

Eppendorf Certificate

Certificate of Quality – Quality Assurance of epT.I.P.S.^{®*}, epT.I.P.S.[®] 384, ep Dualfilter T.I.P.S.^{®*}, ep Dualfilter T.I.P.S.[®] 384 and ep Dualfilter T.I.P.S.[®] SealMax*

All epT.I.P.S. pipette tips and all ep Dualfilter T.I.P.S. filter tips are single-use plastic tips which, in combination with all Eppendorf manual and electronic air-cushion pipettes, form a perfectly functioning pipetting system.

Quality Assurance

Eppendorf confirms that all data for random error and systematic error according to EN ISO 8655 of Eppendorf pipettes are valid only when original Eppendorf pipette tips are used.

All variants of epT.I.P.S. pipette tips and ep Dualfilter T.I.P.S. filter tips 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.

The Eppendorf Quality Management System is certified according to the international standards ISO 9001, ISO 13485, and ISO 14001.

Composition

epT.I.P.S. pipette tips and ep Dualfilter T.I.P.S. filter tips are made of virgin polypropylene of highest purity and quality. Our material suppliers do not use or intentionally incorporate the following agents into the materials Eppendorf uses for the production of pipette tips:

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

* applies also to the BioBased variants

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The raw materials used for epT.I.P.S.® pipette tips and ep Dualfilter T.I.P.S.® filter tips 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.

All resin material is tested, qualified, and shows non-toxic biocompatibility according to the Standards USP Class VI Chapter 88, USP 661.1., EP 3.1.3, EP 3.1.6, and ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-11.

epT.I.P.S.® pipette tips and ep Dualfilter T.I.P.S.® filter tips and all product components do not contain:

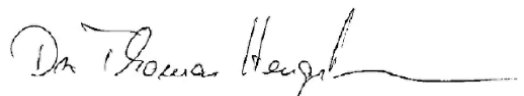
- Metallic dyes
- Latex
- Glucan
- Cellulose

Hamburg, April 2024

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Joana Tziolis
Product Life Cycle Manager
Division Consumables



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Head of Global Quality Operations

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ISO 9001
Certified

ISO 13485
Certified

ISO 14001
Certified

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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.

Hamburg, September 2023

* applies also to the SafeCode variants

*¹ applies also to the BioBased variants



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Monika Schneider
Vice President Global Quality Management &
Regulatory Affairs

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ISO 9001
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ISO 13485
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ISO 14001
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Eppendorf®, Eppendorf Brand Design, epT.I.P.S.[®], Combitips[®] advanced, ViscoTip[®], Eppendorf Tubes[®], Eppendorf Plates[®], Biopur[®] and UVette[®], are registered trademarks of Eppendorf SE, Germany.
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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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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® <i>microbiology</i> PCR Plates Eppendorf twin.tec® <i>real-time</i> PCR Plates PCR Tube Strips Fast PCR Tube Strips <i>real-time</i> 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

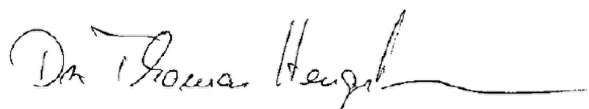
*applies also to the SafeCode variants *1applies also to the BioBased variants

Hamburg, February 2024

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