



EC DECLARATION OF CONFORMITY

Manufacturer's name:

Thermo Fisher Scientific Oy Liquid Handling Consumables

Manufacturer's address:

Ratastie 2

FIN-01620 Vantaa

Finland

Declares that the product:

Product name:

Thermo Scientific F1-ClipTip Pipetting System

Product type:

Pipettes and pipette tips

conform to

Directive 98/79/EC

In vitro diagnostic medical devices

Standard EN ISO 13485:2003

Medical devices – Quality management systems – Requirements for regulatory purposes

Standard ISO 14971:2007

Medical devices - Application of risk management to medical devices

Standard EN ISO 18113-3:2009

Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use

Standard EN 980:2008

Graphical symbols for use in the labelling of

medical devices

Standard ISO 11137:1995

Sterilization of healthcare products -

Requirements for validation and routine control

- radiation sterilization

Standard EN 556-1:2001

Sterilization of medical devices – Requirements for medical devices to be designed "STERILE" –Part 1: Requirements for terminally sterilized

medical devices.

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Liquid Handling Consumables Thermo Fisher Scientific Oy

Thermo Fisher Scientific Ov

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