

Certificate of Quality

The AseptiLink SC γ have been manufactured in a **mdi** facility which adheres to the Good Manufacturing Practices.

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

The quality management system complies with ISO 9001 standards

AseptiLink SC γ **Genderless Sterile Connector**

Catalog No. : ASCXXXXXXXXXXXXX
Lot Number : ACXXXXA
Ster. No. : RXXX
Sterilization Date : XXXX - XX
Expiry Date : XXXX - XX

LOT RELEASE CRITERIA

The above lot of AseptiLink SC γ was released based on following criteria:

100% Visual Inspection : Passes
Pressure Leak Test at 45 psi : Passes
Film Peel off Test : Passes
Sterilization : By gamma irradiation at ≥ 25 kGy

VALIDATED FOR

Sterility : The gamma sterilization process has been validated as per 11137 to ensure a Sterility assurance level (SAL) of 10^{-6}
Microbial Ingress : Resistance to microbial ingress against a challenge of 10^7 org/mL of B. diminuta
Endotoxin Level : < 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test
Bioburden Level : The bioburden level of AseptiLink SC γ have been tested as per ISO 11737
Biosafety : Passes Biological Reactivity tests , *In Vivo* for Class VI plastic as per USP<88>
Extractables : Passes NVR test as per USP<661>
Particle release : Passes test as per USP<788> Particulate matter in Injections
Fiber release : Complies with USFDA Title 21 CFR Part 210.3(b)(6)
Burst pressure (Mated Connectors) : > 4 bar (60psi)

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: XX-Jan-18

Advanced Microdevices Pvt. Ltd.
21, Industrial Area, Ambala Cantt, INDIA,
Tel: +91-171-2699290/ 2699274
Website: www.mdimembrane.com
Email: info@mdimembrane.com

An ISO 9001 Company