



PRODUCT CHANGE NOTIFICATION

27 June 2018

Notification ID: CN-180606

Notification Type: Component Labeling Change

Dear Customer,

We would like to take this opportunity to notify you of a change to the lot numbering scheme for *3M™ Attest™ Rapid Readout Biological Indicator 1294-S for Ethylene Oxide Sterilization* and *3M™ Attest™ Biological Indicator 1264-S for Ethylene Oxide Sterilization*. See attached notification dated May 14, 2018 which Mesa recently received from 3M.

This change notification impacts the following PCD catalog numbers:

PCD 2.6	PCD 4.9	PCD 6.9
PCD 2.9	PCD 5.4	PCD 7.6
PCD 3.6	PCD 5.62	PCD 7.9
PCD 3.9	PCD 5.92	
PCD 4.6	PCD 6.6	

There is no impact to performance of the PCD due to this change, as the 3M biological indicators have not changed. The labeling change was made due to 3M's implementation of UDI labeling for their products.

There are changes to Mesa labeling of the PCD part numbers above due to this change in 3M's labeling. The primary and carton labels have always included 3M's lot number. Effective immediately, our labeling will include the lot number in the new scheme.

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



 Robert Bradley, Director - Manufacturing

27 Jun 2018

 Date



 Janis E. Smoke, Director - Quality & Regulatory Affairs

27 Jun 2018

 Date

Attachment:

3M Change Notification dated May 14, 2018

3M Health Care


3M Center
St. Paul, MN 55144-
1000 651 733 1000



September 17, 2018

Subject: Addendum to 3M UDI implementation notification for 3M™ Attest™ biological indicators

3M provided a notification of UDI implementation to the 3M™ Attest™ biological indicators dated May 14, 2018. That notification is attached. The intent of this notification is to clarify the format options for the new lot coding. The initial description inaccurate. This provides the accurate description of potential new lot coding format:

- The batch (lot) code is indicated by the lot-in-the-box symbol followed by the batch code (e.g.,  3335JL). Note that the format of the batch (lot) code will be a 6-digit string which may be notated in various formats include: numeric or alphanumeric or letters only.

Please note this clarification and modify your documentation as needed. If further information is required, please contact me directly.

Sincerely,

A handwritten signature in black ink, appearing to read 'Janet Prust'.

Janet Prust
Scientific Affairs and Life Science Segment Sr. Manager
Bldg. 275-4SE-01
Mobile: (612) 306 0324
Email: jmprust1@mmm.com

May 14, 2018

RE: UDI Implementation on 3M™ Attest™ Standard and Rapid Readout Biological Indicator and Test Pack Labels. Cat. #s 1261, 1261P, 1262, 1262P, 1262-S, 1264, 1264P, 1264-S, 1276, 1278, 1291, 1292, 1292E, 1292-S, 1294, 1294-S, 1296, 1298, 41380, 41382

Dear Customer,

3M understands that customers document biological indicator (BI) lot codes and would like to make you aware that the labels for 3M™ Attest™ biological indicators and test packs are being updated as we implement Unique Device Identifier (UDI) compliant labelling to the 'each' level. The new label format will be implemented beginning in May 2018.

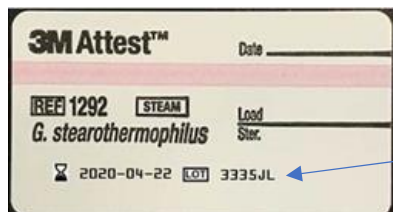
In compliance with the U.S. Food and Drug Administration's UDI format requirements, the product's batch (lot) code and 'Use by Date' date will be provided as two separate data strings on both BI and test pack labels.

- The 'Use by Date' is indicated by an hourglass symbol followed by the 4-digit year, 2-digit month, and 2-digit day of expiration (e.g., ⌚ YYYY-MM-DD)
- The batch (lot) code is indicated by the lot-in-the-box symbol followed by the batch code (e.g., **LOT** 3335JL). Note that the format of the batch (lot) code will be a 6-digit alphanumeric string.

Examples of the new label design for representative steam BI (1292, left) and test pack (41382, right) labels are provided below for your reference. The change is to the labels only, the products have not changed.

Attest™ 1292 Biological Indicator Label

Attest™ Rapid 5 Steam-Plus Pack 41382 Label



Lot Code



Thank you for your continued support of 3M™ Attest™ products. Please contact your 3M representative if you have questions or need additional information.

Sincerely,



Ericka Lutz
Global Marketing Manager
Sterilization Assurance
3M Health Care