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 60173466-0002
Report No.:	DE23UWMX-002
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.:	3403010-00

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.

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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.