



MesaLabs

## LABELING AND TESTING CHANGE NOTIFICATION

08 Apr 2019

**Notification ID:** CN-190202

**Notification Type:** Product Labeling and Testing Change

Dear Customer,

We would like to take this opportunity to notify you of a change that will be made to the Certificates of Compliance for the Mesa Chemical Indicator Catalog Numbers in the table below.

Effective 08 July 2019, the Certificates of Compliance accompanying each shipment of chemical indicators will be issued by the manufacturer of the chemical indicator. Mesa will no longer issue a Certificate of Compliance.

The change is being made because Mesa will no longer verify performance of each lot prior to distributing to our customers. Mesa has verified performance of these private-labeled products for many years and has not confirmed any failure to perform as required per the relevant ISO 11140 standard. Mesa has fully qualified the Manufacturer as a Critical Supplier, and maintains oversight of the Manufacturer according to our approved procedure QS-203 *Selection and Evaluation of Suppliers*.

The Manufacturer's Certificate of Compliance accompanying each shipment will report the same information as was reported in Mesa's Certificates, with the following exceptions:

- The statement that Mesa tested the product to confirm performance will be removed.
- The certificates will be issued by the Manufacturer on behalf of Mesa Laboratories, and therefore the certificate part and revision numbers will be changed. The new certificate part numbers are provided in the table below.
- The prefix "77-05-" will be removed from the part number. This was an internal designation that was not part of the part number in all other product labeling. The part number on the certificate of conformance will match all other product labeling.
- The indications for use will not be included in the new certificate of conformance. The indications for use are provided in the Directions for Use, either as an enclosure in the secondary packaging or on the product labeling. The labeling part number and location where the Directions for Use are found are provided in the table below. **The Indications for Use have not changed**, nor have any of the part numbers by which the Indications for Use are provided to the user.
- For CI-DHI only, the Certificate of Compliance from the manufacturer will include additional information regarding the product's regulatory status.

Sample Certificates of Compliance which are attached to this notification.

**PRODUCTS INCLUDED IN THIS CHANGE NOTIFICATION**

Mesa Catalog Number / Product Name	Mesa Certificate Part Number (obsolete)	Manufacturer's Certificate Part Number (current)	Directions for Use Part Number / Location
CI-BD110 Bowie Dick Test Sheets	7973	COC-PL243	DF-019 Insert
CI-BDTLF ProChem Bowie-Dick Test Pack	7972	COC-PL246	BP-056 Labeling
CI-BDTLF20 ProChem Bowie-Dick Test Pack	7971	COC-PL246	BP-056 Labeling
CI-BDTLF121 ProChem BD 121 Bowie-Dick Test Pack	7970	COC-PL791	DF-791 Insert
CI-BDTLF121-20 ProChem BD 121 Bowie-Dick Test Pack	7969	COC-PL791	DF-791 Insert
CI-DHI Dry Heat Indicator Labels	7974	COC-PL191	LB-013 Labeling
CI-OK ProChem OK Cycle	7978	COC-PL334	DF-162 Insert
CI-SINT ProChem SSI	7967	COC-PL140	DF-236 Insert DF-236-1 Labeling

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

  
 Robert Bradley  
 Director – Manufacturing
 
  
 Date

  
 Nicole DeWald  
 Manager – Quality Assurance
 
  
 Date

**ATTACHMENTS** Sample Manufacturer's Certificates of Compliance

## Certificate of Compliance

Product(s) Name(s) ProChem SSI

Catalogue Number	Lot Number	Expiration Date
CI-SINT		

The ProChem SSI strips are designed for utilization in steam sterilization cycles operating at 132°C - 135°C (270°F - 276°F) for 3 minutes or longer.

The manufacturer of this product certifies that the ProChem SSI strips conforms to all applicable portions of ANSI/AAMI/ISO 11140-1 Type 4 test methods

The manufacturer 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.

The manufacturer 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.

Certified by the Manufacturer's Quality Representative:

*Jon Battigliano*

Director, Regulatory Affairs and Quality Assurance

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Manufactured for:  
Mesa Laboratories, Inc.  
625 Zoot Way, Bozeman MT 59718  
Phone: 303-987-8000 mesalabs.com

COC-PL140-Rev.C

## Certificate of Compliance

Product(s) Name(s): Dry Heat Indicator Label

Catalogue Number	Lot Number	Expiration Date
CI-DHI		

Dry Heat Indicator Labels are designed for use in dry heat sterilizers at 160°C. The label provides clear identification of processed and unprocessed items. When used as directed, dry heat indicator labels give visible confirmation that the sterilized item was exposed to dry heat.

