



Add value.  
Inspire trust.

## 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-801345 24 10 069945

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

**Product:** **Seraclone Anti-B (ABO2)**

**Testplan:** TP-BRM-801345

**Batch:** 3435013-00

**Basic UDI-DI:** 361052A003838G

**Expiry Date:** 2026-08-18

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 0009 Rev. 00.

This verification report is valid for REF 801345 (1 x 10ml) and REF 801350 (10 x 10ml).

**Date,** 2024-10-18

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAAHDSL0sWh0tTYCbsSvNlvOgOQoEq7m4fm

pp Dr. Carsten Krumbholz  
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:

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
VAT ID No. DE129484267  
Information pursuant to § 2 [1] DL-InfoV  
(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
In-vitro Diagnostics  
Ridlerstrasse 65  
80339 Munich  
Germany

**tuvsud.com/ps**  
Phone: +49 89 50084-483  
Fax: +49 89 50084-475

**TUV®**