

# Certificate of Quality

The Single Use Assemblies have been manufactured in a cGMP compliant **mdi** facility.

These are produced using validated production processes in classified ISO 7 area.

The quality management system complies with ISO 9001 standards.

## Single Use Assembly

Catalog No. : A122XXXXXXXXC301  
Lot Number : AS0398H SI.No. 159  
Ster. No. : R089  
Date of Sterilization : 2018 - 08  
Expiry Date : 2020 - 08

### LOT RELEASE CRITERIA

The above lot was released based on following criteria:

- 100% Integrity Testing by pressure leak test** : Passes
- 100% Conformance to approved drawing** : Components verified for specifications, orientation and placement.
- 100% Visual Inspection** : Passes the visual inspection criteria.
- Sterilization** : By gamma irradiation at  $\geq 25$  kGy.

### VALIDATED FOR

- Bioburden Level** : The bioburden level of Single Use Assembly components have been tested as per ISO 11737.
- Sterility** : The gamma sterilization process has been validated as per ISO 11137 to ensure a Sterility assurance level (SAL) of  $10^{-6}$ .
- Endotoxin Level** :  $< 0.25$  EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.
- Particle release** : Passes test as per USP<788> Particulate matter in Injections.
- Biosafety** : Passes Biological Reactivity tests, *In Vivo* for Class VI plastic as per USP<88> and Biological Reactivity tests, *In Vitro* for Cytotoxicity as per USP<87>.
- Shelf Life** : Gamma irradiated Single Use Assembly components have a shelf life of 2 years.

### FILTERS USED

Cat. No. 1: DKS15236AARX101 Lot No. 1: DK4238H

### CUSTOMER SUPPORT

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.



Quality Assurance

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**An ISO 9001 Company**