

Change Notice No.	Notification date	Implementation date
CN/F/22/009	January 05, 2023	February 05, 2023

Subject : Change in sterilization cycle number of mdi Gamma sterilized products

Scope : This change notification will affect the products with following catalog numbers: (# can be any alphabet or numeral):

- A#####3##
- D#####3##
- F#####3##
- HH#####3##
- I#####3##
- L#####3##
- MH#####3##
- MV#####3##
- Q#####3##
- S#####3##
- VG#####3##
- VN#####3##
- VK#####3##
- VW#####3##
- VFP#####3##

Background:

This change notice has been initiated to update our customers/users regarding the products they are using. The sterilization cycle number of mdi Gamma sterilized products having catalog numbers as mentioned above has been re-defined from existing 04 characters to 05 characters. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

Currently, a sterilization cycles number is assigned to every sterilization cycle of mdi Gamma sterilized products. The sterilization cycle number includes a single alphabet for sterilization type (R) and three numerals as serial number. The serial number starts from 001 at the beginning of every calender year.

As the demand for gamma sterilized products has increased, the requirement for more sterilization cycle numbers has been identified. But, due to limitations in our existing system, the maximum serial number a sterilization cycle number can be assigned in a calender year is 999. To overcome this limitation, it has been decided to use 05 characters sterilization cycle number instead of existing 04 characters sterilization cycle number.

No change has been done in any materials of construction or any performance parameters or any critical dimensions or manufacturing/packaging process.

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How Does It Affect the User:

From a practical point of view, this change only affects the sterilization cycle number of **mdi** Gamma sterilized products having catalog numbers as mentioned above. All performance specifications, product attributes, materials of construction, product packaging and traceability shall remain unchanged. The product/package label as well as related product literature such as certificate of quality, validation guide, product insert etc. will reflect the said changes.

	EXISTING	PROPOSED
Sterilization cycle number	R001	R0001
Description	R stands for Gamma sterilization 001 are 3 numerals assigned as serial number in that particular calender year	R stands for Gamma sterilization 0001 are 4 numerals assigned as serial number in that particular calender year

Implementation of Change:

mdi Gamma sterilized products having catalog numbers as mentioned in scope, sterilized after the implementation date will have the said changes. However, the available stock of **mdi** Gamma sterilized products with catalog numbers as mentioned above and having four characters sterilization cycle number will be received by you till the stocks last.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



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