

# Certificate of Quality

The **ASESS Aseptic Sampling Systems** have been manufactured in a cGMP complaint **mdi** facility.

These products are produced using validated production processes in classified ISO 7 (Class 10, 000) area.

The quality management system complies with ISO 9001 standards.

## **ASESS Aseptic Sampling System**

Catalog No.	: A028XXXXXXSS301
Lot Number	: AS0118E      SI.No. 009
Ster. No.	: R021
Date of Sterilization	: 2018 - 05
Expiry Date	: 2020 - 05

### **LOT RELEASE CRITERIA**

The above lot of ASESS Sampling System meet the following lot release criteria:

**100% Integrity Testing by pressure leak test** : Passes

**100% Component Verification for specifications, orientation and placement** : Conforms

**100% Visual Inspection** : Passes the visual inspection criteria

**Sterilization** : By gamma irradiation at  $\geq 25$  kGy

### **VALIDATED FOR**

**Bioburden Level** : The bioburden level of sampling system 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

**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>

**Particle release** : Passes test as per USP<788> Particulate matter in Injections

**Functionality** : The sampling port of the sampling system withstands inline Steam Sterilization at 125 °C for 60 minutes and provides a sterile pathway for aseptic sampling

**Shelf Life** : Gamma irradiated ASESS Aseptic sampling system have been validated to have a shelf life of 2 years

### **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

Issue Date: 23-May-18

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