TO WHOM IT MAY CONCERN

Certificate of Sterility

Nerbe Plus GmbH & Co. KG hereby certifies that the product described below has been manufactured in accordance with established manufacturing guidelines and product specifications as well as DIN EN ISO 13485. The product conforms to all quality requirements and is certified to be RNase, DNase, and endotoxin (pyrogen) safe, and sterile. The sterilization process is validated and nerbe plus certifies sterile products to have a sterility assurance level of 10 –6

Product	Lot Number Expiry Date	Laboratory Test Type	Specification
12-441-9105 Serological pipette PS, 5ml, single peel-pack, transparent, color code: blue, grad., np pcr ready, sterile R	A20210618B	ENDOTOXIN via LAL	Levels < 0,06 EU/ml
		DNase via electrophoretic detection	<10-7 Kunitz U/µL
		RNase via electrophoretic detection	<10-7 Kunitz U/µL
	2026-06	NUCLEIC ACIDS via electrophoretic detection	No amplicons detected

RNase/DNase Testing Protocol: Extractions from product sample were incubated with RNA and DNA standards for one hour at 37°C. Samples were then loaded onto a 1% agarose gel, along with positive and negative controls. Results were analysed and documented.

Endotoxin (pyrogen) Testing Protocol: In accordance with FDA and USP guidelines, samples were extracted for one hour at 37°C with pyrogen-free water. The sample extraction was evaluated against a control standard series (CSE) and a negative control using the kinetic turbidometric LAL assay. Current USFDA guidelines for End-Product Testing requires that medical device eluates not exceed 0,5 EU/ml, while devices coming into contact with cerebrospinal fluid not exceed 0,06EU/ml. Though nerbe's products are not classed as medical devices, certification criteria will require that products demonstrate less than 0,06 EU/ml. Test sample extraction had an undetectable level of endotoxin at <0,06 EU/ml

Nerbe Plus GmbH & Co. KG warrants and represents that all inspections and testing for the article described above have been performed at a microbiology laboratory located on-site at the manufacturing plant.
Both, Nerbe Plus and the purchaser acknowledge that for medical items labeled as sterile, product sterility is assured provided that the packaging in which the product is contained is intact and not open or damaged.

nerbe plus GmbH & Co. KG
23. November 2021
This certificate was created digitally and is valid without a signature /
Dieses Zertifikat wurde digital erstellt und ist ohne Unterschrift gültig
Christian Lambeck
Manager Quality Control

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