

Certificate of Quality

The **AseptiBag Gold** has been manufactured using validated production processes in classified ISO 7 (Class 10, 000) **mdi** facilities.

The quality management system complies with ISO 9001 standards.

AseptiBag Gold

Catalog No. : ABDXEJJRXXXX302
Lot Number : AB0128E
Ster. No. : R021
Date of Sterilization : 2018 - 05
Expiry Date : 2020 - 05

LOT RELEASE CRITERIA

The above lot of AseptiBag Gold meet the following lot release criteria:

- 100% Integrity Testing by pressure leak test** : Passes
100% Visual Inspection : Passes the visual inspection criteria
Sterilization : By gamma irradiation at ≥ 25 kGy

VALIDATED FOR

- Bioburden Level** : The bioburden level of AseptiBag Gold has 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
Fiber release : Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6)
Storage temperature : -80°C to 45°C

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