



PRODUCT CHANGE NOTIFICATION

September 18, 2017

Notification ID: CN-170901

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 certificates of conformance for the following Mesa Catalog Numbers:

- 77-05-CI-BD110 ProChem Lead-Free Bowie-Dick Test Sheet
- 77-05-CI-BDTLF Mesa Labs ProChem Bowie-Dick Test Pack
- 77-05-CI-BDTLF20 Mesa ProChem Bowie-Dick Test Pack
- 77-05-CI-BDTLF121 Mesa ProChem BD 121 Bowie-Dick Test Pack
- 77-05-CI-BDTLF121-20 Mesa ProChem BD 121 Bowie-Dick Test Pack
- 77-05-CI-DHI Mesa Dry Heat Indicator Labels
- 77-05-CI-EXT ProChem EXT
- 77-05-CI-OK ProChem OK Cycle
- 77-05-CI-SSIX ProChem SSE Emulator

Effective immediately, the certificates of conformance for these products will be changed as follows:

- The address has been changed to reflect the decommissioning of our Omaha facility, resulting in testing and distribution of these products from a new facility in Bozeman, MT.
- A certificate part and revision number has been added to the footer.
- The indications for use have been expanded to include the full indications for use in our product labeling.
- The compliance statement has been revised to align with the manufacturer’s certificate and with Mesa testing procedures.
- Formatting changes throughout, not considered changes to content, to align with formatting of other site documents.

Examples of the revised certificates are attached.

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


 Robert Bradley, Director of Production 18 Sep 2017
Date


 Janis E. Smoke, Director of Quality & Regulatory Affairs 18 Sep 2017
Date

CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Bowie-Dick Test Sheets
Catalog No.: 77-05-CI-BD110
Lot Number:
Expiration Date:
Product Description: The ProChem Lead-Free Bowie-Dick Test Sheet is for daily monitoring of pre-vacuum sterilizers operating at 134 °C for 3.5 minutes. The test sheet is designed for use with Bowie-Dick towel packs assembled at the health center as described in ISO 11140-3.
Indications for Use: The indicator sheet will change from blue to black when exposed to a steam sterilization cycle with acceptable vacuum cycles.

The manufacturer of this product certifies that the ProChem Lead-Free Bowie-Dick Test Sheet conforms to all applicable portions of ISO 11140-1 Type 2 indicators for use in specific tests and ISO 11140-3; certifies compliance with the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations 21 CFR Part 820 for all manufacturing and testing procedures; and declares that the chemical indicator sheet does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 2 process indicators.

Certified by: _____

Quality Representative

_____ Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Mesa ProChem Bowie-Dick Test Pack
Catalog No.: 77-05-CI-BDTLF
Lot Number:
Expiration Date:
Product Description: The Mesa Labs ProChem Bowie-Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 132 °C (270 °F) for 3.5 minutes.
Indications for Use: Color Change:
132 °C – Pink to Black
121 °C – Pink to Brown

The Mesa Labs ProChem Bowie-Dick Test Pack has received 510(k) clearance by the United States Food and Drug Administration (FDA).

The manufacturer of this product certifies that the Mesa Labs ProChem Bowie-Dick Test Pack conforms to all applicable portions of ANSI/AAMI/ISO 11140-5, and declares that the chemical indicator sheet does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 2 process indicators.

Certified by: _____

Quality Representative

_____ Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Mesa ProChem Bowie-Dick Test Pack
Catalog No.: 77-05-CI-BDTLF20
Lot Number:
Expiration Date:
Product Description: The Mesa Labs ProChem Bowie-Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 132 °C (270 °F) for 3.5 minutes.
Indications for Use: Color Change:
132 °C – Pink to Black
121 °C – Pink to Brown

The Mesa Labs ProChem Bowie-Dick Test Pack has received 510(k) clearance by the United States Food and Drug Administration (FDA).

The manufacturer of this product certifies that the Mesa Labs ProChem Bowie-Dick Test Pack conforms to all applicable portions of ANSI/AAMI/ISO 11140-5, and declares that the chemical indicator sheet does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 2 process indicators.

Certified by:

Quality Representative

Date

CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Mesa ProChem BD 121 Bowie-Dick Test Pack
Catalog No.: 77-05-CI-BDTLF121
Lot Number:
Expiration Date:
Product Description: The ProChem BD 121 Test Pack is for daily monitoring of pre-vacuum steam sterilizers at 121C for 11 minutes. The BD 121 is designed to operate in sterilizers with sub-atmospheric or trans-atmospheric cycles.
Indications for Use: The indicator will change from red violet to black when exposed to a steam sterilization cycle with acceptable vacuum cycles.

The manufacturer of this product certifies that the ProChem BD 121 Bowie-Dick Test Pack conforms to all applicable portions of ISO 11140-1 Type 2 indicators for use in specific tests and ISO 11140-4; certifies compliance to the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations 21 CFR Part 820 for all manufacturing and testing procedures; and declares that the chemical indicator sheet does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 2 process indicators.

