



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

**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  
CE\_IVDR\_DoC\_Coombscell-E\_version 1

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	<p>Signiert von: <i>Marc Gorzellik</i></p> <p> Name des Unterzeichners: Marc Gorzellik Signiergrund: Ich genehmige dieses Dokument Signierzeit: 22-Okt-2024   10:52:58 PM CST 00CF62D143614096B5743DE3F0AC1B73</p>