

# Eppendorf Certificate

## Certificate of quality

### **Eppendorf Cell Imaging Consumables**

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

### **Production process and Quality control**

The consistent reliable quality of Eppendorf Cell Imaging Consumables is ensured by monitored process controls and checks from the raw material to the final packed product. Production of Eppendorf Cell Imaging Consumables takes place in a class 8 cleanroom according to ISO 14644-1. Performance of the TCT surface of each lot of Eppendorf Cell Imaging Consumables is approved by cell attachment tests using two anchorage-dependent cell lines. Each lot of Eppendorf Cell Imaging Consumables is approved to be leakage-free.

### **Purity and Cytotoxicity**

For certification of absence of DNA, DNase and RNase, and pyrogens as well as for assurance of sterility, please refer to lot-specific certificates of the respective product. Eppendorf Cell Imaging Consumables have been tested in a cell-based assay for in-vitro cytotoxicity according to ISO 10993-5 from an external partner and show no cytotoxicity. The adhesives are non-cytotoxic and biocompatible according to DIN EN ISO 10993-5:2009. Sterilization is performed by irradiation according to DIN EN ISO 11137-2:2007 or ethylene oxide sterilization with a SAL (sterility assurance level) of  $10^{-6}$ .

### **Material**

Only virgin materials are used for production of Eppendorf Cell Imaging Consumables. Eppendorf confirms that Eppendorf Cell Imaging Consumables and the packaging materials comply to REACH regulation of the European Union EC No 1907/2006.

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## Release of substances

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

- Slip agents (including oleamide, erucamide, stearamides)
- Biocides (including di(2-hydroxyethyl)methyl dodecyl ammonium salts (DiHEMDA))
- Plasticizers (including phthalates)
- Bisphenol A
- Latex

## BSE/TSE

Eppendorf only works with granulate suppliers who guarantee that their used animal components come exclusively from countries without BSE occurrences. Risk materials are not used. The granulate production includes process steps with conditions of above 235 °C/3,000 kPa for several hours that destroy any virus, bacteria, or substance causing immunological diseases (TSE, BSE, CJD).

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ISO 9001  
Certified

ISO 13485  
Certified

ISO 14001  
Certified

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