

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' mechanical pipette, Proline®, has been designed, manufactured, and tested in accordance with established manufacturing guidelines and product specifications.

Proline® Mechanical Pipettes

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

98/79/EC, ISO 14971, ISO 15223-1, ISO 18113-3, ISO 8655-2, ISO 8655-6

ISO Registrations

Quality systems

Sartorius Biohit Liquid Handling Oy and its manufacturing sites are certified according to ISO 9001/ISO 13485 quality management standards. ISO 9001/ISO 13485 Certificate No. 108129-2011-AQ-FIN-FINAS, issued by DNV. The calibration laboratories of Sartorius Biohit Liquid Handling Oy have been certified according to ISO 17025. ISO 17025 Certificate No. KO41/A10/2016, issued by FINAS.

Sartorius Biohit (Suzhou): ISO 9001 Certificate No. 4623-2008-AQ-RGC-RvA, issued by DNV. ISO 13485 Certificate No. 58452-2009-AQ-RGC-NA, issued by DNV. ISO 17025 Certificate No. CNAS L5145, issued by CNAS.

Environmental system

Sartorius Biohit Liquid Handling Oy and its manufacturing sites are certified according to the ISO 14001 environmental standard. ISO 14001 Certificate No. 108133-2011-AE-FIN-FINAS, issued by DNV.

Sartorius Biohit (Suzhou): ISO 14001 Certificate No. 4624-2008-AE-RGC-RvA, issued by DNV.

Testing

Every pipette manufactured by Sartorius Biohit Liquid Handling Oy is individually tested during the manufacturing process and must pass both the internal quality check and the gravimetric test. Every individual pipette is gravimetrically performance-tested according to ISO 8655 part 6. The gravimetric test results and a Quality Control certificate are sent to the customer with the pipette.

April 1st, 2016



Jussi Heiniö

CEO

Sartorius Biohit Liquid Handling Oy



Seppo Riikonen

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Sartorius Biohit Liquid Handling Oy