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/18/04	April 10, 2018	May 10, 2018

Subject : Change in lot release criteria for mdi pre-sterilized Products (Gamma sterilized)

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

- AK##########3##
- D##########3##
- F##########3##
- I##########3##
- L##########3##
- Q##########3##
- SY##########3##
- V##########3##

Background:

In our efforts to keep our customers updated about the improvements affected from time to time, certain changes have been made in lot release criteria of **mdi** Gamma sterilized products with catalog numbers as mentioned above. These products are currently being released based on lot sterility testing and shall now be released on the basis of actual dose of Gamma radiations applied to the product against the substantiated sterilization dose. The sterility testing shall still be carried out periodically as required by relevant ISO standards. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

mdi has been manufacturing Gamma sterilized products with catalog numbers as mentioned above for more than 05 years. Every lot of **mdi** Gamma sterilized product is sampled and tested for Sterility in accordance with United States Pharmacopoeia (USP <71>, STERILITY TESTS).

Based on the verification of Gamma sterilization process to assure Sterility Assurance Level (SAL) of 10^{-6} (in accordance with ISO 11137) and Sterility test results of Gamma sterilized products for the past as many years, it has been decided that the Sterility Test shall be removed from lot release criteria and release of **mdi** Gamma sterilized products with catalog numbers as mentioned above shall be done on the basis of actual dose of Gamma radiations applied to the products against the substantiated sterilization dose.

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/18/04	April 10, 2018	May 10, 2018

However, the Sterility test will be carried out during regular sterilization dose audit (as per ISO 11137) 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 change 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 with respect to Sterility Test. 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 Gamma sterilized products with catalog number as mentioned above, sterilized after the implementation date **(May 10, 2018)** will have the said change in the lot release criteria. However, the available stock of **mdi** Gamma sterilized products with catalog numbers as mentioned above having Sterility Test as lot release criteria 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'.

Head - Quality Assurance
Advanced Microdevices Pvt. Ltd.