Sterilization and Purity Certificate – Ecostep *bioproof*™

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_2, 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™ 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 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 ⧖

SOCOREX SWISS
socorex@socorex.com www.socorex.com

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Jean-Marc Ammann
Quality System & Regulatory Affairs Manager

DNA-RNase-DNase-Pyrogen-free CERTIFIED