

Single Use Assembly for Inoculum Transfer (LDPE Bottle)

mdi Single Use Assembly for inoculum transfer is a gamma sterilized vented assembly to transfer cell culture to bioreactors.

These assemblies have been designed to provide a closed system to prevent extraneous contamination during inoculum transfer.

Application

- Aseptic inoculum transfer to bioreactors

Materials of Construction

Bottle	LDPE
Tubing	Thermoplastic Elastomer (TPE)*
	Platinum Cured Silicone
Vent Membrane	Hydrophobic PVDF
Vent Body	Polypropylene
Connector	Polypropylene

Specifications

Capacity

500ml, 1 litre and 2 litre

Vent Pore Size

0.2µm

Max. Operating Temperature

45 °C

Sterilization

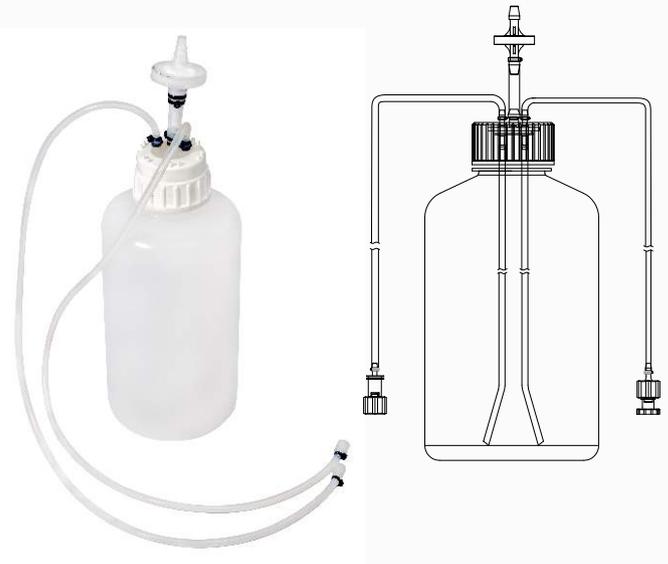
Gamma irradiated @ 25kGy

Bacterial Endotoxin (0.2µm Hydrophobic PVDF Vent)

Aqueous extracts exhibit <0.25 EU/ml

Biosafety

Passes Bioreactivity test, In-vivo, as per USP <88> for Class VI plastics



Endotoxin Testing

Aqueous extract exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) test

100% integrity tested

Pressure Leak Test

Fiber Release

Passes test as per USP and comply with USFDA 21 CFR Part 210.3 (b) (6) for fiber release

Particle Release

Complies with USP <788> test for particulate matter in injection

Sterility Assurance

mdi LDPE vented bottle assemblies are sterilized by gamma irradiation to provide a sterility assurance level of 10^{-6} . The sterilization process has been validated as per ISO 11137-2 which includes dose verification, dose mapping and quarterly dose audits.

The sterilization dose of 25 kGy has been substantiated through careful definition of the test samples, bio-burden testing of multiple lots of the selected test samples, calculation of verification dose and sterility testing.

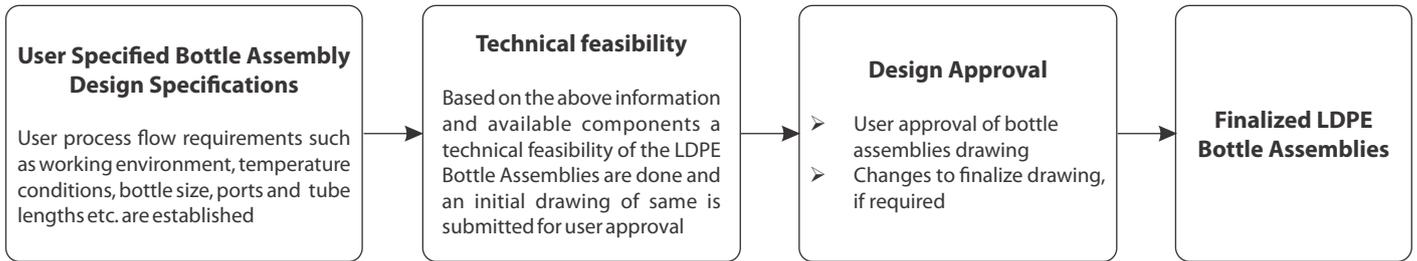
Quality Management System

mdi LDPE vented bottle assemblies are well designed products with in-built quality assurance. ISO-9001:2018 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality assemblies.

Customization

mdi LDPE vented bottle assemblies can be customized to suit user requirements in terms of tubing, fittings, end connections, bottle sizes and connectors.

Product Realization Flow Chart



Manufacturing Facilities

These are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

mdi Membrane Technologies INC.

Utley Drive STE 103, Camp Hill, PA 17011
Phone: +1-717-412-0943, Fax: +1-717-695-9637
E-mail: rs@mdimembranetech.com
Website: www.mdimembranetech.com

ADVANCED MICRODEVICES PVT. LTD.

20-21, Industrial Area, Ambala Cantt- 133 006, India
Tel: +91 - 171-2699290, 2699471
E-mail: info@mdimembrane.com
Website: www.mdimembrane.com