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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 0013 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 0013 Rev. 00

**Report No.:** 713335766

**Valid from:** 2024-09-20
**Valid until:** 2029-09-19

Marta Carnielli
Head of Certification IVD

**Issue date:** 2024-09-20

Digitally signed by Levinţa Alexandru
Date: 2025.10.20 13:50:54 EEST
Reason: MoldSign Signature
Location: Moldova
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| | |
|---|---|
| **Classification:** | Class D |
| **Device Group:** | W0103030401 - COOMBS CONTROL CELLS |
| **Basic UDI-DI:** | 361052A004448B |
| **Intended Purpose:** | Coombscell-E is a positive qualitative control, intended to control the reactivity of anti-human globulin reagents used in the Indirect and Direct Antiglobulin Test (IAT, DAT) as part of immunohematology testing in the manual tube method.<br>For in vitro diagnostic use, by trained laboratory personnel. |
| **Device(s):** | Coombscell-E<br>REF ID: 816030 |

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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 | 2024-09-20 | 713335766 | Initial issuance |


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany