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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-816017 25 05 072788

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

Product: **Biotestcell-P3**

Testplan: **TP-BRM-816017**

Batch: **3520021-00 (REF 816017)**

Basic UDI-DI: **361052A004398J**

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 0015 Rev. 00.

Date, 2025-05-22

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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

cc: