



MesaLabs

PRODUCT CHANGE NOTIFICATION

June 28, 2017

Notification ID: CN-170604

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 all Certificates of Conformance for PCD products. This change notification impacts all PCD catalog numbers.

Beginning with the first PCD lots to be released from Bozeman's manufacturing facility located at 625 Zoot Way, Bozeman MT 59718, the following changes will be made to PCD Certificates of Conformance:

- The address of the manufacturing facility will be changed.
- PCD manufacturing date will be formatted per 21 CFR 801.18.
- The reference to the organism strain will no longer be reported on the Certificate of Conformance as this is duplicated from the BI manufacturer's certificate. The genus and species will continue to be reported.
- Mesa's Liability and Indemnity Policy will be added.
- Certificates will be assigned new part numbers and revision numbers, located in the footer.
- The footer will be reformatted to include only the certificate part and revision number.

An example of a revised certificate is attached.

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


Robert Bradley, Director of Production


Date


Janis E. Smoke, Director of Quality & Regulatory Affairs


Date



By Mesa Labs
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 Phone: (303) 987-8000 www.mesalabs.com

CERTIFICATE OF CONFORMANCE

Product Description: Process Challenge Device
PCD Reorder/Part Number: PCD 4.5
PCD Lot: ENTER LOT
PCD Pouch Lot No.: ENTER POUCH LOT
Pouch Material Lot No.: ENTER MATERIAL LOT
PCD Manufacturing Date: YYYY-MM-DD

BI Manufacturer: Mesa Laboratories
BI Manufacturer's Part Number: SGMG/6
Organism: *Bacillus pumilus*
BI Manufacturer's Lot: USE MFG'S FORMAT
BI Manufacturer's Expiration Date: USE MFG'S FORMAT
BI Manufacturer's Spore Population: USE MFG'S FORMAT
BI Manufacturer's D₁₀₀ Value: USE MFG'S FORMAT

This document certifies that this lot of Process Challenge Devices meets Mesa Labs' quality specifications. Please see the BI manufacturer's certificate accompanying this shipment for all other information.

Mesa Labs is registered to ISO 13485 standards.

LIMITATION OF LIABILITY AND INDEMNITY: In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer's Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to injuries to employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.

Mesa Labs Quality Assurance

Date