



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-802080 25 01 071189

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

Product: **Seraclone anti-CDE (RH2,1,3)**

Testplan: **TP-BRM-802080**

Batch: **3434098-00**

Basic UDI-DI: **361052A003998X**

Expiry Date: **2026-01-31**

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 0005 Rev. 00.

This verification report is valid for REF 802080 (1 x 10ml).

Date, 2025-01-31

Ilja Ovsiy

Adobe Acrobat Sign-Transaktionsnummer: CBJCHBCAABAALVL0x-HApHWPWcYmoxSqeyYYyZn1u0mv

pp Dr. Ilja Ovsiy
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

