Ansell Healthcare Europe NV/SA

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19/12/2024

Addendum to LSCCN049 - Additional sterilization facility products announcement

Dear Valued Customer,

As part of the earlier announcement, LSCCN049 - Additional sterilization facility – Ansell Melaka, Malaysia, we would like to hereby announce that we would also be extending the sterilization process to the rest of the BioClean™ product portfolio as per below, in addition to those products that have already been listed in the previous announcement.

The additional products are listed as follows.

Styles			
BioClean™-BLAS	BioClean™-S-BCRL	BioClean™-MEA210-1	BioClean™-BISW
BioClean™-BASL	BioClean™-GGL15NIT59	BioClean™-MTA210-1	BioClean™-S-BIWP 9
BioClean™-BENS	BioClean™-GGL20NIT59	BioClean™-VFM-L	BioClean™-S-BIWP 12
BioClean™-BSNS	BioClean™-GGL10NIT59	BioClean™-VFM-T-SLOT	BioClean™-S-BCPM
BioClean™-S-BFAP	BioClean™-GGL36NIT59	BioClean™-BDBS	BioClean™-S-CPE-16
BioClean™-BUPS	BioClean™-GGL30NITM9	BioClean™-BDBS-G	BioClean™-S-BPBP-1
BioClean™-BEXS	BioClean™-GSL15NITPP26	BioClean™-BOWS 9	BioClean™-S-BPFP
BioClean™-BPZS	BioClean™-GSL20NITPP26	BioClean™-BOWS 9B	BioClean™-S-BBPN
BioClean™-BPSL	BioClean™-GSL33NITPP26	BioClean™-BOWS 12	BioClean™-BAFS 601
BioClean™-AL300	BioClean™-GSL36NITPP26	BioClean™-BOWS 18V	

For now, dose validations are being conducted for these products according to the plant's schedule, so please do expect the official implementation to vary according to the time frame of validation completion. The sterilizations for these products will be conducted in time in the same three premises as stipulated in LSCCN049. In addition, the indication of the sterilization will be also following the same process mentioned in LSCCN049. Once sterilized, the Certificate of Irradiation (COI) from either sterilization center will be available online via the link; https://www.ansell.com/eu/en/certificates/life-sciences. Moving forward in future, please be informed that all our BioClean™ sterile product range will be sterilized in these 3 premises.

Please contact your local Ansell Customer Service department or your local Ansell sales representative if you have any questions regarding any of the information contained within this announcement.

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Thank you for your continued loyalty and trust in Ansell.

Best regards,
Suresh Chandra Bose
Sr Manager, Product Portfolio
GPMO BU Clean Room