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Correction

Change Control No. 017-20: Integrity Test of Sartofluor® filters produced at Yauco, P.R.

Dear Valued Customer,

As an international leading provider of process technologies to the bio-pharmaceutical industry, Sartorius Stedim Biotech GmbH is committed to continuously improving its products and services to best serve its customers.

This letter is intended to inform you about a change that affects our Sartofluor® filters produced at Yauco, Puerto Rico's manufacturing site.

Change description

In the course of the current pandemic of COVID19 affecting all countries worldwide, an increased global demand for air filters have been observed. To ensure security of supply for certain air filters where we see a particularly high demand we change the in-process integrity test from Water Intrusion Test to Diffusion and Bubble-Point testing after wetting the filters with an IPA/Water solution at our production site in Yauco, Puerto Rico. This will allow us to increase our output of filters. The Diffusion and Bubble Point Tests after IPA/Water wetting are established integrity testing methods for air filters and the corresponding Integrity Test values are in place and correlated to the ASTM Bacteria Challenge Test.

All established integrity testing procedures for Sartofluor airfilters in our production site in Goettingen, Germany remain unchanged.

Affected Products:

Affected Products	Part No.
Sartofluor Mini_0.2µm_size9_5pc	5181507T9-----B
Sartofluor Mini_0.2µm_size9_5pc	5181507T9---E--B
Sartofluor Mini_0.2µm_size9_5pc	5181507T9---V--B
OEM – Filter Cartridge, 0.2µm	5182107T0----A-K
OEM-PTFE Filter Cartridge, 0.2µm, 5"	5182107T0----GF
Sartofluor GA Cartridge_0.2µm_5"	5182507T0----GA
Sartofluor GA Cartridge_0.2µm_5" 25pc	5182507T0----GAG
Sartofluor GA Cartridge_0.2µm_5"	5182507T0---EGA
Sartofluor GA Cartridge_0.2µm_5"	5182507T0---TGA
Sartofluor GA Cartridge_0.2µm_5"	5182507T0---VGA
Sartofluor MidiCaps_0.2µm_Size0_2p	5185307T0--SO--V
Sartofluor MidiCaps_0.2µm_size0_2pc	5185307T0--SS--V
Sartofluor MidiCaps_0.2µm_size9_4pc	5185307T9--FF--A
Sartofluor MidiCaps_0.2µm_size9_4pc	5185307T9--NN--A
Sartofluor MidiCaps_0.2µm_size9_4pc	5185307T9--OO--A
Sartofluor MidiCaps_0.2µm_size9_4pc	5185307T9--SO--A
Sartofluor MidiCaps_0.2µm_size9_4pc	5185307T9--SS--A

As a result of the change, the Quality Assurance Certificate of Release of these products produced in Yauco needs to be updated and changed from Water Intrusion Test to Diffusion and Bubble-Point testing after IPA/Water wetting on the corresponding section:

Current Paragraph:

Integrity test values: Each filter has been individually tested for integrity by Water Intrusion Test.
 For Sartofluor 5" Cartridges: The measured integrity test result corresponds to a WIT value $\leq 7.0\text{ml}/10\text{ min}$, at a test pressure of 2.5 bar / 36 psi which is equivalent to a water flow rate $\leq 0.2\text{ ml/min}$ at a test pressure of 2.5 bar / 36 psi
 For Sartofluor Mini Cartridges and Midicaps size 9: The measured integrity test result corresponds to a WIT value $\leq 4.0\text{ml}/10\text{ min}$, at a test pressure of 2.5 bar / 36 psi which is equivalent to a water flow rate $\leq 0.114\text{ ml/min}$ at a test pressure of 2.5 bar / 36 psi

New Paragraph:

Integrity test values: Each membrane filter element has been individually tested for integrity by means of diffusion and bubble point testing. These tests have been performed according to the procedures stated in the corresponding Validation Guide.

For this filter element the bubble point measured was $\geq 1.0\text{ bar} / 14.5\text{ psi}$.
 (Wetting agent: Isopropanol/ water, 60/ 40 Vol%).

Diffusion rate measured for Sartofluor 5" Cartridges were found to be $\leq 6.0\text{ml/min}$, at a test pressure of 0.7 bar/10psi. (Wetting agent: Isopropanol/water, 60/40 Vol %).

Diffusion rate measured for Sartofluor Mini Cartridges and Midicaps size 9 were found to be $\leq 4.0\text{ml/min}$, at a test pressure of 0.7 bar/10psi. (Wetting agent: Isopropanol/water, 60/40 Vol %).

The 100% in-process testing by diffusion and bubble point provides the same degree of filters integrity assurance as the water intrusion test currently performed. The production process and materials used for Sartofluor® products remain completely unchanged. The function, quality, performance and all specifications of these products remain unchanged. Thus, the change is classified as minor change.

Change Implementation

This change is controlled internally according to our change management procedures and managed with full lot traceability.

Due to the high urgency of our customers' needs of product supply because of the COVID-19 situation, this change needs to be in effect immediately. We kindly ask for your comprehension in regard of QAA breach of the 3-month notification period applicable. The new integrity testing method with IPA will be implemented in our manufacturing processes effective May 22, 2020 and certificates of release for the applicable lots produced will be also changed accordingly.

Should you need any further information or assistance in implementing this change, please reach out to your local Sartorius sales representative.

We thank you for your trust and your continuous use of Sartorius products and look forward to assisting you in managing this change.

Sincerely,



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Sartorius Stedim Biotech



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