SARTORIUS

CERTIFICATE OF RELEASE

Product Description:

Product description:	Filter Tip: 5-300 µL		
Reference:	790301F		
Batch number:	502381353	Quantity:	
Expiry date:	2031 - 04	Revision level:	

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Specifications:

The product is certified to be DNase, RNase, endotoxin and human DNA free and is tested by an independent laboratory.

STATEMENTS

Endotoxins:	Sample preparation was carried out according to FDA guidelines for medical devices by extracting the pipette tips cut into pieces for 1 hour at 37°C with an optimized volume of pyrogen-free water. Endotoxins in the extractions were detected with Chromogenic kinetic method according to Ph.Eur. 2.6.14, Method D, which is based on development of colour after cleavage of a synthetic peptide-chromogen complex. Validated test result for endotoxin-free pipette tips is <0.005 IU/ml (EU/ml).
RNase:	The tips were pipetted up and down in an optimized volume of pure water using maximal pipette tip capacity. RNase activity in the extraction was measured with fluorometric assay by detecting degradation of labelled RNase substrate. RNase-free pipette tips show no evidence of RNase activity in the assay with the detection level of $<10^{-8}$ U/µl when RNase A was used as a standard.
DNase:	The tips were pipetted up and down in an optimized volume of pure water using maximal pipette tip capacity. DNase activity in the extraction was measured with fluorometric assay by detecting degradation of labelled DNase substrate. DNase-free pipette tips show no evidence of DNase activity in the assay with the detection level of $<6{,}25*10^{-5}$ U/µl when DNase I was used as a standard.
Human DNA:	The tips were pipetted up and down in an optimized volume of pure water using maximal pipette tip capacity. The sample, positive and negative controls and a dilution series of stock DNA were analyzed in quantitative PCR (qPCR) using human DNA specific primers. The analysis shows no evidence of human DNA in the assay with the detection level of <1 pg/µl.

The sterilization process is electron beam (beta irradiation) in accordance with ISO 11137 and is validated by using 20 kGy as the minimum dose with SAL (sterility assurance level) of 10^{-6}.

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This is to certify that the product described has been manufactured in accordance with ISO 9001:2015, Certificate No. FI17/5101 and ISO 13485:2016, Certificate No. FI17/5103 quality management protocols and has passed all relevant Quality Assurance procedures related to this product.

The expiry date of the product is 5 years from the manufacturing date and is stated on the product label of the packaging.

2026-06-02

Date of Release

This is an electronic document and valid without signature

Manufactured by
Sartorius Liquid Handling oy

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