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Belimed Steam Sterilizers now announced compatible for crisis strategy decontamination of specific single-use FFP (N95) respirators by industry-leading manufacturer 3M

ZUG, SWITZERLAND / CHARLESTON, SC (Oct 1st , 2020) – Can FFP respirators be decontaminated in a steam sterilization cycle for reuse in situations of severe personal protective equipment (PPE) shortage? That question has been explored through collaboration between a world-leading respirator manufacturer, 3M, and a global leader in sterilization solutions, Belimed.

"The expert team at 3M was open-minded and very supportive in evaluating this question," says Markus Auly, Head of Scientific Affairs at Belimed. "After two rounds of testing six different respirator models steam-treated by Belimed, and a thorough technical analysis of the data, 3M felt confident in the compatibility of the process with certain respirator models."

3M's latest version of the Technical Bulletin confirms that one standard 121°C/250°F steam sterilization cycle in Belimed Medical Steam Sterilizer models MST-H or MST-V does not compromise the form, fit and function of their flat-fold respirators.

The benefit of evaluating and confirming compatibility with this standard steam sterilization process is that it is the gold standard among decontamination technologies because of its high microbicidal efficacy, even in the presence of residual soils. Moreover, it is safe to use due to freedom from toxic residues, easy to administer, widely available, and has low processing costs, using only water and electricity.

Steam decontamination of N95 respirators can double the availability of 3M flat-fold respirators during a supply crisis in any healthcare center that has a Belimed Steam Sterilizer MST-H or MST-V.

The process is designed to achieve sterilization (including full inactivation of thermostable bacterial spores) of clean medical devices. Since N95 respirators cannot be cleaned without losing parts of their filtering properties they go to the steam process without prior cleaning and the process is considered only a "decontamination", without claiming that the respirators come out of the process sterile. However, due to the 20 min treatment with 121° hot steam after a prevacuum phase the total risk of applying this method can be considered significantly lower compared to other available methods like steam treatment at lower temperatures, hydrogen peroxide, dry heat or ultraviolet light.

Different countries have taken different paths concerning the use of steam sterilization for contingency reprocessing of FFP respirators. In the Netherlands and Austria a close collaboration between health authorities, infection control specialists and technical research teams concluded that specific commonly used FFP respirators (especially flat folded, valve-less models of high quality) were compatible with at least one standard steam sterilization cycle at 121°C. Corresponding, data was also published in peer reviewed scientific journals like the Brithis medical journal and Journal of Hospital Infection.



Many other countries rejected this option mainly because there was no approval or validation studies from the respirator manufacturers.

Now, with the evaluation by 3M of steam decontamination of FFP respirators, the standard 121°C cycles specific for Belimed's Steam Sterilizer MST-H or MST-V were determined to be compatible with specific 3M respirator models.

Previously, Belimed had cooperated with independent research institutes like the Technical University of Delft, NL on that topic and published a white paper explaining the crisis reprocessing options that different countries known for a high health care standard were adopting to alleviate the scarcity of disposable personal protective equipment (PPE) like FFP respirators, surgical gowns, or face shields. The goal was to share this information with facilities across the globe. The whitepaper can be downloaded on the Belimed website.

"Belimed's number one priority has always been to protect the health and safety of hospital staff and their patients. With our expertise in sterile processing we want to contribute our part and create certainty in uncertain times," says Dominik Arnold, CEO of Belimed. "Now our customers and the healthcare community can be confident to have a reliable fall-back solution in times of short supply of FFP respirators."

For more information please check 3M's technical bulletin "Decontamination of 3M Filtering Facepiece Respirators, such as FFP Respirators, in the – Global Considerations" and Belimed's website (<u>www.belimed.com</u>).

About Belimed

Belimed AG is a leading supplier of medical and surgical instrument sterilization, disinfection, and cleaning products and services. The company, with its headquarters in Zug (Switzerland), has offices in 9 countries around the world and is represented in over 80 countries thanks to a strong network. For more than 50 years we have been continually evolving our technology-driven portfolio; innovating ways to improve reliability, efficiency, and sustainability in central sterile services departments.

As engineers of confidence, we build trust and value by precisely identifying and resolving customer challenges and optimizing requirements to improve their overall work environment. Our complete spectrum of sterile workflow solutions includes planning and design, market-leading equipment, consumables, servicing, data connectivity, education and training.

Our focus is to instill living, breathing, confidence within our customers; empowering them to advance medical care and protect the lives of patients and staff.

For more information, visit www.belimed.com.