Eppendorf Certificate

Certificate of Quality

Eppendorf Tubes®*

All Eppendorf Tubes are produced in a controlled environment according to ISO class 8 of ISO 14644-1 and are subject to regular quality inspections within a statistical process control. Tests being performed are e.g. vapor tightness, lid-opening force, wall strength, and centrifugal stability.

The Eppendorf Quality Management System is certified according to the international standards ISO 9001:2015-09, ISO 13485:2016-03, and ISO 14001:2015-09.

Eppendorf Tubes are made of virgin polypropylene of highest purity and quality. Neither the material suppliers of Eppendorf nor Eppendorf use or intentionally incorporate the following agents into the materials Eppendorf is using for the production of Tubes:

- Slip agents (including oleamide, erucamide, stearamide)
- Biocides (including di(2-hydroxyethyl)methyl dodecyl ammonium salts (DiHEMDA))
- Plasticizers (softeners/phthalates)

Eppendorf confirms that all plastic materials fulfill the requirements as described in the current version of the FDA, CFR, Title 21 (Food and Drugs) in chapter 178.2010 “Antioxidants and Stabilizers for Polymers” and chapter 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.

* applies also to the SafeCode variants & BioBased variants

Hamburg, April 2024

DOMINIQUE DUTSCHER SAS

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ISO 9001 Certified
ISO 13485 Certified
ISO 14001 Certified

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General Certificate of Quality for epT.I.P.S.®*, Combitips® advanced, ViscoTip®, Eppendorf Tubes®*,*1, Eppendorf Plates®*,*1, UVette®

STATEMENT ON NITROSAMINE

N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) are classified as potential human carcinogens, that have been found in human medicinal products. Hence in accordance with Article 5(3) of Regulation (EC) No 726/2004 the EMEA published an Assessment report EMA/369136/2020 regarding the detection, management, and prevention of presence of N-nitrosamines in medicinal products for human use.

One possible root cause is that N-nitrosamine impurities can be carried over during the manufacturing process when using already contaminated equipment. Therefore, Eppendorf performed an additional risk evaluation with focus on N-nitrosamine potentially included in Eppendorf Consumables. As a result, Eppendorf confirms as manufacturer of Laboratory Consumables the following:

There is no risk of formation of nitrosamines during the manufacturing process:

- Eppendorf Consumables are made of virgin polypropylene, polyethylene, polycarbonate of highest purity and quality. Material suppliers do not use or intentionally incorporate Nitrosamine as specified in the absence of substances list.
- No reagents, solvents, or catalysts that could be a possible source of nitrosamines are used in the manufacturing process of Eppendorf Consumables.
- No packaging material/printing ink that could be a possible source of nitrosamines are used in the manufacturing process of Eppendorf Consumables.

There is no risk of contamination with nitrosamines during the cleaning process of product-contacting parts

- No cleaning agents based on quaternary ammonium salts are used for cleaning process equipment.

* applies also to the SafeCode variants
*1applies also to the BioBased variants

Hamburg, September 2023

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ISO 9001 Certified
ISO 13485 Certified
ISO 14001 Certified

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