ADVANCED MICRODEVICES PVT. LTD.
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Change Notice No.	Notification date	Implementation date
CN/F/23/005	October 30, 2023	November 30, 2023

Subject : Change in lot release criteria for mdi Stericheck

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

- SHFC0902#######
- SHLC0902#######
- SHPC0902#######
- SH1#0902#######
- SH2#0902#######
- SH3#0902#######
- SLV#0902#######
- SMLC0902#######
- SMP#0902#######
- SPC#0902#######
- SPF#0902#######
- SVCC0902#######
- SV1#0902#######
- SV2#0902#######
- SV3#0902#######
- SV4#0902#######

Background:

In our efforts to keep improving our products/product testing and documentation, certain changes have been made in lot release criteria of **mdi** Stericheck with catalog numbers as mentioned in the scope. The lot release criteria with respect to microbial recovery and microbial retention efficiency shall be changed as mentioned below:

1. **Microbial Recovery:** The Stericheck shall be released on the basis of retrospective validation having compliance to microbial recovery as per USP <61> Microbiological examination of non-sterile products: microbial enumeration tests, instead of microbial recovery testing of every lot.
2. **Microbial Retention Efficiency:** The Stericheck shall now be released based on the microbial retention efficiency test carried out as per ASTM D 3863, Standard test method for retention characteristics of 0.40 to 0.45 µm membrane filters used in routine filtration procedures for the evaluation of microbiological water quality.

The changes as mentioned above will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

mdi has been manufacturing Stericheck for more than 20 years. Every lot of **mdi** Stericheck is sampled and tested for microbial recovery as specified in USP. Based on the verification of microbial recovery test results of **mdi** Stericheck for the past as many years, it has been decided that the microbial recovery test shall be removed from lot release criteria and release of **mdi** Stericheck shall be done on the basis of retrospective validation having compliance to microbial recovery test results against the pre-defined acceptance criteria and verification of critical sterilization process parameters. However, the microbial recovery testing shall be carried out at the time of validation of product and validation of sterilization process and will be reflected as part of the validation activity in respective documents (Including Certificate of Quality).

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Every lot of Stericheck is also sampled and tested for microbial retention efficiency of 0.45 µm rated membrane used in **mdi** Stericheck. This test is carried out using Serratia marcescens (ATCC 14756) and as per the methodology analogous to ASTM F 838 Standard test method for determining bacterial retention of membrane filters utilized for liquid filtration. It is found that the ASTM F 838 is specifically applicable to 0.2 µm rated membrane filters and not directly related to 0.45 µm rated filters. The ASTM D 3863 is found to be the standard test method for retention characteristics of 0.40 to 0.45 µm membrane filters used in routine filtration procedures for the evaluation of microbiological water quality. So, it has been decided to use ASTM D3863 for microbial retention testing of 0.45 µm membrane used in **mdi** Stericheck and compliance to the same will be reflected in respective documents (Including Certificate of Quality).

No change has been done in any critical dimensions or materials of construction or manufacturing process or traceability or other performance parameters of Stericheck.

How Does It Affect the User:

From a practical point of view this change re-defines the lot release criteria for in terms of microbial recovery and microbial retention efficiency. All other product specifications including materials of construction as well as other performance specifications remain unchanged. The said changes will be reflected in the accompanying product literature e.g. Certificate of quality, product data sheets, validation guide etc.

Implementation of Change:

mdi Stericheck with catalog numbers as mentioned in scope, manufactured after the implementation date will have the said changes. However, the available stock of **mdi** Stericheck with catalog numbers as mentioned in the scope and without the above mentioned changes 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
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