Declaration of Conformity

Sartorius Biohit Liquid Handling Oy hereby certifies that the products named below fulfil the relevant parts of EC-directives and international standards. Sartorius' tips have been designed, manufactured, and tested in accordance with established manufacturing guidelines and product specifications.

Sartorius Optifit Tips, SafetySpace Filter Tips

This certificate of compliance is valid as long as the tips are used in accordance to their intended use. The relevant EC-directives and international standards are:

98/79/EC, ISO 14971, ISO 15223-1

2011/65/EU for RoHS Directive.

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.

All product lines are designed and manufactured according to the Essential Requirements listed in Annex I of EC Directive 98/79/EC (In Vitro Medical Devices).

Sartorius Liquid Handling Products are registered through The National Supervisory Authority for Welfare and Health with the registration numbers and their Global Medical Device Nomenclature Codes (GMDN):

Sartorius Optifit Tip	Reg.Number: FI-CA01-2016-1560	GMDN: 16822
Sartorius Safety Space Filter Tips	Reg.Number: FI-CA01-2016-1557,	GMDN: 16822

This declaration is supported by following EC quality system approval certificates:

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/A10/2016 issued by FINAS, valid 20th March 2020
ISO 14001:2015 Certificate No. FI17/5102, issued by SGS,Finland, valid 14th December 2020

02. February 2019

Matti Pilviö
Director of Operations
Sartorius Biohit Liquid Handling Oy

Seppo Riikonen
Director, Quality & Process Development
Sartorius Biohit Liquid Handling Oy

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