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Change Notification – BioClean BCGS1 EtO sterilization source

July 2023

Dear Valued Customer,

We have received communication from our EtO Sterilization supplier, Steris Sterilization (M) Services, that they have decided to decommission their EtO sterilization line for the BioClean BCGS1 goggles and will cease activity on this line from 1st of Oct 2023.

A new supplier called Hospitech Manufacturing Services SDN. BHD has been selected to replace Steris to sterilize the goggles. We are preparing the samples to run the dose mapping validation of the BioClean BCGS1 at Hospitech, with the plan to start EtO sterilization at Hospitech as of September 2023 production.

With this timeframe in place we do not foresee any disruption to the sterilization process or supply of the goggles. Please also note the new sterilization facility in no way changes the design, quality or performance of this product.

An example of the Hospitech Certificate of Processing (COP) is shown below:



EG-PBC-C001 Rev 0
 Certificate No. 0001

HOSPITECH
MANUFACTURING SERVICES

HOSPITECH MANUFACTURING SERVICES SDN. BHD
 199601034155 (406507-H)

CERTIFICATE
OF ET0 STERILIZATION

CUSTOMER : _____
 ADDRESS : _____

PRODUCT DESCRIPTION: _____
 PRODUCT CODE: _____
 STERILIZATION BATCH NO. _____ LOT NO. _____

STERILIZATION DATE	QUANTITY OF CARTONS	REMARKS

IT IS HEREBY CERTIFIED THAT THE ABOVE MENTIONED STERILIZATION PROCESS HAS PASSED THE SET QUALITY CONTROL PARAMETERS

APPROVED BY : _____
 NAME : _____
 TITLE : _____
 DATE OF ISSUE :

The Certificate of Processing (COP) will be downloadable via the online certificate page on www.ansell.com/life-sciences/certificates as soon as they become available. Click on the BioClean™ link and enter the product lot number or sterilization batch/lot number where prompted to retrieve the certificate.

The new EtO sticker will appear on the outside of the carton, an example of what it will look like before and after sterilization is shown below:



Before sterilization sticker



After sterilization sticker

Should you have any questions regarding any items covered by this announcement please contact your local Ansell Nitritex customer service or sales representative.

Thank you for your continued loyalty and support.

Yours faithfully,

François le Jeune
Chief Commercial Officer
EMEA/APAC

Martijn Spaans
Director Sales, Life Sciences Solutions
EMEA/APAC