

# **Eppendorf Certificate**

General Quality Certificate for epT.I.P.S.®, Combitips® advanced, ViscoTip®, Eppendorf Tubes®, Eppendorf Plates®, UVette®

Eppendorf certifies that all consumables have been manufactured in accordance with established manufacturing guidelines and product specifications. The products conform to all Eppendorf quality requirements. Controlled environment with restrictive handling procedures avoids direct human contact with the products.

#### **ISO Certification**

The Eppendorf Quality Management System is certified according to ISO 9001:2015-09, ISO 13485:2016-03, and ISO 14001:2015-09.

#### **Materials**

All products are produced with materials such as virgin polypropylene, polyethylene, polycarbonate, polystyrene, or UV-transparent plastic. No recycled materials are used. Our material suppliers do not use or intentionally incorporate the following agents into the materials Eppendorf uses for production:

- Slip agents (including oleamide, erucamide, stearamide)
- Biocides (including di(2-hydroxyethyl) methyl-dodecyclammonium salts (DIHEMDA))
- Plasticizers (softeners/phthalates)
- Melamine
- Silicone
- Latex

During production, no slip agents, biocides, or plasticizers are used. Colorants are free of biological material, free of heavy metals, and free of melamine. Eppendorf confirms that all plastic materials fulfil the requirements as described in the current version of the FDA, CFR, Title 21 (Food and Drugs) in chapter 178.2010 "Antioxidants and Stabilizers for Polymers" and chapter 177.1520 (a)(1), (b) and (c)1.1 "Olefin polymers" regarding substances used for manufacturing of materials and articles or components of articles intended to come into contact with food. Eppendorf does not use any silicone or latex for manufacturing or packaging.

### **Production**

Products are manufactured in a controlled ISO class 8 clean room environment according to ISO 14644-1:2016-06.



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## **Quality Assurance/Quality Control**

## **Functional Testing**

Products undergo continuous quality controls regarding function, tightness, precision, and reproducibility. Dimensional checks, testing of precision and accuracy, resistance to high centrifugational forces, vapor tightness, flow properties, leak tightness, transparency, etc. are part of Eppendorf Quality Assurance Standards.

# **Sterility**

Sterile products are sterilized by irradiation according to DIN EN ISO 11137-2:2015-11. Each lot of sterilized products is certified by an independent, ISO/IEC 17025-accredited laboratory.

### **Purity Grade Testing**

Purity criteria of the purity grades "Biopur®", "Sterile", "PCR clean" and "Protein-free" are tested and certified lot-specific by an independent, ISO/IEC 17025-accredited laboratory. Biological testing procedures ensure that the certified Eppendorf consumables are free from specific detectable contaminants.

Lot-specific purity certificates can be downloaded at <a href="https://www.eppendorf.com/certificates">www.eppendorf.com/certificates</a>.

#### **Traceability**

All products are fully traceable by lot number.

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Joana Tziolis Expert Liquid Handling LH-Consumables

Your local distributor: www.eppendorf.com/contact Eppendorf AG · Barkhausenweg 1 · 22339 Hamburg · Germany

E-mail: eppendorf@eppendorf.com

ISO 9001 Certified ISO 13485 Certified

Monika Schneider

Head of Global Quality Management &

Regulatory Affairs

ISO 14001 Certified

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