SARTORIUS

Certificate of Quality

General Quality Certificate for:

Sartorius Optifit Tip and SafetySpace Filter Tips

Sartorius Biohit Liquid Handling Oy hereby certifies that all Sartorius pipette tips have been manufactured in accordance with established manufacturing guidelines and product specifications. The manufacturing facility fulfills the class 8 cleanroom conditions according to ISO 14644: Cleanrooms and associated controlled environments.

Each production lot is tested according to our certified quality management system.

ISO Certifications

Sartorius Biohit Liquid Handling Oy and its manufacturing sites are certified according to following certificates, all valid from 15th December 2023:

ISO 9001:2015 Certificate No. FI17/5101, issued by SGS, Finland
ISO 13485:2016 Certificate No. FI17/5103, issued by SGS, Finland
ISO 14001:2015 Certificate No. FI17/5102, issued by SGS, Finland

Materials

Sartorius pipette tips are produced of non-recycled, virgin polypropylene, and filters of polyethylene. The tips have been tested free of erucamide, oleamide and stearamide. In addition, material processing conditions are in accordance with Section 3 of Annex I of Commission Regulation (EC) No 722/2012 and EMA/410/01 rev. 3.

Following agents are not used or intentionally added by Sartorius or the raw material supplier: biocides (including di(2-hydroxyethyl)methyldodecyl-ammonium salts (DIHEMDA)), plasticizers (softeners/phthalates), silicone or latex.

Sartorius Biohit Liquid Handling Oy confirms that all plastic materials used in tip manufacturing meets the requirements of FDA, 21 CFR 177.1520(a)(1)(i), (b) and (c)1.1a, is tested according to USP 661.1 chapter 88 - USP Biological Reactivity tests, In Vivo for a Class VI plastic and according to chapter 87 - Biological Reactivity Tests, in Vitro for polymeric materials and meets the requirements of Ph. Eur. 3.1.3 and 3.1.6.

Pipette tips and packaging materials are 100% recyclable. Please refer to your local recycling regulation for correct sorting of materials

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Sterility

Pre-sterilized pipette tips are sterilized in accordance with ISO 11137-1: Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ISO 11737-2: Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

Purity Testing

Each lot of purity certified pipette tips are tested to be free of DNase, RNase, human DNA and endotoxins (pyrogens) by an independent laboratory, and results verified regularly in a GMP certified quality control laboratory.

Lot-specific Certificates

Lot-specific certificates for purity tested products are available at https://my.sartorius.com/

8th January 2024, Helsinki, Finland

Matti Pilviö
Managing Director
Sartorius Biohit Liquid Handling Oy

Tuomas Huhmarniemi
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Sartorius Biohit Liquid Handling Oy

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