November 16th, 2017

STATEMENT

Removal of CE-IVD Marking on pipettes and consumables related to European Commission decision on "products for general laboratory use."

At the end of 2013, the European Commission declared that borderline products, such as single and multichannel pipettes, could no longer be declared as in-vitro diagnostic (IVD) products anymore in the *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices* (MEDDEV 2.14, Chapter 2.3, page 2).

In this framework, the CE IVD mark will be gradually phased out on Gilson mechanical pipettes and pipette consumables, although these products will still be manufactured with the same high quality.

Gilson has not changed the design or the manufacturing processes of the pipettes and consumables; therefore, pipetting systems can still be part of the instruments used in in-vitro diagnostics.

The key characteristics listed below form the basis of IVD specification and still apply to Gilson pipetting systems, which can be used in an IVD process with the same confidence as those products previously marked with CE IVD.

• Relating to the prevention of cross contamination, such as specific filters, pistons for positive displacement, and single-use disposable pipette tips.

• Linked to the material compatibility with biological samples and reagents, such as the choice of raw materials and sterilization processes for single-use consumables.

• Affecting the result of the diagnosis, such as the accuracy of volumes and "container / content" interactions.

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