CERTIFICATE OF QUALITY

Autofil®

Catalog Number:	1101-RLS
Membrane Type:	**PES**
Pore Size:	**0.22 UM**
Lot Number:	26571899
Expiration Date:	07/2023

Materials of Construction:
Filter Housing and Bottle: Polystyrene
Membrane: Polyethersulfone (PES)
Cap: Polypropylene

Component Material Toxicity:
All component materials have been tested and met the requirements for United States Pharmacopoeia (USP) class VI Biological Test for Plastics, current edition. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.1640.

Cytotoxicity:
Plastic component materials are non-cytotoxic and meet the Elution Test 10993-5, 1999

Pyrogens:
An aqueous extraction from the unit contains less than 20 EU/device as determined using the Limulus Amebocyte Lysate (LAL) test.

Maximum Operating Vacuum:
20in Hg (51 cm) Hg
15in Hg (38 cm) Hg recommended

Temperature Range:
Operating Range: 39° to 98° F (4° to 37° C)
Unit Storage: -20° to122° F (-4° to 50° C)

Flammability:
UL94 flame rating

Audit Criteria:
Audit criteria tests are conducted to determine the viable microbial bioburden of the product.

Sterilization Dose Audit:
Gamma irradiation dose is audited on a quarterly basis.

Sterilization:
Individually bagged and sterilized by gamma irradiation VDMax 10^{-6} in the USA.

Membrane Bubble Point:
Each membrane pore size was certified according to an established Foxx Life Sciences' procedure to determine the water bubble point.
Autofil®:

0.1µm Pore Size	29.9 psi (2.1bar)
0.2µm Pore Size	62.4 psi (4.3 Bar)
0.45µm Pore Size	43.5 psi (3.0 Bar)

Autofil® SS:

0.2µm Pore Size	69.6 psi (4.8 Bar)

Bacterial Retention:
0.2 micron membrane samples were quantitatively retentive of a minimum Brevundimonas diminuta challenge concentration of 1x 10^{-7} cfu per cm^2 using ASTM methodology.

0.45 micron membrane samples were quantitatively retentive of a minimum S. marcescens challenge concentration of 1x 10^{-7} cfu per cm^2 using ASTM methodology.

Good Manufacturing Practice:
This product was manufactured in a Class 100,000 clean room facility that is registered to ISO 13485 Device manufacturing.

ISO 13485 Quality Standard:
This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 13485 Quality Systems Standard.

Foxx Life Sciences
www.foxxlifesciences.com

ISO 9001 Foxx Certified ISO 13485

Brian J. Abbott
Manager, Regulatory Affairs and QA

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