

Eppendorf Certificate

Certificate of Quality - Eppendorf CryoStorage Vials

Eppendorf CryoStorage Vials are free of detectable RNase, DNase, human DNA, and free of endotoxins (pyrogens).

CryoStorage Vials are manufactured from granulates specifically suited for laboratory applications and the manufacturing process of laboratory consumables.

Virgin polypropylene of highest purity and quality is used for all parts coming into direct contact with the sample. The material suppliers do not use or intentionally incorporate the following agents into the materials that are used for the production of Vials:

- Slip agents (including oleamide, erucamide, stearamide)
- Biocides (e.g., di(2-hydroxyethyl)methyl dodecylammonium salts (DIHEMDA))
- Plasticizers (e.g. phthalates)

For the outer black parts of the CryoStorage Vials and the CryoStorage Racks partially recycled polymers of the original materials are used to minimize the environmental impact of plastics.

During production of Eppendorf Vials no slip agents, no biocides, and no plasticizers are used. The used raw materials comply with the international purity criteria of JHOSPA, with REACH regulation of the European Union (EU), and they are non-cytotoxic according to EN ISO 10993-5. Furthermore, they are free of metallic dyes, latex, glucane, cellulose, and bisphenol A.

PP, PC, and PE granulates may contain small amounts of materials derived from animals. Due to the granulate production procedures any virus, bacterium or substance causing immunological diseases (TSE, BSE, CJD), is destroyed. Eppendorf states that the materials and laboratory consumables are to be considered safe with respect to BSE and TSE transmission when used in consumer applications.

All Eppendorf CryoStorage Vials are manufactured in class 8 cleanroom areas according to EN ISO 14644. They are subject to regular quality inspections within a statistical process control. Tests being performed are, e.g., tightness, lid-opening force, and wall strength.

The Eppendorf Quality Management System is certified according to the international standards ISO 9001, ISO 13485, and ISO 14001.

Date: January, 2020



Dr. Cordula Kroll
Business Manager
Business Unit Sample Management



Monika Schneider
Head of Global Quality Management &
Regulatory Affairs

Your local distributor: www.eppendorf.com/contact
Eppendorf AG · Barkhusenweg 1 · 22339 Hamburg · Germany
E-mail: eppendorf@eppendorf.com

ISO 9001
Certified

ISO 13485
Certified

ISO 14001
Certified