Pall Corporation

Date : August 27, 2019

Change in the Regulatory status of CE mark Point-of-Use Water Filters in Europe

Dear Customer,

The Regulatory framework is in constant evolution in Europe and we would like to make you aware of a recent decision made by the European Commission related to CE marked Point-of- Use Water Filters.

A working group chaired by the European commission and composed of representatives of all member states concluded that CE marked Point-of-Use Water Filters should be regarded as general hospital equipment and no longer considered as medical devices according to 93/42/EEC. The decision made in 2018 and excerpted from the "Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices" is summarized below:

The product is a water filter with a membrane for removing microorganisms from the water without changing its chemical composition. The manufacturer claims that filtered water is specifically intended for washing wounds and rinsing invasive medical equipment (e.g. endoscopic material) and that the filter should be classified as a medical device.
The question has arisen as to whether such a product meets the definition of medical device or accessory of medical device.
- Outcome: The water filter does not come into contact with injured skin and it does not disinfect medical devices. Water filtration systems that use mechanical barriers such as a membrane for removing microorganisms should be regarded as general hospital equipment and **should not** be qualified as a medical device or accessory of medical device.

In virtue of this regulatory change within EU, Pall is working on complying with the decision and therefore, as of September 12, 2019, the CE mark on Pall Point-of-Use Water Filters will be removed. The claims formerly associated to Medical Devices will be adapted to reflect this.

We would like to emphasize that this change is limited to the above mentioned regulatory decision and that no change will be made on the product itself in terms of manufacturing processes or materials of construction used and **we can confirm that the quality of the Pall Point-of-Use Water Filters remains unchanged**. This decision is not related to the implementation of the Medical Device Regulation (EU) 2017/745 and Pall Medical's ability to meet the MDR requirements. There is also no change to our ISO 13485:2016 and ISO 9001:2015 certifications.

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Moreover, the performance and safety of the product remain unchanged: sterile Pall Point-of-Use Water Filters containing sterilising grade filtration membranes will be maintained to efficiently remove waterborne pathogens. For customers requiring water filters that are CE marked medical devices, the Pall Point-of-Use Water Filter products will continue to be supported by our comprehensive validation data and full product traceability will remain in place. The CE marked Water Filters placed on the market before September 12, 2019 can continue to be used by customers.

In view of this decision, it is expected to see a market change in a near future and manufacturers of Water Filters still bearing CE mark, will progressively comply with this regulatory change independently of the country specific guidelines/regulations. We are pleased to share with you that we will be ready to face this regulatory change as of September 12, 2019.

We trust the above information is satisfactory. If we can be of further assistance, please contact your Sales representative.

Sincerely,

Pall International Sàrl

Sandra Racordon-Pape
Director QARA Medical