



PRODUCT CHANGE NOTIFICATION

11 May 2018

Notification ID: CN-180501

Notification Type: Component Specification Change

Dear Customer,

We would like to take this opportunity to notify you of a change to the D-value specification for *3M™ Attest™ Rapid Readout Biological Indicator 1294-S for Ethylene Oxide Sterilization* and *3M™ Attest™ Biological Indicator 1264-S for Ethylene Oxide Sterilization*. See attached notification dated July 19, 2017 which Mesa recently received from 3M.

This change notification impacts the following PCD catalog numbers:

PCD 0.6	PCD 3.9	PCD 5.92
PCD 0.9	PCD 4.6	PCD 6.6
PCD 2.6	PCD 4.9	PCD 6.9
PCD 2.9	PCD 5.4	PCD 7.6
PCD 3.6	PCD 5.62	PCD 7.9

There is no impact to performance of the PCD due to this change, as the 3M biological indicators have not changed. The specification change was made due to the elimination of the use of Oxyfume industry-wide. An article published December 2014 in *Pharmaceutical Technology* further examines this change; it is available on our website as *Spore News Vol. 11 No. 5*. <https://biologicalindicators.mesalabs.com/newsletter/>. The reference is included below¹.

There are no changes to Mesa labeling or certifications due to this change in 3M's specification. A copy of the biological indicator manufacturer's certificate of analysis is included with each PCD shipment. Our customers may notice that this change has already been made in the Product Description section of 3M's instructions for use.

As always, if you have any questions, please contact your Mesa Laboratories Representative.



Robert Bradley, Director - Manufacturing

11 May 2018

Date



Janis E. Smoke, Director - Quality & Regulatory Affairs

11 May 2018

Date

Attachment:

3M Change Notification dated July 19, 2017

¹G. Krushefski et al., "Effects of 100% Ethylene Oxide Test Gas on the Resistance of Ethylene Oxide Biological Indicators," *Pharmaceutical Technology* 38 (12) 2014.



3M Health Care

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July 19, 2017

Subject: Notification of impending change in D-value specification for 3M™ Attest™ Rapid Readout Biological Indicator 1294-S for Ethylene Oxide Sterilization and 3M™ Attest™ Biological Indicator 1264-S for Ethylene Oxide Sterilization.

Dear Valued Customer:

This correspondence is intended to advise you that 3M will be changing the minimum D-value specification for both the Attest 1264-S and Attest 1294-S biological indicators for ethylene oxide (EO). This change is to maintain alignment with the new D-value specifications in the recently published ISO 11138-2:2017, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*. The minimum D-value specification for these 3M biological indicators (BIs) will change from 2.5 minutes to 2.0 minutes.

There are no changes in design, materials, or manufacturing processes for the 3M Attest 1264-S or the Attest 1294-S, associated with this specification change. The change is simply to maintain alignment with the published international standards.

Background: The ISO working group responsible for standards that define the performance of biological indicators, ISO TC198, WG 4, has recently completed the revision process for the ISO 11138 series standards. During the revision of Part 2 (biological indicators for EO), the Working Group decided to make a change to the D-value specification as data generated and published by members of the Working Group indicated that the D-value of EO BIs can depend on whether the BI is tested in a mixed gas or 100% EO. A copy of the 3M Notification, with its reference to the publication and further background on the reasons for this change, are attached to this letter.

Timing: This change in specification will occur in the 4th quarter of 2017. A subsequent correspondence will detail the first lot number with the new specification, for both products.

Please feel free to contact me if you require additional information.

Sincerely,

Craig Wallace
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