

## Declaration of Conformity $C \in$

Sartorius Biohit Liquid Handling Oy hereby certifies that the products named below fulfil the relevant parts of ECdirectives 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 and Low Retention Tips

This certificate of compliance is valid as long as the tips are used in accordance to their intended use. The relevant ECdirectives and international standards are: 98/79/EC, ISO 14971, ISO 15223-1, ISO 8655

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/ISO 13485 Quality Management System (certificate no. 108129-2011-AQ-FIN-FINAS, issued by DNV). The Environmental Quality Management System is certified according to ISO 14001 (certificate no. 108133-2011-AE-FIN-FINAS, issued by DNV).

April 1st, 2016

Jussi Heiniö CEO Sartorius Biohit Liquid Handling Oy

Seppo Buto

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

Sartorius Biohit Liquid Handling Oy, head office: Laippatie 1, 00880 HELSINKI, FINLAND Tel: +358 9 755 951, Fax: +358 9 755 95 200, Business ID: Fl2441885-8. Website www.sartorius.com. Contact us: lhinfo.finland@sartorius.com. Factory in Finland, Tietokatu 4, 87400 KAJAANI, FINLAND.