

## Sterilization and Purity Certificate – Ecostep *bioproof*<sup>TM</sup>

Socorex<sup>®</sup> certifies that Ecostep *bioproof*<sup>TM</sup> syringes, intended for use with the Stepper<sup>TM</sup> 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  $10^6$  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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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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