

Certificate of Quality

Eppendorf CCCadvanced™ FN1 motifs Cell Culture Consumables

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

Environment and Production Process

Eppendorf CCCadvanced FN1 motifs Cell Culture Plates, Dishes and Flasks (in the following: FN1 motifs Consumables) are developed and manufactured according to ISO 9001. Production of all Eppendorf Cell Culture Consumables takes place in a controlled class 5 clean room environment according to ISO 14644-1 and EU-GMP Grade A. Eppendorf FN1 motifs Consumables are manufactured using aseptic processing according to ISO 13408-1 "Aseptic processing of healthcare products". Each step was validated to ensure that the Eppendorf FN1 motifs Consumables meet the Sterility Assurance Level (SAL) 10⁻³. The consistent reliable quality of Eppendorf FN1 motifs Consumables is ensured by monitored process controls and checks from the raw material to the final packed product.

The growth surface is ensured to fulfill all requirements concerning homogeneous coating and to be animal- and xeno-free.

An in-line leakage testing ensures the integrity of Eppendorf FN1 motifs Flasks.

Purity and Cytotoxicity

For certification of absence of DNA, DNase, RNase, and pyrogens as well as for assurance of sterility and performance of the FN1 motifs coated surface, please refer to the lot-specific certificates of the respective product.

The Eppendorf FN1 motifs 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 FN1 motifs Consumables complies with USP Class VI standards.

Eppendorf confirms that Eppendorf FN1 motifs 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 FN1 motifs 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 FN1 motifs 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".

Hamburg, April 2018

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0038 100.004-02/042018

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ISO 9001
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ISO 13485
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