Document Number: BR-DOC-03887 version: 2.0
CE_IVDR_DoC_Coombscell-E_version 1

EU DECLARATION OF CONFORMITY

Coombscell-E

REF 816030

BUDI-DI: 361052A004448B

Bio-Rad Medical Diagnostics GmbH
Industriestraße 1, 63303 Dreieich, Germany
SRN: DE-MF-000019864

Digitally signed by Levinţa Alexandru
Date: 2025.10.20 13:50:45 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s) / Directive(s):

■ Regulation EU 2017/746 on *in vitro* Diagnostic medical devices

Risk CLASS:

☐ A ☐ B ☐ C ☒ D

CONFORMITY ROUTE

☒ ANNEX IX Technical File Examination

EC CERTIFICATE No.: V70 118577 0013
Name of Notified Body: TÜV Süd Product Service GmbH
Address of Notified Body:
Ridlerstraße 65
80339 Munich
Germany

Notified Body Identification No.: 0123

Expiration Date: 2029-09-19

Document Number: BR-DOC-03887 version: 2.0
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☒ ANNEX IX Full Quality System

EC CERTIFICATE No.: V10 118577 0002
Name of Notified Body: TÜV Süd Product Service GmbH
Address of Notified Body:
Ridlerstraße 65
80339 Munich
Germany

Notified Body Identification No.: 0123
Expiration Date: 2027-03-08

Common Specification (CS): Not Applicable

Date of the first issuance of the EU Declaration of Conformity: 2024-10-22

Place, Date	Dreieich, 2024-10-22
Signed by	Marc Gorzellik
Function	Associate Director, Product Quality Assurance
Signature	Signiert von: Marc Gorzellik Name des Unterzeichners: Marc Gorzellik Signiergrund: Ich genehmige dieses Dokument Signierzeit: 22-Okt-2024 | 10:52:58 PM CST 00CF62D143614096B5743DE3F0AC1B73