

20th April 2023

Change Notification

Sterilisation of Contec Sterile HydroPure

Manufacture by aseptic filling into irradiated components

Dear Distributor

Further to the Change Notification sent out on 21st June 2022 which stated from Jan 2023 we would move to the terminal sterilization of all Contec Sterile HydroPure products we unfortunately need to amend this decision.

Quality is at the forefront of our processes and information gained from recent development batches at full batch scale, indicated we could not achieve a reproducible and coherent product to our required standards using a terminally sterilised process.

To minimise impact on supply, and to allow time for a full root cause analysis within the quality investigation, we will be reverting back to aseptic filling of all Contec Sterile HydroPure products. This process has been used without issue prior to the recent change and will allow for continued product supply. This is not a decision that was taken lightly, however Contec wish to ensure our customers receive high quality products that meet their cleanroom requirements.

Effective Date

This change to aseptically manufactured product will take place with immediate effect. However, implementing the change will mean an extension to the usual lead times for this product. We expect Sterile HydroPure products to be available from 1st July 2023.

In order to get sterile product back into the supply chain as quickly as possible the first few batches of Sterile HydroPure even though aseptically filled with still be labelled with

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 for terminal sterilization by irradiation on the labels.

Over the coming months, we will update all the Sterile HydroPure labelling to reflect that the product is sterile by aseptic processing. The Product Information File (PIF) will also be updated to reflect the move back to aseptic processing and include the new labels.

Affected Products

The products affected by this change are listed in the table below.

Part Number	Description
SBT16HPW	Contec Sterile HydroPure with Water for Injection, Trigger Spray, 1L
SBC16HP	Contec Sterile HydroPure, Capped 1L
SBC56HP	Contec Sterile HydroPure Capped, 5L
SSWC16HP	Contec Sterile Amplitude Theta SATWIPES System with HydroPure 100 wipes

Affected Regions

These changes affect products sold in all EMEA countries.

If you require additional information concerning this notice, please do not hesitate to contact your Contec Sales Representative.

Sincerely,



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