

Eppendorf Certificate

General Certificate of Quality for epT.I.P.S.[®], Combitips[®] advanced, ViscoTip[®], Eppendorf Tubes^{®*}, 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 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, April 2022

* applies also to the SafeCode 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.