## eppendorf

# **Eppendorf Certificate**

### General Quality Certificate for epT.I.P.S.<sup>®</sup>, Eppendorf Tubes<sup>®</sup>, Eppendorf Plates<sup>®</sup>, UVette<sup>®</sup>

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-dodecyclammonium salts (DIHEMDA)), plasticizers (softerners/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).

#### **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.

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#### Sterility

Sterile products are sterilized in accordance with EN ISO 11137:2013. Each lot of sterilized products is tested and certified by an independent, EN 17025–accredited laboratory. Lots are only released when products have passed the respective testing.

#### **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 <u>ww.eppendorf.com/certificates</u>.

#### Traceability

All products are fully traceable by lot number.

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Brigitte Klose Global Product Manager Liquid Handling Consumables/Instruments

Your local distributor: www.eppendorf.com/contact Eppendorf AG · 22331 Hamburg · Germany E-mail: eppendorf@eppendorf.com Page 2 of 2

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Eppendorf<sup>®</sup>, the Eppendorf logo, epT.I.P.S.<sup>®</sup>, Biopur<sup>®</sup>, Eppendorf Tubes<sup>®</sup>, Eppendorf Plates<sup>®</sup> and Uvette<sup>®</sup> are registered trademarks of Eppendorf AG, Germany. U.S. Design Patents are listed on www.eppendorf.com/ip. All rights reserved, incl. graphics and pictures. Copyright 2015 <sup>©</sup> by Eppendorf AG.

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