# Certificate of Quality

## General Quality Certificate for:

## Sartorius Optifit Tips, SafetySpace Filter Tips and Low Retention 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. Sartorius tips have been manufactured in a highly automated and controlled environment, where direct human contact with the products is avoided to ensure maximal product purity. The manufacturing facility fulfills the class 8 cleanroom conditions according to ISO 14644: Cleanrooms and associated controlled environments.

### ISO Registrations

Sartorius Biohit Liquid Handling Oy and its manufacturing sites are certified according to:
ISO 9001:2015 Certificate No. FI17/5101, issued by SGS, Finland , valid 14th December 2020
ISO 13485:2016 Certificate No. FI17/5103, issued by SGS, Finland, valid 14th December 2020
ISO 17025:2005 Certificate No. K041 issued by FINAS, valid 20th March 2024
ISO 14001:2015 Certificate No. FI17/5102, issued by SGS, Finland, valid 14th December 2020

### Materials

Sartorius pipette tips are produced of non-recycled, virgin polypropylene, and the filters of polyethylene.

During production of these materials the following agents are not used or intentionally added: slip agents (including oleamide, erucamide, stearamide), 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. The used raw material is considered safe and free of any BSE/TSE substances.

Pipette tips and racks are 100% recyclable.

### Testing

Sartorius Biohit Liquid Handling Oy continuously controls the quality of the pipette tips in accordance with their certified Quality Management System.

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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

Purity certified pipette tips are tested to be free of DNase, RNase, human DNA and endotoxins (pyrogens) by an independent laboratory.

All Sartorius pipette tips are fully traceable by lot number. Lot-specific purity certificates can be downloaded, once the products have passed the respective tests, at www.sartorius.com.

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