# Sterilization and Purity Certificate – Qualitix® pipette tips

Socorex<sup>®</sup> certifies that pipette tip products are free of detectable DNase, RNase, Pyrogen (Endotoxins) and ATP. Filter tip products are additionally certified as free of detectable human DNA and protease. Quality controls performed on each lot by independent laboratories according to procedures below. Sterile products have a Sterility Assurance Level (SAL) of 10<sup>-6</sup> using a continuously audited process.

## **Sterility SAL (sterility assurance level)**: 10<sup>-6</sup>

#### Sterilization ref:

Ph. Eur. (European Pharmocopeia) and USP (United States Pharmacopeia)

# USP <71> Sterility Tests

Sterility test ref:

Method:

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ISO 11137 Sterilization of Health Care Products- Radiation

# Method:

Products are irradiated with a dose range of 12-35kGy. Validation: Quarterly bioburden and sterility audits

Minimum 100 samples,14 days incubation at 28-32°C **Validation:** No growth detected

Deoxyribonuclease (	<b>DNase) &lt;</b> 10 <sup>-1</sup>	'Kunitz Units
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Test ref:	Labcon, Laboratory SOP 09-0	)004 v8, 2017
Method:	Incubation on agarose gel of [ product.	DNA molecular scale. Test performed on DNase-free water exposed to
	<ol> <li>Product from tested lot</li> <li>Negative control</li> </ol>	<ul> <li>2) Product plus 10<sup>-7</sup> K Unit of DNase</li> <li>4) Positive control</li> </ul>
Validation:	No degradation on agarose ge in samples 2) and 4)	el of the DNA molecular scale in samples 1) and 3), degradation

## **Ribonuclease (RNase)** < 10<sup>-9</sup> Kunitz Units

Test ref:	Labcon, Laboratory SOP 09-0	Labcon, Laboratory SOP 09-0003 v9, 2017	
Method:	Incubation on agarose gel of RNA molecular scale. Test performed on RNase-free water exposed product.		
	<ol> <li>Product from tested lot</li> <li>Negative control</li> </ol>	<ul> <li>2) Product plus 10<sup>-9</sup> K Unit of RNase</li> <li>4) Positive control</li> </ul>	
Validation:	No degradation on agarose gel of RNA molecular scale in samples 1) and 3), degradation in samples 2) and 4)		

<b>Pyrogen (endotoxins)</b> < 0.005 IU or EU/mL, < 0.5 IU or EU/ item tested		
Test ref:	LAL turbidometric method, Europear and United States Pharmacopeia 40	n Pharmacopeia 9th edition (2017), NF 35 (2017), chapter 85
Method:	Preparation of a standard curve from 5 IU (or EU/mL) to 5 10 <sup>-2</sup> IU (or EU/mL). Bacterial endotoxin rates determined using plate reader measurements at 405 nm. Test performed on Pyrogen-free water exposed to product.	
	1) Product from tested lot2)3) Negative control	Product plus 0.5 IU (or EU/mL) of endotoxin
Validation:	Less than 0.05EU in sample 1) and	3), detection in sample 2)



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Adenosine T	riphosphate (ATP) < 2X10 <sup>-12</sup> mg/ul	
Test ref:	Labcon, Laboratory SOP 09-0028 v2, 2017	
Method:	Detection of surface ATP using the 3M Clean-Trace NG Luminometer and ATP Clean-Trace Swabs. Test performed on swab that has contacted surface of product.	
	<ol> <li>Product from tested lot</li> <li>Product plus 2X10<sup>-12</sup> mg/ul of ATP</li> <li>Negative control</li> </ol>	
Validation:	Relative light units (RLU) results indicating less than 2X10 <sup>-12</sup> mg/ul of surface ATP.	
Human Deox	yribonucleic Acid (DNA) < 1 pg (filter tips only)	
Test ref:	Labcon, Laboratory SOP 09-0017 v7, 2017	
Method:	Amplification by PCR of "Alu" genomic area in human DNA. Migration of PCR product on agarose gel. Test performed on DNA-free water exposed to product.	
	1) Product from tested lot2) Product plus 1 pg of Human DNA,3) Negative control4) Positive control	
Validation:	No DNA amplification in samples 1) and 3) compared to amplification in samples 2) and 4)	
Protease < 2	ng protease activity (filter tips only)	
Test ref:	Labcon, Laboratory SOP 09-0019 v7, 2017	
Method:	Incubation on polyacrylamide gel of protein molecular scale. Test performed on protease-free water exposed to product.	
	1) Product from tested lot2) Product plus 2ng/ul Proteinase K3) Negative control4) Positive control	
Validation:	No degradation on polyacrylamide gel of protein molecular scale in samples 1) and 3), degradation in samples 2) and 4)	

LOT SPECIFIC CERTIFICATE AVAILABLE FROM SOCOREX@SOCOREX.COM



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Ecublens, March 2017