

Certificate of Quality

Eppendorf Cell Culture Consumables

The Eppendorf Quality Management System is certified according to ISO 9001/13485/14001. This converts for our customers to a constantly high and reliable quality of products and processes covering the complete product life cycle.

Environment & Production Process

Eppendorf Cell Culture Plates, Dishes and Flasks (in the following: Eppendorf Cell Culture Consumables) are developed and manufactured according to ISO 9001/13485/14001. Production of all Eppendorf Cell Culture Consumables takes place in a controlled class 7 clean room environment according to ISO 14644-1 and EG-GMP Class C.

The consistent reliable quality of Eppendorf products is ensured by monitored process controls and checks from the raw material to the final packed product.

The sterilization process is performed according to ISO 11137. The growth surface is ensured to fulfill all requirements concerning wettability and homogeneity.

Purity and Cytotoxicity

For certification of absence of DNA, DNase, RNase, and pyrogens as well as for assurance of sterility and performance of the TC-treated surface, please refer to the lot-specific certificates of the respective product.

The Eppendorf Cell Culture Consumables have been tested in a cell-based assay for in-vitro cytotoxicity according to ISO 10993-5 by an external partner and show no cytotoxicity.

Material

The raw material used to produce the Eppendorf Cell Culture Consumables complies with USP Class VI standards.

Eppendorf confirms that Eppendorf Cell Culture Consumables and the packaging materials comply with the REACH regulation of the European Union EC No 1907/2006.

Release of Substances

Leachables

Material suppliers of Eppendorf do not use or intentionally incorporate the following agents into the materials Eppendorf uses for the production of Eppendorf Cell Culture Consumables:

- > Slip agents (including oleamide, erucamide, stearamides)
- > Biocides (including di(2-hydroxyethyl)methyl dodecyl ammonium salts (DiHEMA))
- > Plasticizers (including phthalates)
- > Bisphenol A
- > Latex
- > Antistatic agents
- > Metallic dyes
- > Mineral oil

Release of Trace Metals

The release of trace metals from Eppendorf Cell Culture Consumables has been evaluated in a one-time measurement. For detailed information please refer to the respective Certificate of Quality (Cell Culture Consumables: Typical values for trace metals).

BSE/TSE

Eppendorf only works with granulate suppliers who guarantee that the animal components they use come exclusively from countries without BSE occurrences. Risk materials are not used. The granulate production includes process steps with conditions above 235 °C/ 3,000 kPa for several hours that destroy any virus, bacteria or substance that may cause immunological diseases (TSE, BSE, CJD). For detailed information please refer to the respective Certificate of Quality (Eppendorf Laboratory Consumables: Statement on BSE/TSE).

i The operating manual can be found on the Internet at www.eppendorf.com/manuals

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ISO 9001
Certified

ISO 13485
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ISO 14001
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