

PRODUCT CHANGE NOTIFICATION

June 08, 2020

Notification ID: CN-200501 Rev B

Notification Type: Product Labeling Change

Dear Customer,

We would like to take this opportunity to notify you of a change that will be made to the certificate of analysis for Mesa Catalog #: PL-3-6-15.

ProLine is a process challenge device (PCD) utilized for monitoring the sterility assurance level of tubing. Because this device is adulterated from its original form, by adding varying lengths of tubing, Mesa does not perform resistance testing directly on the finished ProLine PCD itself. Instead, resistance testing is performed on a paper disc in a standard 1" x 3" glassine envelope. The resulting D-value is intended to serve as a reference so that the customer will know how resistant the bacterial spores of a given lot of ProLine are compared to previous lots of ProLine they have received.

The impending changes are as follows:

- The reference D-value will switch to using a 0.25" x 1.5" paper strip in a standard 1" x 3" glassine envelope.
- There will no longer be a Z-value or USP calculated Survival and Kill values listed on the CoA.
- The CoA will be updated to state, "Units are manufactured in compliance with Mesa Laboratories' quality standards, ISO 11138 guidelines and all appropriate subsections with the exception of z-value and calculated survival and kill times".

This change is being made because Mesa has minimal historical resistance data on paper discs in glassine so it limits the level of support we can provide customers who are trying to identify what products are appropriate for their sterilization cycles. Switching to a paper strip in glassine will allow Mesa to utilize decades of historical data to support customers with their sterilization needs.

Mesa will also be removing the Z-value and USP calculated Survival & Kill values listed on the CoA, as these are values based off of the reference D-value and not a direct measurement of resistance on the finished ProLine PCD.

No changes are being made to the actual device, only to the reference D-value listed on the CoA. This change will become effective with the next lot manufactured, lot #PL-007. Please see attachment 1 for a draft of the updated Certificate of Analysis.

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



Robert Bradley
Sr. Director - Bozeman Operations

08 Jun 2020

Date



Nicole DeWald
Manager - Quality Assurance

08 Jun 2020

Date

