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Sartorius Biohit Liquid Handling Oy, 00880 Helsinki, Finland

June 1st 2020

Notification/Information letter
ECR 016869, ECR 016850 IVD markings on Sartorius pipettes and pipette tips

Dear customers and partners,

As an international leading supplier of high-quality laboratory instruments and consumables, Sartorius is committed to continuous improvement of its products and procedures in order to serve its customers in an optimal way.

This letter is to inform you about upcoming product changes to the regulatory status of Sartorius pipettes and pipette tips.

Background for the change

In 2022 the IVD Regulation (2017/746) replaces the IVD Directive (98/79/EC) under which Sartorius pipettes and pipette tips were registered as IVD product. Under the IVD Regulation (2017/746) mechanical and electronic pipettes and pipette tips are classified as products for general laboratory use. They can be used to perform in-vitro diagnostic procedures, but do not fall under the scope of in-vitro diagnostic medical devices.

Products for general laboratory use are not in-vitro diagnostic medical devices unless such products, in view of their characteristics, are solely intended and promoted by their manufacturer to be used for in vitro diagnostic examination in association with specific reagents and/or apparatus.

Currently, the IVD Directive, and soon the IVD Regulations, provide the regulatory framework for manufacturers and for authorized representatives who wish to place in vitro diagnostic (IVD) products on the EU market. Products that satisfy the regulatory requirements are permitted to carry the CE IVD mark. Dual-use products that can be used both in general laboratory use and in vitro diagnostics are not solely and specifically intended for use in in-vitro diagnostic examination and thus are not allowed to be affixed with the CE IVD mark.

In practice this requires CE IVD marked pipettes and pipette tips to be an irreplaceable part of the in-vitro examination.

To comply with the upcoming regulations Sartorius will remove the CE IVD marking from pipettes and pipette tips and the relevant documentation like product labels, technical specification sheets, technical manuals and future marketing material.

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Sartorius will continue to manufacture our pipettes and pipette tips with the same high quality our customers are accustomed to and we will continue to operate under ISO 9001, ISO 14001 and ISO 13485 compliance. Sartorius will continue to provide our products with unchanged design and performance as up to now but without the CE IVD marking.

In 2012 the European Commission Directorate General for Health and Consumers issued guidelines on certain products to clarify the position on CE IVD marking.

Download the document from the link below.
https://ec.europa.eu/docsroom/documents/10322/attachments/1/translations/en/renditions/native

Further guidelines were issued in 2014 (and updated in 2017).
http://ec.europa.eu/DocsRoom/documents/12867/attachments/1/translations/en/renditions/pdf

Change description:

Sartorius will remove CE IVD markings from above listed pipettes and pipette tips. Electronic pipettes will remain to be CE marked based on electrical safety directive (IEC 61010-1 ed. 3.0 2010-06) and electromagnetic compatibility directive (EN 61326:2013).

Products affected:

Sartorius Picus® Nxt electronic pipettes
Sartorius Picus® electronic pipettes
Sartorius Tacta mechanical pipettes
Sartorius mLINE® mechanical pipettes
Sartorius Proline® Plus mechanical pipettes
Sartorius Proline® mechanical pipettes
Sartorius Optifit tips
Sartorius SafetySpace™ filter tips

Change Implementation:

Removal of IVD from the products will begin during June 2020 and will be done in steps before end of August 2020.

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Contact:

Please direct any questions you might have to quality.finland@sartorius.com

Sincerely