



MesaLabs

PRODUCT CHANGE NOTIFICATION

Notification ID: CN-171005

Notification Type: Change in Product Specification for ProLine Steam

23 October 2017

Dear Valued Customer,

The resistance data reported on the Certificate of Analysis for our ProLine Steam product (Catalog # PL-3-6-15) was the result of assembled ProLine units being exposed in our steam resistometer. Cycles where fraction-negative data was obtained were used to calculate the D-value. Since the intended use of the ProLine is for validation of the sterilization of tubing, and the diameter and length of the tubing can vary greatly per customer, any resistance data reported on the CofA should be viewed as 'for reference only' by the end user.

Moving forward, resistance data will be collected on the inner paper disc carrier packaged in glassine only and not inside the fully-assembled ProLine unit. This change will occur starting with the initial lots of Proline Steam product manufactured at our new Zoot location in Bozeman, MT.

Sincerely,


Robert Bradley, Director of Production 23 Oct 2017
Date


Janis E. Smoke, Director of Quality & Regulatory Affairs 23 Oct 2017
Date