag-Ab Cat# 72386-72388	2027-12-31	8977 - rev.6 9150 - rev.15	2024-05-26 2025-05-26
Monolisa HBs Ag ULTRA Confirmatory Cat# 72408	2027-12-31	9927 - rev.5 9150 - rev.15	2024-05-26 2025-05-26
Monolisa HCV Ag-Ab ULTRA V2 Cat# 72561-72562	2027-12-31	26307 - rev.4 9150 - rev.15	2023-10-24 2025-05-26
Monolisa Anti-HBs PLUS Cat# 72566	2027-12-31	9330 - rev.6 9150 - rev.15	2024-05-26 2025-05-26

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

Bio-Rad
SAS au capital de 254 968 187 Euros, 789 947 322 RCS Nanterre - N° TVA Intracommunautaire FR 58 789947322 - Siret 789 947 322 00010

Bio-Rad Laboratories

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)
Geenius™ HCV Supplemental Assay Cat# 92501	2027-12-31	35247 - rev.4 9150 - rev.15	2024-02-19 2025-05-26
Geenius™ HCV Supplemental Controls Cat# 92502	2027-12-31	35246 - rev.2 9150 - rev.15	2024-02-19 2025-05-26
Genie™ Fast HIV 1/2 Cat# 72327-72330	2027-12-31	20857 - rev.3 8323 - rev.14	2025-05-26 2025-05-26
Geenius™ HIV 1/2 Confirmatory Controls Cat# 72329	2027-12-31	24928 - rev.5 9150 - rev.15	2025-05-26 2025-05-26
Geenius™ HIV 1/2 Confirmatory Assay Cat# 72460	2027-12-31	24927 - rev.7 9150 - rev.15	2025-05-26 2025-05-26
Access HCV Ab V3 Cat# B33458 Access HCV Ab V3 Calibrators Cat# B33459 Access HCV Ab V3 QC Cat# B33460	2027-12-31	30701 - rev.2 9150 - rev.15	2025-05-26 2025-05-26
Access HIV combo V2 Cat# C28430 Access HIV combo V2 Calibrators	2027-12-31	38149 - rev.3 9150 - rev.15	2025-05-26 2025-05-26

Bio-Rad
SAS au capital de 254 968 187 Euros, 789 947 322 RCS Nanterre - N° TVA Intracommunautaire FR 58 789947322 - Siret 789 947 322 00010

Bio-Rad Laboratories

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)
Cat# C28431 Access HIV combo V2 QC Cat# C28432 Access HIV combo V2 QC plus Cat# C43576			

Bio-Rad
SAS au capital de 254 968 187 Euros, 789 947 322 RCS Nanterre - N° TVA Intracommunautaire FR 58 789947322 - Siret 789 947 322 00010