



Add value.
Inspire trust.

Verification Report

according to Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices – Annex IX, sec. 4.12 or Annex XI sec. 5

No. BRM-816030 25 05 072791

Manufacturer: **Bio-Rad Medical Diagnostics GmbH**
Industriestraße 1
63303 Dreieich

Product: **Coombscell-E**

Testplan: **TP-BRM-816030**

Batch: **3520021-00 (REF 816030)**

Basic UDI-DI: **361052A004448B**

Expiry Date: **2025-07-14**

The above mentioned batch meets the batch release criteria established during technical documentation assessment and may be placed on the market. The EU Technical Documentation Assessment Certificate (IVDR) issued for this product is V70 118577 0013 Rev. 00.

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAATJJJoz_-zdl7r-UYKGgWwLZKH7pXsiBnz

Date, 2025-05-22

pp Dr. Jürgen Püls
In-vitro Diagnostics

TÜV SÜD Product Service GmbH is Notified Body according to Council Vitro Diagnostic Regulation 2017/746 concerning In-vitro Diagnostic Medical Devices with Identification No. 0123.

To:

Bio-Rad Medical Diagnostics GmbH

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
In-vitro Diagnostics
Ridlerstrasse 65
80339 Munich
Germany

tuvsud.com/ps
Phone: +49 89 50084-483
Fax: +49 89 50084-475

TUV®