ADVANCED MICRODEVICES (PVT.) LTD.
21, INDUSTRIAL AREA, AMBALA CANTT –133 001, INDIA
Phone : + 91 - 171 - 2699290, 269947, 2699274
Fax : + 91 - 171 - 2699221, 2699008

Change Notice No.	Notification date	Implementation date
CN/17/27	December 20, 2017	January 20, 2018

Subject : **Change in lot release criteria for mdi pre-sterilized products (EO sterilized)**

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

- A############2##
- C############2##
- CMK30L-S
- D############2##
- DMK30L-S
- E############2##
- F############2##
- G############2##
- H############2##
- I############2##
- L############2##
- M############2##
- N############2##
- P############2##
- R############2##
- S############2##
- V############2##

Background:

In our efforts to keep our customers updated about the changes effected from time to time, certain changes have been done in respective product literature of **mdi** EO Sterilized products with catalog numbers as mentioned above. The sterility testing has been moved from lot release criteria to a validation activity. The EO sterilized products will be released on the basis of compliance to the validated EO Sterilizer's critical performance parameters. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

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Need for Change:

mdi has been manufacturing EO sterilized products with catalog numbers as mentioned above for more than 12 years. Every lot of **mdi** EO sterilized products is sterilized using an EO sterilization process which is validated to assure Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO11135. All critical parameters for EO sterilization cycle such as Sterilant Gas Concentration, Exposure Time, Temperature, Humidity and Load Pattern meet the validated process criteria. In addition to this, every lot of **mdi** sterilized products (EO sterilized) are sampled and tested for Sterility in accordance with United States Pharmacopoeia (USP <71>, STERILITY TESTS).

Based on trend analysis of EO sterilization data and Sterility test results of (EO sterilized)products for the past so many years, it has been decided that the Sterility Test shall be removed from lot release criteria and release of **mdi** Ethylene Oxide (EO) sterilized products with catalog numbers as mentioned above shall be done after verification of critical sterilization cycle parameters as suggested by ISO 11135 (clause - 9: Validation and clause - 10: Routine monitoring and control). However, the Sterility test will still be carried out during regular process validation and will be reflected as part of the validation activity in respective documents. No changes whatsoever have been made in process and product specifications.

The related product literature such as Certificate of Quality (CoQ), Certificate of Sterility (CoS) etc. will reflect the changes to lot release criteria.

How Does It Affect the User:

From the user point of view this change only re-defines the lot release criteria in terms of Sterility Test as suggested by ISO 11135. All other product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said change will be reflected in the accompanying product literature e.g. Certificate of quality, Certificate of Sterility etc.

Implementation of Change:

mdi EO sterilized products with catalog number as mentioned above, sterilized after the implementation date **(January 20, 2018)** will have the said change in the lot release criteria. However, the available stock of **mdi** EO sterilized products with catalog numbers as mentioned above having Sterility Test as lot release criteria will be received by you till the stocks last.

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

Head - Quality Assurance
Advanced Microdevices Pvt. Ltd.