

Eppendorf Certificate

Mechanical pipettes, epT.I.P.S.® pipette tips, **Eppendorf Tubes®**

Discontinuation of EU-IVD product lines and applicability of remaining product lines for IVD applications in EU/EFTA

In Sept 2021, leading European Life Science Organizations (Gambica, FHI, Labmas, Laborama, Spectaris) published an agreed recommendation to not CE mark products like manual pipettes, pipette tips as well as tubes as EU-IVD products.

As of January 2022, Eppendorf SE decided to follow this recommendation.

Therefore, the former dual product lines for:

- Eppendorf Research® plus pipettes
- Eppendorf Reference® 2 pipettes
- epT.I.P.S.® pipette tips
- Eppendorf Tubes®

will be reduced to one product line each.

In the EU & EFTA countries, the products may be used for all general laboratory applications including the usage in IVD.

Regarding performance and safety, the products remain technically identical. There will be no compromise in accuracy and precision. The product quality and production conditions comply unchanged to an ISO 9001/ISO 13485 certified Quality Management System.

The pipette test protocol remains part of the delivery package for each mechanical pipette.

epT.I.P.S.® and Eppendorf Tubes® in the purity grades PCR clean and Biopur® are continuously tested in an external, ISO 17025 accredited laboratory and remain equipped with lot number specific certificates (download under www.eppendorf.com/certificates via lot number).

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Eppendorf®, the Eppendorf Brand Design, Eppendorf Research®, Eppendorf Reference®, epT.I.P.S.®,

9001 Certified

ISO 13485 Certified

Head of Global Regulatory Affairs

ISO 14001 Certified

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