

# Confirmation of Verification of Manufactured Products

**REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices  
Annex IX Chapter II, Section 4.12.**

Registration No.: UX 60173466-0001

Report No.: DE23UWMX-001

Manufacturer: Bio-Rad Medical Diagnostics GmbH  
Industriestr. 1  
63303 Dreieich

EUDAMED Single  
Registration No.: DE-MF-000019864

Product name: Seraclone Anti-K (KEL1)

Reference No.: 808090

Basic UDI-DI: 361052A003077Y

Batch No.: 3340041-00

The notified body hereby declares that a verification relating to the listed device has been performed according to REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapter II, Section 4.12. and that the device conforms to the requirements of the abovementioned section of the REGULATION (EU) 2017/746.

Issue date: 2023-11-09

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.



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