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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-816040 25 03 071978

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

**Product:** **Coombszym-K**

**Testplan:** **TP-BRM-816040**

**Batch:** **3509090-00**

**Basic UDI-DI:** **361052A004458D**

**Expiry Date:** **2026-02-22**

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 0014 Rev. 00.

This verification report is valid for REF 816040 (1 x 10ml).

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAZpTUZikZ7GyDFioJtdpK7b29kd-Mlq57

**Date,** 2025-03-27

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

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