EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1037243-1

Manufacturer: Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Germany

Products:
- HLA SSP Kits
- Anti-Humanglobulin reagents
- Anti-Kidd reagents (monoclonal, polyclonal)
- Anti-Duffy reagents
- Solidscreen II reagents
- Seraclone® ABO reagents
- Seraclone® Control ABO + Rh
- Seraclone® and Seraclone®(2) Anti-C, -c, -E, -e
- Seraclone® Anti-CDE
- Seraclone® Anti-D
- Seraclone® Anti-K
- Erytype, Erytype S

Digitally signed by Levinţa Alexandru
Date: 2023.07.14 10:40:14 EEST
Reason: MoldSign Signature
Location: Moldova

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1109157-10

Effective date: 2021-12-14

Expiry date: 2025-05-26

Issue date: 2022-03-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1037243-1

Manufacturer: Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Germany

- Biotestcell®, Erytypecell, Control Set E, Coombscell-E
- Coombszym K
- AB-Serum
- Control Set S

Report No.: 1109157-10

Effective date: 2021-12-14

Expiry date: 2025-05-26

Issue date: 2022-03-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1037243-1

Manufacturer: Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Bio-Rad Medical Diagnostics GmbH Industriestr. 1 63303 Dreieich Germany	Management, Design and Development
/02	Bio-Rad Medical Diagnostics GmbH Industriestr. 4 63303 Dreieich Germany	Manufacture
/03	Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 1 63303 Dreieich Germany	Warehousing and Logistics

DIALAB SOLUTIONS 2 S.R.L.

Report No.: 1109157-10

Effective date: 2021-12-14

Expiry date: 2025-05-26

Issue date: 2022-03-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.