# 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

Joana Tziolis
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ISO 9001 Certified
ISO 13485 Certified
ISO 14001 Certified

# 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

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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

# 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.

Hamburg, April 2024



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# Eppendorf Certificate

## Certificate of Quality

### Eppendorf Tubes® – Typical values of trace metal release

The values in the table indicate typical values of trace metal concentrations obtained by incubating Eppendorf Tubes with concentrated nitric acid for 1 hour (see Materials and Methods. page 2).

As the indicated values were determined in a one-time measurement. they cannot be guaranteed for every lot of Eppendorf Tubes. Rather. they provide an indication of the extent trace elements. that can be eluted from Eppendorf Tubes.

| | Trace metal release [ng/µL] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Al | Cd | Cr | Cu | Hg | Mn | Ni | Pb | Zn |
| **Eppendorf Safe-Lock Tubes*1** | | | | | | | | | |
| 0.5 mL* | 0.003 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 1.5 mL | 0.002 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 2.0 mL* | 0.002 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| **Eppendorf Tubes® 3810X** | | | | | | | | | |
| 1.5 mL | 0.002 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| **Eppendorf Protein LoBind® Tubes** | | | | | | | | | |
| 0.5 mL* | 0.006 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 1.5 mL | 0.004 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 2.0 mL* | 0.004 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 5.0 mL | < 0.001 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| **Eppendorf DNA LoBind® Tubes** | | | | | | | | | |
| 0.5 mL* | 0.004 | < 0.00002 | 0.0001 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 1.5 mL | 0.003 | < 0.00002 | 0.0001 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 2.0 mL* | 0.003 | < 0.00002 | 0.0001 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 5.0 mL | < 0.001 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| **Eppendorf Tubes® 5.0 mL*1** | | | | | | | | | |
| 5.0 mL | < 0.001 | < 0.00002 | < 0.00005 | < 0.0001 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 5.0 mL with screw cap *2 | < 0.001 | < 0.00002 | < 0.00005 | 0.000183 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| **Eppendorf Conical Tubes** | | | | | | | | | |
| 15 mL*1. *2 | < 0.001 | < 0.00002 | < 0.00005 | 0.00016 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 45 mL (SnapTec® 50) | < 0.001 | < 0.00002 | < 0.00005 | 0.000086 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 50 mL*. *1. *2 | < 0.001 | < 0.00002 | < 0.00005 | 0.000086 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |
| 25 mL*. *2 | < 0.001 | < 0.00002 | < 0.00005 | 0.00016 | < 0.001 | < 0.00005 | < 0.00005 | < 0.00005 | < 0.001 |

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





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# Eppendorf Certificate

| | Trace metal release [ng/µL] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Al | Cd | Cr | Cu | Hg | Mn | Ni | Pb | Zn |
| **PCR Tubes** | | | | | | | | | |
| 0.2 mL | 0.0013 | <0.00002 | 0.00016 | <0.00010 | <0.0010 | <0.00005 | <0.00005 | <0.00005 | <0.0010 |
| 0.5 mL | 0.0011 | <0.00002 | 0.00048 | <0.00010 | <0.0010 | <0.00005 | 0.00006 | <0.00005 | 0.0029 |
| **PCR Tube Strips** | | | | | | | | | |
| 0.1 mL with Cap Strips domed | <0.0010 | <0.00002 | 0.00007 | <0.00010 | <0.0010 | <0.00005 | <0.00005 | <0.00005 | <0.0010 |
| 0.2 mL | <0.0010 | <0.00002 | <0.00005 | <0.00010 | <0.0010 | <0.00005 | <0.00005 | <0.00005 | <0.0010 |
| **Fast PCR Tube Strips** | | | | | | | | | |
| 0.1 mL with Cap Strips flat | <0.0010 | <0.00002 | <0.00005 | <0.00010 | <0.0010 | <0.00005 | <0.00005 | <0.00005 | <0.0010 |
| ***real-time* PCR Tube Strips** | | | | | | | | | |
| 0.1 mL with Masterclear Cap Strips | 0.0061 | <0.00002 | 0.00010 | 0.00037 | <0.0010 | 0.0015 | <0.00005 | 0.00008 | <0.0010 |

## Materials and Methods

Eppendorf Tubes were filled to their nominal volume with concentrated nitric acid (65 %) and incubated for 1 hour at room temperature. The eluate was then analyzed by inductively coupled plasma-mass spectrometry (ICP-MS). The trace metal concentrations are stated in ng/µL.

The values represent an average of three individually analyzed samples. All values labeled with "<" indicate concentrations below the detection limit of the ICP-MS method. The trace metal release values of tube sizes indexed with “*” were calculated from their surface/volume ratio of the tube.

No metal release was observed after 5 to 10 times rinsing with concentrated nitric acid or after rinsing with 10 % acetic acid or water.

All analyses were performed by GALAB Laboratories. Geesthacht. Germany accredited according to DIN EN ISO/IEC 17025.

Hamburg. August 2022



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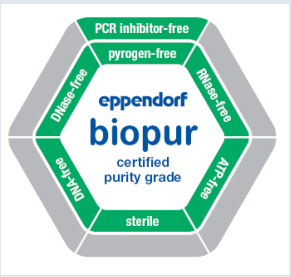
# Eppendorf Certificate

## Certificate of Purity - Biopur®

This package contains a high-quality consumable manufactured under the Biopur® Purity Standard. The Biopur consumables are produced in a controlled environment according to ISO class 8 of ISO 14644-1 .

For this product Eppendorf certifies the following:

> Sterile
> Pyrogen/Endotoxin-free
> Human DNA-free
> Bacterial DNA-free
> DNase-free
> RNase-free
> PCR inhibitor-free
> ATP-free




These parameters are continuously monitored by an independent certified laboratory. Eppendorf guarantees the conformity within the following limits:

| | |
|---|---|
| Sterility | in accordance with USP, Ph. Eur. 2.6.12 |
| Pyrogens | < 0.001 EU/mL (tested according to Ph. Eur. 2.6.14 (LAL test)) |
| Human DNA | < 2 pg |
| Bacterial DNA | < 50 fg |
| DNase | < $1.0 \times 10^{-7}$ Kunitz units |
| RNase | < $1.0 \times 10^{-9}$ Kunitz units |
| PCR inhibition | fewer than 10 targets amplifiable |
| ATP | < $5.5 \times 10^{-12}$ mg |

Lot-specific certificates can be downloaded from the internet at www.eppendorf.com/certificates.

Hamburg, June 2024

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