The manufacturer of this product certifies the dry heat label conforms to all applicable portions of ISO 11140-1, Type 4 multicritical process variable indicators and FDA requirements for process indicator status.

The manufacturer certifies the Dry Heat Indicator Label has received 510(k) approval by the United States Food and Drug Administration (FDA).

Certified by the Manufacturer's Quality Representative:

*Jon Rutigliano*

Director, Regulatory Affairs and Quality Assurance

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Manufactured for:  
Mesa Laboratories, Inc.  
625 Zoot Way, Bozeman MT 59718  
Phone: 303-987-8000 mesalabs.com

COC-PL191-Rev.B

## Certificate of Compliance

Product(s) Name(s): ProChem Lead Free Bowie-Dick Test Sheet

Catalogue Number	Lot Number	Expiration Date
CI-BD110		

ProChem Lead Free Bowie-Dick Test Sheet is for daily monitoring of pre-vacuum steam 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.

The manufacturer of this product certifies 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.

The manufacturer 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.

The manufacturer also declares compliance with the requirements set out by the U.S. Food and Drug Administration (FDA) Quality System Regulations CFR 21 Part 820 for all manufacturing and testing procedures.

Certified by the Manufacturer's Quality Representative:

*Jon Rutigliano*

Director, Regulatory Affairs and Quality Assurance

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Manufactured for:  
Mesa Laboratories, Inc.  
625 Zoot Way, Bozeman MT 59718  
Phone: 303-987-8000 mesalabs.com

COC-PL243-Rev.B

## Certificate of Compliance

Product(s) Name(s) ProChem BD 121 Bowie-Dick Test Pack

Catalogue Number	Lot Number	Expiration Date
CI-BDTLF121, CI-BDTLF121-20		

The ProChem BD 121 Test Pack is for daily monitoring of pre-vacuum steam sterilizers operating at 121°C for 11 minutes. The BD 121 is designed to operate in sterilizers with sub-atmospheric or trans-atmospheric cycles.

The manufacturer of this product certifies that the ProChem BD 121 Test Pack indicator conforms to all applicable portions of ISO 11140-1 Type 2 indicators for use in specific tests and ISO 11140-4.

The manufacturer 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.

The manufacturer 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.

Certified by the Manufacturer's Quality Representative:

*Jon Rutigliano*

Director, Regulatory Affairs and Quality Assurance

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Manufactured for:  
Mesa Laboratories, Inc.  
625 Zoot Way, Bozeman MT 59718  
Phone: 303-987-8000 mesalabs.com

COC-PL791-Rev B

## Certificate of Compliance

Product(s) Name(s) ProChem O.K. Cycle Integrator

Catalogue Number	Lot Number	Expiration Date
CI-OK		

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

The manufacturer of this product certifies that the product listed above satisfies performance requirements after exposure to dry saturated steam when tested under the conditions described in EN ISO 11140-1: 2014. This chemical indicator is classified as a Type 5 integrator as specified by EN ISO 11140-1:2014.

The manufacturer 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.

The manufacturer 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.

Certified by the Manufacturer's Quality Representative:

*Jon Rutigliano*

Director, Regulatory Affairs and Quality Assurance



## Certificate of Compliance

Product(s) Name(s): ProChem B-D Bowie-Dick Type Test

Catalogue Number	Lot Number	Expiration Date
CI-BDTLF, CI-BDTLF20		

The ProChem B-D Bowie-Dick Type Test is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 132°C (270°F) for 3.5 minutes. The Test may be exposed for 10 minutes at 121°C (Industrial Users or outside USA).

The manufacturer of this product certifies that the ProChem B-D Bowie-Dick Type Test conforms to all applicable portions of ANSI/AAMI/ISO 11140-5 test methods.

The manufacturer 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.

The manufacturer certifies the Mesa Labs ProChem B-D Bowie-Dick Type Test has received 510(k) approval by the United States Food and Drug Administration (FDA).

Certified by the Manufacturer's Quality Representative:

*Jon Rutigliano*

Director, Regulatory Affairs and Quality Assurance