Regulatory information

MANUFACTURER'S NOTIFICATION

Upcoming product change – CE mark removal from Socorex pipettes and tips.

Socorex, a worldwide supplier of high-quality liquid handling instruments and consumables, is working on continuous improvement of its products and procedures.

With a May 2022 deadline, the **IVD Regulation 2017/746** replacing former **IVD Directive 98/79** brings new detailed classification rules. As a result, pipettes and pipette tips are ranked as products for general laboratory use. They can be used to perform in-vitro diagnostics, but without falling under the scope of in-vitro diagnostic medical devices.

Henceforth, products for general laboratory use are not considered as in-vitro diagnostic medical devices unless such products, given their characteristics, are intended to be used for in-vitro diagnostic examination in association with specific reagents and/or apparatus.

Products used for both general laboratory and in-vitro diagnostics are not allowed to be identified with the CE IVD mark. Should pipettes and pipette tips bear a CE-IVD marking, they would be considered as an irreplaceable link of the in-vitro examination, which in fact they are not.

To comply with the IVDR requirements, Socorex will gradually remove the CE IVD marking from its pipettes and pipette tips, including from packaging/labeling and relevant documentation.

Product lines concerned are

Acura® 810 / 815 / 825 / 826 / 835 / 855 instruments,
Qualitix® micropipette tips,

which descriptions and references will remain unchanged.

We shall continue to manufacture and supply pipettes and pipette tips with the same high-quality level and outstanding performances our customers are used to. For this purpose, we shall maintain our ISO 9001/ISO 13485 certified quality system.

The transition phase of the CE marking removal as per above will start in the fourth quarter of 2021 and be completed by May 2022.

Acura® electro pipettes will retain their CE mark, solely based on the electrical safety Directive 2014/35/EC and the electromagnetic compatibility Directive 2014/30/EC.

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