D03818-T01

Certificate of Quality

for

Filter Tip:	**2 – 120 µl**
Cat. Number:	**790101F**
Lot. Number:	**PR121438**
Expiry Date:	**2019 – 12**
Manufacturing Date:	**4.12.2014**

This is to certify that the product described above has been manufactured in accordance with ISO 9001/ISO 13485 quality management protocols (certificate no. 108129-2011-AQ-FIN-FINAS) and has passed all relevant Quality Assurance procedures related to this product.

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

The sterilization process is electron beam (beta irradiation) in accordance with EN 552 and ISO 11137 and is validated by using 25 kGy as the minimum dose with SAL (sterility assurance level) of 10^{-6}.

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

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 LAL gel clot method according to Ph. Eur.5, 2.6.14, Method A, which is based on clotting of the Limulus amoebocyte lysate in the presence of bacterial endotoxins. Validated test result for Endotoxin-free pipette tips is < 0.03 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 $<3{,}125*10^{-9}$ 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.

12.01.2015

Seppo Riikonen

Director, Quality & Process Development