CORNING

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Life Sciences
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978/442-2200

September 5, 2018

Subject: Costar® Stripette™ Serological Pipette Qualification of Alternative Sterilization Method - Plastic Wrap and Bulk Packaging Styles

Dear Valued Customer,

Thank you for choosing Corning Laboratory Products. We appreciate your continued business. The reason you are receiving this letter is because you have requested to receive product change information from Corning.

To further improve the service of our Costar® Stripette™ serological pipettes, we have qualified an alternative method of sterilizing product using electron beam irradiation also referred to as E-Beam. Today, product is sterilized using gamma irradiation. Both E-Beam and gamma are industry recognized radiation based sterilization techniques. We consider both methods of sterilization qualified and acceptable for the affected products.

There is no change to the sterility assurance level (SAL). There is also no impact to product form, fit and/or function. Both E-Beam and gamma are industry recognized radiation based sterilization techniques per the ANSI/AAMI/ISO 11137 standard. This change has been qualified per the requirements in the ANSI/AAMI/ISO 11137, Sterilization of Health Care Products - Radiation standard. All inspections and testing performed have met the requirements per the standard as well as Corning Life Sciences internal requirements.

1) A dose audit was performed utilizing the E-Beam sterilization mode to demonstrate that the differences in operating conditions between gamma and E-Beam have no affect on microbicidal effectiveness.

2) The differences in irradiation conditions between gamma and E-Beam do not affect the validity of the maximum dose based on material compatibility per AAMI TIR17, Compatibility of materials subject to sterilization. Product was sterilized via E-Beam at the maximum dose and visual and functional testing was completed to include appearance, pipet volumetrics, chemical resistance, and poly paper pipet peel testing.

3) The contract sterilizer executed Performance Qualification Dose Mapping Protocols for each pipet processing group to obtain the distribution of absorbed dose across the product and to establish the processing parameters required to achieve the Sterility Assurance

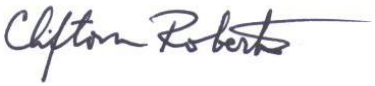
Effective Date of Change: October 2018

Affected Products: 4010, 4011, 4012, 4020, 4021, 4050, 4051, 4100, 4101, 4250, 4251, 4484, 4491, 4492, 4500, 4501, 9099, 9199

CCNN 2018-0035

For more information regarding this change please contact your local Corning representative, technical support or *customer service (1-800-492-1110) or email us at* [*scientificsupport@corning.com*](mailto:scientificsupport@corning.com) .

Sincerely,



Clifton Roberts
Product Line Manager, Liquid Handling

David Matheus
Regional Quality Manager, NA

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