

Eppendorf Certificate

General Certificate of Quality for epT.I.P.S.[®], Combitips[®] advanced, ViscoTip[®], Eppendorf Tubes[®]*,*¹, Eppendorf Plates[®], 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, August 2022

* applies also to the SafeCode variants

*¹ applies also to the BioBased variants



Joana Tziolis
Product Life Cycle Manager
Division Consumables



Monika Schneider
Vice President Global Quality Management &
Regulatory Affairs

Your local distributor: www.eppendorf.com/contact
Eppendorf SE · Barkhausenweg 1 · 22339 Hamburg · Germany
E-mail: eppendorf@eppendorf.com

ISO 9001
Certified

ISO 13485
Certified

ISO 14001
Certified

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. All rights reserved, incl. graphics and images. Copyright ©2022 by Eppendorf SE.