

Eppendorf Certificate

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

Eppendorf hereby 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 and ISO 13485.

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-dodecylammonium salts (DIHEMDA)), plasticizers (softeners/phtalates), melamine, silicone, or 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 fulfill the requirements as described in the actual version of the FDA, CFR, Title 21 “Antioxidants and Stabilizers for Polymers”, 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 under clean room conditions in a class 8 clean room environment (according to ISO 14644)

Eppendorf Certificate

Quality Assurance/Quality Control

Functional Testing

Products undergo continuous quality control 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 11137:2015. Each lot of sterilized products is certified by an independent, EN 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, EN 17025-accredited laboratory. Biological testing procedures ensure on a lot-by-lot basis that the certified Eppendorf consumables are free from specific detectable contaminants.

Lot-specific purity certificates can be downloaded on www.eppendorf.com/certificates.

Traceability

All products are fully traceable by lot number.

August 2017

Page 2 of 2



Brigitte Klose
Global Product Manager
Liquid Handling Consumables/Instruments



Dr. Birgit Schreiber
Vice President
Quality Management & Regulatory Affairs

Your local distributor: www.eppendorf.com/contact
Eppendorf AG · 22331 Hamburg · Germany
E-mail: eppendorf@eppendorf.com

ISO 9001
Certified

ISO
13485
Certified

ISO
14001
Certified