



Document Number: BR-DOC-03887 version: 2.0  
CE\_IVDR\_DoC\_Biotestcell-P1,-P2, Biotestcell-P3, Biotestcell-I8, Biotestcell-11\_version 1

## EU DECLARATION OF CONFORMITY

### Biotestcell-P1, -P2



816012

BUDI-DI: 361052A0044083

### Biotestcell-P3



816017

BUDI-DI: 361052A004398J

### Biotestcell-I8



816020

BUDI-DI: 361052A0044185

### Biotestcell-I11



816021

BUDI-DI: 361052A0044287



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):



Document Number: BR-DOC-03887 version: 2.0

**CE\_IVDR\_DoC\_Biotestcell-P1,-P2, Biotestcell-P3, Biotestcell-I8, Biotestcell-11\_version 1**

- 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 0015  
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: 2029-11-24

- 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:** 2025-01-28

Place, Date	Dreieich, 2025-01-28
Signed by	Marc Gorzelli
Function	Associate Director, Product Quality Assurance
Signature	<p>Signiert von: <i>Marc Gorzelli</i></p> <p> Name des Unterzeichners: Marc Gorzelli Signiergrund: Ich genehmige dieses Dokument Signierzeit: 29-Jan-2025   3:01:27 PM CST 00CF62D143614096B5743DE3F0AC1B73</p>