ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 118577 0002 Rev. 03

Manufacturer:

Bio-Rad Medical Diagnostics GmbH
Industriestraße 1
63303 Dreieich
GERMANY

SRN Manufacturer - DE-MF-000019864

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.
All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:V10 118577 0002 Rev. 03

Report No.: 713336068_CN

Preceding Certificate No.: V10 118577 0002 Rev. 02

Valid from: 2024-10-01
Valid until: 2027-03-08

Date of Initial Issuance: 2023-07-12

Marta Carnielli
Head of Certification IVD

Issue date: 2024-09-24

Digitally signed by Levința Alexandru
Date: 2026.03.23 10:54:52 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Classification:	Class D
Device Group:	W010303 - IMMUNOHAEMATOLOGY (BLOOD GROUPING)
Intended Purpose:	IVR 0101 - Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]

Classification:	Class D
Device Group:	W010303 - IMMUNOHAEMATOLOGY (BLOOD GROUPING)
Intended Purpose:	IVR 0102 - Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]

Classification:	Class D
Device Group:	W010303 - IMMUNOHAEMATOLOGY (BLOOD GROUPING)
Intended Purpose:	IVR 0103 - Devices intended to determine markers of the Kell system [Kel1 (K)]

Classification:	Class D
Device Group:	W010303 - IMMUNOHAEMATOLOGY (BLOOD GROUPING)
Intended Purpose:	IVR 0104 - Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]

Classification:	Class D
Device Group:	W010303 - IMMUNOHAEMATOLOGY (BLOOD GROUPING)
Intended Purpose:	IVR 0105 - Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-07-12	713277223	Initial issuance
01	2023-12-22	713302946-01	Supplemented: Device(s)/group of device(s) added
02	2024-03-19	713319259-01	Supplemented: Device(s)/group of device(s) added
03	2024-10-01	713336068_CN	Supplemented: Device(s)/group of device(s) added

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