Certified by: _____

Quality Representative

_____ Date

CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Mesa ProChem BD 121 Bowie-Dick Test Pack
Catalog No.: 77-05-CI-BDTLF121-20
Lot Number:
Expiration Date:
Product Description: The ProChem BD 121 Test Pack is for daily monitoring of pre-vacuum steam sterilizers at 121C for 11 minutes. The BD 121 is designed to operate in sterilizers with sub-atmospheric or trans-atmospheric cycles.
Indications for Use: The indicator will change from red violet to black when exposed to a steam sterilization cycle with acceptable vacuum cycles.

The manufacturer of this product certifies that the ProChem BD 121 Bowie-Dick Test Pack conforms to all applicable portions of ISO 11140-1 Type 2 indicators for use in specific tests and ISO 11140-4; certifies compliance to the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations 21 CFR Part 820 for all manufacturing and testing procedures; and declares that the chemical indicator sheet does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 2 process indicators.

Certified by: _____

Quality Representative

_____ Date

CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: Mesa Dry Heat Indicator Labels

Catalog No.: 77-05-CI-DHI

Lot Number:

Expiration Date:

Product Description: Mesa Dry Heat Indicator Labels are designed for use in dry heat sterilizers operating at 160 °C.

Indications for Use:

- 1) All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
- 2) Affix pressure sensitive label to each item to be sterilized.
- 3) Sterilize item as usual in Dry Heat Sterilizer.
- 4) Chemical indicator bar turns from green to dark brown/black in approximately 10 minutes at 160 °C.
- 5) If indicator bar has not completed color change from green to dark brown/black, investigate as a cycle failure.

Mesa Dry Heat Indicator Labels should be stored at room temperature. Protect from moisture and excessive humidity. Labels are valid for three years beyond the date of manufacture. The first four digits of the Lot number indicate the year and month of manufacture (YY/MM).

The Mesa Labs Dry Heat Indicator Labels has received 510(k) clearance by the United States Food and Drug Administration (FDA).

The manufacturer of this product certifies it to be in full compliance with product specifications.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to dry heat at 160 °C + 5.0 °C for 10.0 min ± 1 min.

Certified by:

Quality Representative

Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: ProChem EXT
Catalog No.: 77-05-CI-EXT
Lot Number:
Expiration Date:
Product Description: ProChem EXT is for use at 121 °C or 132-135 °C.
Indications for Use: When used as directed, ProChem EXT integrator strips provide immediate visual confirmation of adequate steam penetration into packs.

During exposure to steam, the indicator strips turns from green to black. If the strips become as dark or darker than the color standard, sterilization conditions were met at the point of placement.

ProChem EXT has received 510(k) clearance by the United States Food and Drug Administration (FDA).

The manufacturer of this product certifies that the product was manufactured and approved for use in compliance with quality control tests required by ISO 11140-1.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 5 process indicators.

Certified by:

Quality Representative

Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: ProChem OK Cycle

Catalog No.: 77-05-CI-OK

Lot Number:

Expiration Date:

Product Description: The ProChem O.K. Cycle chemical integrator strips are designed for use in pre-vacuum steam sterilizers operating at 121 °C and at 134 °C.

Indications for Use: Used as directed, the ProChem O.K. Cycle integrator strips give visual confirmation that sterilization conditions were met at point of placement in the sterilizer chamber.

During steam sterilization, the four indicator spots change from purple to green.

The manufacturer of this product certifies that the ProChem O.K. Cycle integrator strips satisfies performance requirements after exposure to dry saturated steam when testing under the conditions of EN ISO 11140-1; certifies that this chemical indicator is classified as a Type 5 integrating indicator as specified by EN ISO 11140-1; certifies compliance to the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations 21 CFR Part 820 for all manufacturing and testing procedures; and declares that the chemical indicator does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 5 process indicators.

Certified by:

Quality Representative

Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: ProChem SSE Emulator

Catalog No.: 77-05-CI-SSIX

Lot Number:

Expiration Date:

Product Description: The ProChem SSE Emulator is for use in a pre-vacuum steam sterilization process operating at 132 °C for 4 minutes or 135 °C for 3 minutes. When used as directed, the ProChem SSE Emulator strips give visual confirmation that sterilization conditions were met at the point of placement in the sterilizer chamber.

Indications for Use: When used as directed, the ProChem SSE Emulator strips give visual confirmation that sterilization conditions were met at the point of placement in the sterilizer chamber.

During steam sterilization, the indicator bar changes from purple to green.

The manufacturer of this product certifies compliance to the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations 21 CFR Part 820 for all manufacturing and testing procedures; declares that the chemical indicator does not contain toxic substances in quantities harmful to the health of individuals before, during, or after exposure to sterilization processes; and claims the product remains stable after exposure to steam and may be kept as a permanent record.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 6 process indicators.

Certified by:

Quality Representative

Date