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June 2023
Ref: LSCCN047

Change Notification - BioClean™ coverall & garment accessories new aseptic fold

Dear Valued Customer,

As you're aware EU GMP Annex 1 is being implemented in August, to ensure you meet the requirements set out in the guidelines (shown below) when using BioClean™ coveralls and garment accessories, we are pleased to announce an improvement to the current fold process to enable aseptic donning, and where applicable, legs of coveralls/apron ties etc. do not touch the floor.

Part 7.13 of Annex 1 highlights garments should be packed and folded in such a way as to allow operators to don the gown without contacting the outer surface of the garment and to prevent the garment from touching the floor.

This new aseptic folding method means that the coveralls will now be packed unzipped with the chest area opened and folded back around the arms and legs. Garment accessories and aprons will be folded to ensure operators will only touch the inside of the garment when taking the item out of the packaging, this will enable aseptic donning and avoid the risk of cross contamination.

The full list of styles which will be aseptically folded are listed below in table 1

Table 1.

Product Styles
S-BDLC/ BDLC
S-BCAS/ BCAS
S-BCDA/ BCDA
S-BDHD-L/ BDHD-L
S-BDOB/ BDOB
S-BDOB-L/ BDOB-L
S-BDCCT/ BDCCT
S-BDCHT/ BDCHT
S-BDFC/ BDFC
S-BAKCT BioClean-D Kit (S-BDCCT + S-BDHD-L + S-BDOB)

S-BDHB BioClean- D Kit (S-BDCHT + S-BDOB)

Please refer to the attached presentation for before and after images of the folded products.

A donning video, guide and other supporting collaterals for the aseptic fold are being created and will be shared with you via the marketing team ASAP.

The 'production' implementation date for this new fold is May 2023, and will be a rolling change, you will start to see product folded in the new aseptic fold delivered once current stock is depleted.

Please rest assured that this change does not affect the garment form, function, or fit and the product specification remains the same.

Discontinued product styles – BCAS-1, S-BCAS39, S-BDCCT-1, S-BDFC-1, S-BDHD-L1, S-BDOB-1

Please refer to the table below for a list of discontinued styles which will be automatically replaced with the new aseptically folded standard style codes.

Discontinued style code	Standard replacement style code
BCAS-1	BCAS
S-BCAS39	S-BCAS XL
S-BDCCT-1	S-BDCCT
S-BDFC-1	S-BDFC
S-BDHD-L1	S-BDHD-L
S-BDOB-1	S-BDOB

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

Martijn Spaans



Chief Commercial Officer
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