

LABELING CHANGE NOTIFICATION

06 March 2020

Notification ID: CN-200301

Notification Type: Product Labeling Change

Dear Valued Customer,

We would like to take this opportunity to notify you of a labeling size change on Mesa Labs ProChem SSI Strips CI-SINT.

The bag and Instructions for Use labels will change from a 4x4" to a 3x5" label. The change in size is a cosmetic update and is a better fit for the bag. Please see attachment 1 for current labeling and the new size change.

The anticipated timeline for the new size for the bag and IFU's is June 2020, but it is dependent on customer take rate of our current inventory. Lot 11-2022 will use the current 4x4 labels and future lots will use the new label.

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



Robert Bradley
Sr. Director - Bozeman Operations

06 Mar 2020
Date



Nicole DeWald
Manager - Quality Assurance

06 Mar 2020
Date

ProChem SSI

*For Industrial Use Only in pre-vacuum steam sterilizers
operating for 3 minutes or longer at 132°C - 135°C.
ISO 11140-1 Type 4*

STEAM

Catalog #: CI-SINT

Contains: 250 strips



Do not use after expiration date.



MesaLabs

Manufactured For:
Mesa Labs
625 Zoot Way
Bozeman, MT 59718
303-987-8000 or 1-800-992-6372
btsupport@mesalabs.com
www.MesaLabs.com

LB-269 Rev. G

Current Label 4x4"

ProChem SSI

*For Industrial Use Only in pre-vacuum steam sterilizers operating
for 3 minutes or longer at 132°C - 135°C.
ISO 11140-1 Type 4*

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LB-269 Rev. H

Proposed Label 3x5"

ATTACHMENT 1

ProChem SSI

Catalog #: CI-SINT

INDICATIONS FOR USE:

The ProChem SSI strips are designed for Industrial Use Only in steam sterilization cycles operating at 132°C - 135°C (270°F - 276°F) for 3 minutes or longer. When used as directed, the ProChem SSI gives visual indication that sterilizing conditions were met at point of placement. During steam sterilization, the indicator at the end of the strip changes from white to black.

INSTRUCTIONS FOR USE:

1. Place ProChem SSI strip in each pack, peel-pouch or tray to be steam sterilized at a location in the package considered the most difficult for steam to reach. For larger packs, place a strip in multiple locations in the pack. Strips may be cut in half.
2. Sterilize package as usual in a steam sterilizer.
3. Following the sterilization cycle, visually verify that the indicator at the end of the strips have changed color from white to black.
4. If indicator is white or not as dark as or darker than the reference arrow, consider the cycle failed and the items non-sterile.

SAFETY PRECAUTIONS:

*If there are any doubts about the sterility of the item(s), it must be considered NOT sterile.
*DO NOT use strips with indicator that are not white prior to exposure to steam processing.
* ProChem SSI must not be used in place of biological indicators, but should be used in conjunction with a standard infection control monitoring protocol.*

STORAGE: The ProChem SSI should be stored at 50°-100° F (10-38° C) and 10-60% R.H. inside the sealed ziplock bag.

EXPIRY DATE: The expiry date is printed on the product packaging. Do not use after the expiration date listed on the product packaging.



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DF-236-1 Rev. F

Current Label 4x4”

ProChem SSI

Catalog #: CI-SINT

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DF-236-1 Rev. G

Proposed Label 3x5”