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

Joana Tziolis
Product Life Cycle Manager
Division Consumables

Thomas Hengstmann
Head of Global Quality Operations

Your local distributor: www.eppendorf.com/contact
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ISO 9001 Certified
ISO 13485 Certified
ISO 14001 Certified

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Eppendorf Certificate

Certificate of Quality
Eppendorf Laboratory Consumables

STATEMENT ON BSE/TSE

As a leading manufacturer of biotech products, Eppendorf uses PP (polypropylene), PC (polycarbonate), PS (polystyrene), and PE (polyethylene) granulates specifically suited for laboratory applications and the manufacturing process of laboratory consumables. PP, PC, PS, and PE granulates may contain small amounts of materials derived from animals.

Eppendorf only works with granulate suppliers who guarantee that their animal components derive exclusively from countries without BSE (bovine spongiform encephalopathy) occurrences. Risk materials are not used. Thus, the requirements of the EU Regulation 1326/2001 and Commission Decision 2001/2/EC amending Decision 2000/418/EC regulating the use of materials presenting risks regarding transmissible spongiform encephalopathies (TSE) are fulfilled.

The granulate production includes – depending on the process – hydrolysis, esterification, or hydrogenation steps in different variations. The common features of these steps include processing conditions with temperatures above 235°C and pressures above 3,000 kPa with retention times up to several hours. The final product is obtained through fractionation, neutralization, and purification. The subsequent extrusion (for the production of granulate) takes place at minimum 200°C for several minutes.

Thus, the production chain of raw materials by far exceeds the stringent requirement of 200°C for 20 minutes (Annex VI, chapter III of EU Regulation 1774/2002, in EU Directives 2000/6/EC and 1999/82/EC, referring to Document EMEA/410/01-Final, latest version: Rev. 3 – 05.03.2011, and in the Report WHO/CDS/VPH/95.145). 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.

This certificate applies to the following Eppendorf Laboratory Consumables:

Pipette tips	epT.I.P.S.®*1
	epT.I.P.S.® 384
	epT.I.P.S.® Long
	epT.I.P.S.® Motion
	ep Dualfilter T.I.P.S.®*1
	ep Dualfilter T.I.P.S.® 384
	ep Dualfilter T.I.P.S.® SealMax®*1
	GELoader®
	Microloader
	Eppendorf Serological Pipets

*1 applies also to the BioBased variants

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Eppendorf Certificate

Positive displacement tips	Mastertip® Varitips® Combitips® advanced incl. adapters ViscoTip®
Eppendorf Tubes®	Eppendorf Tubes® 3810X/ Flex-Tube® Eppendorf Safe-Lock Tubes* Eppendorf DNA LoBind®/ Protein LoBind® Tubes, Eppendorf Tubes® 5 mL*, *1 incl. adapters Eppendorf Conical Tubes 15 mL*, *1, 50 mL*, *1, SnapTec® 50 Eppendorf Conical Tubes 25 mL*1 incl. adapters
Eppendorf Plates®	Eppendorf Microplates* Eppendorf Deepwell Plates* Eppendorf DNA LoBind®/ Protein LoBind® Plates Eppendorf Assay/Reader Microplates
PCR Consumables	Eppendorf twin.tec® PCR Plates*,*1 Eppendorf twin.tec® PCR Plates LoBind®*1 Eppendorf twin.tec® *microbiology* PCR Plates Eppendorf twin.tec® *real-time* PCR Plates PCR Tube Strips Fast PCR Tube Strips *real-time* PCR Tube Strips PCR Cap Strips PCR Tubes PCR Films & Foils
Cell Culture Consumables	Eppendorf Cell Culture Dishes Eppendorf Cell Culture Plates Eppendorf Cell Culture Flasks Eppendorf Cell Imaging Dishes Eppendorf Cell Imaging Plates CCCadvanced® Cell Imaging Slides & Coverglasses
Cuvettes	UVette® Vis Cuvette
Sample Handling Consumables	Wide-neck bottles

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

Hamburg, February 2024

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Eppendorf Certificate

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

Eppendorf certifies that all consumables have been manufactured in accordance with established manufacturing guidelines and product specifications. The products conform to all Eppendorf quality requirements. Controlled environment with restrictive handling procedures avoids direct human contact with the products.

ISO Certification

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

Materials

All products are produced with materials such as virgin polypropylene, polyethylene, polycarbonate, polystyrene, or UV-transparent plastic. No recycled materials are used. Our material suppliers do not use or intentionally incorporate the following agents into the materials Eppendorf uses for production:

- Slip agents (including oleamide, erucamide, stearamide)
- Biocides (including di(2-hydroxyethyl)methyl dodecycl ammonium salts (DIHEMDA))
- Plasticizers (softeners/phthalates)
- Melamine
- Silicone
- Latex

During production, no slip agents, biocides, or plasticizers are used. Colorants are free of biological material, free of heavy metals, and free of melamine. Eppendorf confirms that all plastic materials fulfil 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. Eppendorf does not use any silicone or latex for manufacturing or packaging.

Production

Products are produced in a controlled environment according to ISO class 8 of ISO 14644-1.

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

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Eppendorf Certificate

Quality Assurance/Quality Control

Functional Testing

Products undergo continuous quality controls regarding function, tightness, precision, and reproducibility. Dimensional checks, testing of precision and accuracy, resistance to high centrifugational forces, vapor tightness, flow properties, leak tightness, transparency, etc. are part of Eppendorf Quality Assurance Standards.

Sterility

Sterile products are sterilized by irradiation according to DIN EN ISO 11137. Each lot of sterilized products is certified by an independent, ISO/IEC 17025–accredited laboratory.

Purity Grade Testing

Purity criteria of the purity grades “Biopur®”, “Sterile”, “PCR clean” and “Protein-free” are tested and certified lot-specific by an independent, ISO/IEC 17025–accredited laboratory. Biological testing procedures ensure that the certified Eppendorf consumables are free from specific detectable contaminants.

Lot-specific purity certificates can be downloaded at www.eppendorf.com/certificates.

Traceability

All products are fully traceable by lot number.

DOMINIQUE DUTSCHER SAS

Hamburg, April 2024

Joana Tziolis
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Eppendorf Certificate

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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