

# Sterilization and Purity Certificate

Socorex® certifies that Ecostep *bioproof*™ syringes, intended for use with the Stepper™ 411 repeater pipette are sterilized and free of detectable human DNA, DNase, RNase and Pyrogen (endotoxins). Quality controls performed on each lot by independent laboratories according to procedures below.

## Sterility SAL (sterility assurance level): $10^{-6}$

**Sterilization ref:**  
CSSR S.A. SOP ref 7.5.1-13, page 1

**Method:**  
Gas mixture 90% EtO, 10% CO<sub>2</sub>, initial vacuum 50 mbar, temperature 50°C, rel. humidity 55%. Theoretical calculated gas concentration 772 mg EtO / L, exposure time 4h, 5 rinsing steps.

**Sterility test ref:**  
CSSR S.A. SOP 7.5.1-30, ISO 11138-1 and -2

**Method:**  
Minimum 22 self-contained biological indicators *Bacillus Atropheus* (*Subtilis* var. *niger*), ATCC No 9372 at  $10^8$  concentration, 2 days incubation at 37°C

**Validation:** No growth detected

## Human Deoxyribonucleic Acid (DNA) < 2 pg

**Test ref:** Scitec Research S.A., SOP ref. SAM5003 v1, 2014-01

**Method:** Amplification by PCR of "Alu" genomic area in human DNA. Migration of PCR product on agarose gel. Test performed on Ecostep™ syringes rinsed with DNA-free water.

- 1) Syringe from tested lot
- 2) Syringe added with 1 pg of Human DNA,
- 3) Negative control
- 4) Positive control

**Validation:** No DNA amplification in samples 1) and 3), detected amplification in samples 2) and 4)

## Deoxyribonuclease (DNase) < $10^{-7}$ Kunitz Units

**Test ref:** Scitec Research S.A., SOP ref. SAM5001 v1, 2014-01

**Method:** Incubation on agarose gel of DNA molecular scale. Test performed on Ecostep™ syringes.

- 1) Syringe from tested lot
- 2) Syringe added with a  $10^{-7}$  K Unit of DNase
- 3) Negative control
- 4) Positive control

**Validation:** No degradation on agarose gel of the DNA molecular scale in samples 1) and 3), degradation in samples 2) and 4)

## Ribonuclease (RNase) < $10^{-9}$ Kunitz Units

**Test ref:** Scitec Research S.A., SOP ref. SAM5002 v1, 2014-01

**Method:** Incubation on agarose gel of RNA molecular scale. Test performed on Ecostep™ syringes.

- 1) Syringes from tested lot
- 2) Syringes added with a  $10^{-9}$  K Unit of RNase
- 3) Negative control
- 4) Positive control

**Validation:** No degradation on agarose gel of RNA molecular scale in samples 1) and 3), degradation in samples 2) and 4)

## Pyrogen (endotoxins) < 0.005 IU or EU/mL, < 0.5 IU or EU/ item tested

**Test ref:** LAL chromogenic method, European Pharmacopeia 8th edition (2014), chapter 2.6.14, and United States Pharmacopeia 37 NF 32 (2014), chapter 85

**Method:** Preparation of a standard curve from 5 IU (or EU/mL) to  $5 \cdot 10^{-3}$  IU (or EU/mL). Bacterial endotoxin rates determined using spectrophotometric measures at 405 nm.

Test performed on Ecostep™ syringes rinsed with Pyrogen-free water.

- 1) Syringes from tested lot
- 2) Syringes added with 0.5 IU (or EU/mL) of endotoxin
- 3) Negative control

**Validation:** No detection in samples 1) and 3), detection in sample 2)

Model

Cat. No.

Lot No.

Expiry



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Eublens, 2015-07-23

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