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

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II (Class D Devices)

No. V70 118577 0015 Rev. 00

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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation 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 and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:V70 118577 0015 Rev. 00

Report No.: 713335771

Valid from: 2024-11-25
Valid until: 2029-11-24

Marta Carnielli
Head of Certification IVD

Issue date: 2024-11-25

Digitally signed by Levinţa Alexandru
Date: 2025.07.21 12:12:45 EEST
Reason: MoldSign Signature
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Annex IX, Chapter II (Class D Devices)

No. V70 118577 0015 Rev. 00

Classification:	Class D
Device Group:	W0103030302 - ANTIBODY 2 CELL SCREENING
Basic UDI-DI:	361052A0044083
Intended Purpose:	Biotestcell-P1, -P2 are Reagent Red Blood Cells intended to be used for the qualitative detection of unexpected human red cell antibodies in donor and patient (recipient) plasma/serum in the manual tube method. Whole blood collected in EDTA, citrate or without anticoagulant may be used. For in vitro diagnostic use, by trained laboratory personnel.
Device(s):	Biotestcell-P1, -P2 REF ID: 816012
Classification:	Class D
Device Group:	W0103030308 - ANTIBODY 3 CELL SCREENING
Basic UDI-DI:	361052A004398J
Intended Purpose:	Biotestcell-P3 are Reagent Red Blood Cells intended to be used for the qualitative detection of unexpected human red cell antibodies in donor and patient (recipient) plasma/serum in the manual tube method. Whole blood collected in EDTA, citrate or without anticoagulant may be used. For in vitro diagnostic use, by trained laboratory personnel.
Device(s):	Biotestcell-P3 REF ID: 816017
Classification:	Class D
Device Group:	W0103030303 - ANTIBODY IDENTIFICATION CELL PANELS
Basic UDI-DI:	361052A0044185
Intended Purpose:	Biotestcell-I8 are Reagent Red Blood Cells intended to be used for the qualitative identification of unexpected human red cell antibodies in donor and patient (recipient) plasma/serum in the manual tube method. Whole blood collected in EDTA, citrate or without anticoagulant may be used. For in vitro diagnostic use, by trained laboratory personnel.
Device(s):	Biotestcell-I8 REF ID: 816020

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Annex IX, Chapter II (Class D Devices)

No. V70 118577 0015 Rev. 00

Classification:	Class D
Device Group:	W0103030303 - ANTIBODY IDENTIFICATION CELL PANELS
Basic UDI-DI:	361052A0044287
Intended Purpose:	Biotestcell-I11 are Reagent Red Blood Cells intended to be used for the qualitative identification of unexpected human red cell antibodies in donor and patient (recipient) plasma/serum in the manual tube method. Whole blood collected in EDTA, citrate or without anticoagulant may be used. For in vitro diagnostic use, by trained laboratory personnel.
Device(s):	Biotestcell-I11 REF ID: 816021
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The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-11-25	713335771	Initial issuance

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