

Certificate of Quality

REF

187262

LOT

18490132

Product description: TUBE, 14 ML, PP, 18/95 MM, ROUND BOTTOM,
TWO-POSITION VENT STOPPER, NATURAL,
GRADUATION, WRITING AREA, STERILE, 25 PCS./BAG

Following inspections were carried out and passed:

raw material	☒	passed
visual	☒	passed
physical	☒	passed

Free of detectable DNase/RNase/human DNA
Representative product was tested by Real-Time-PCR.

Detection limits:

DNase 1.3×10^{-8} Kunitz units
RNase 5.0×10^{-11} Kunitz units
hDNA 5 pg

Free of detectable endotoxins (pyrogens)
Representative product was tested according to the United States Pharmacopoeia (USP) Chapter <85>
Detection limit: 0.03 EU/ml

We hereby certify that our products were manufactured and tested in accordance with the following international standards and meet the required specifications:

ISO 11137 "Sterilization of health care products - Radiation"

We are certified according to the Quality System Standard ISO 9001 and ISO 13485.



2023-12-01

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This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.



Certificate creation date: 2018-12-13

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