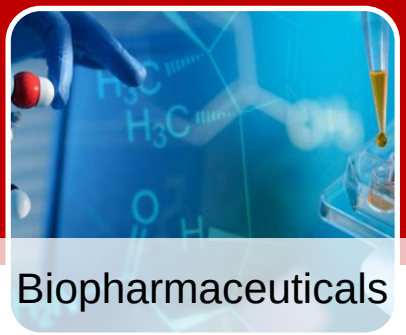
Membrane Technologies

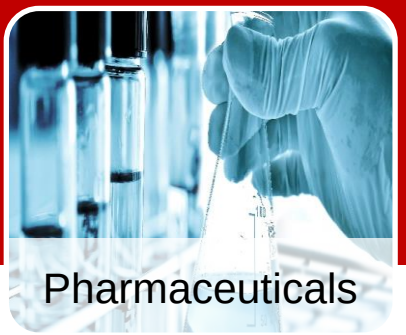
Advanced Microdevices (MDI)

SUS Capabilities Overview

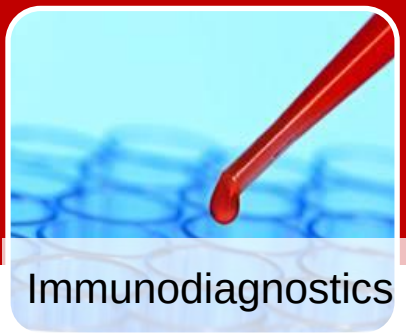
mdi at a glance

We deliver filtration and separation solutions for healthcare industries


Biopharmaceuticals


Pharmaceuticals

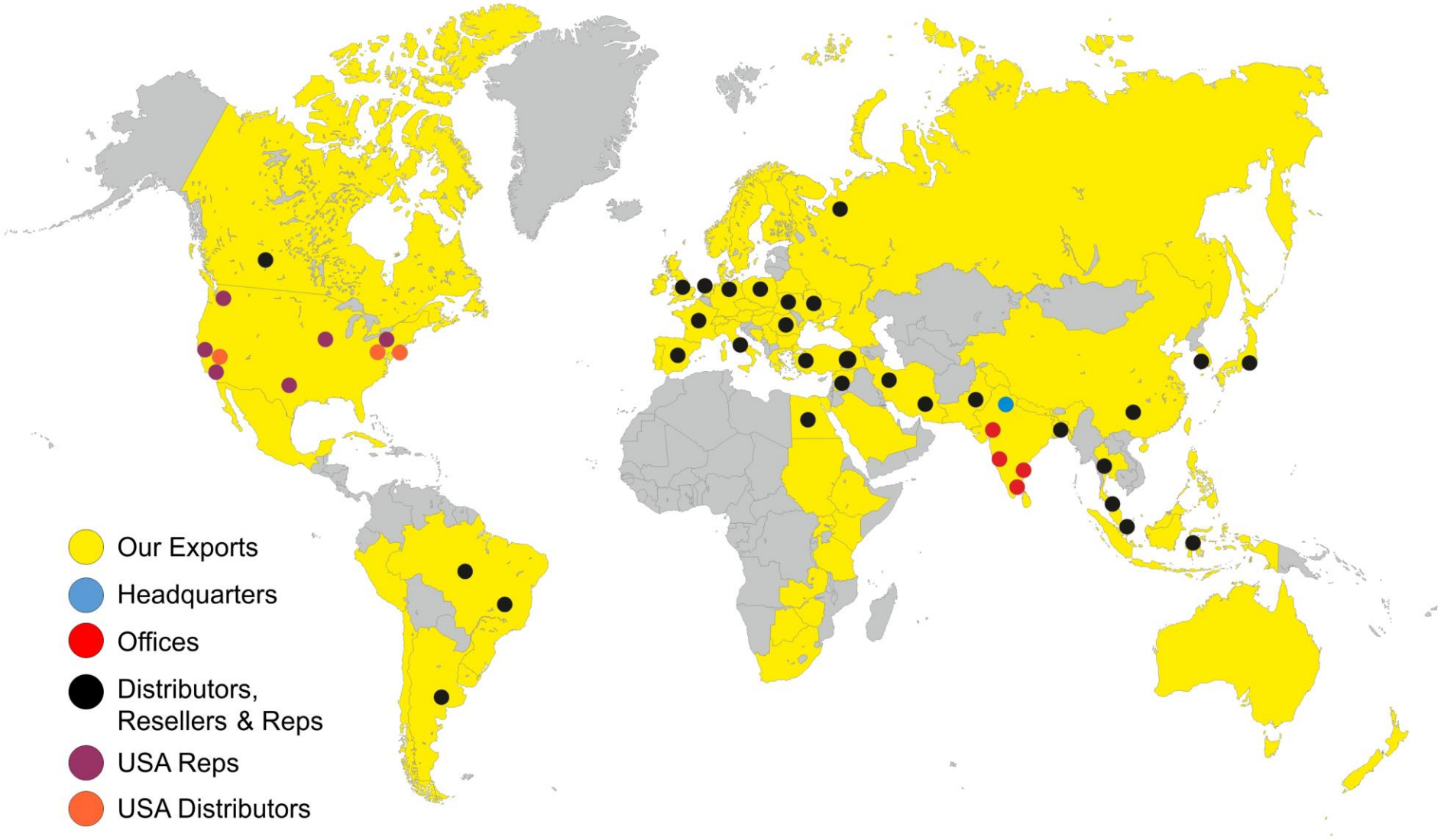

Life Science Research


Immunodiagnostics

- Vertically integrated manufacturer of membranes, filters and Single-Use systems
- 40+ years of expertise providing innovative solutions from lab to production
- 5 manufacturing facilities certified for regulated markets
- Serve global customers in 80+ countries

Membrane Technologies

Global presence



Membrane Technologies

40 years of expertise

Started in Home Garage

Constructed First Facility

Expanded Facility

Set up 100,000 sq. ft., ISO Class 7 facility

Opened US Office

New ISO Class 7 Facility

1976 | 1986 | 1996 | 2006 | 2016 | 2020

Developed Membranes in Sheet Form

- Nitrocellulose Membrane Filters
- Glassfiber Filters

Started Manufacturing Cartridge and Capsule Filters

- Polypropylene Cartridges and Capsules
- Nylon Disc Filters
- Blotting Membrane

Built Immunodiagnostic and Lab Portfolios

- NC Membrane for Diagnostics
- Membrane Laminates
- Conjugate Release Matrices
- Sample Pads
- Paper Cast NC Membranes
- Presterilized Syringe Filters

Expanded Portfolio for Biopharma

- Sterilizing Grade Filters
- Sterility Test Systems
- Microbiology Filters Funnels
- Vacuum Filters
- Integrity Test Equipment
- PES Membrane
- PVDF Membrane
- Nucleic Acid Purification Kits
- Plasma Separation Devices

New SUS Product Line

- Single Use Assemblies
- 2D and 3D Single Use Bags
- Aseptic Connectors and Disconnectors
- Steam to Connectors
- Quick Connectors
- Stainless Steel and Plastic Totes
- Liners and Drums

mdi today

- ISO Class 7 production facilities
- 5 Functional units at two Sites, 6th Unit under construction
- State of the art filter testing and validation labs
- Produce thousands of m^2 of membranes per day

- Products validated to meet global regulatory requirements
- Manufacture 8+ membrane materials (PES, PVDF, Nylon etc.)
- Complete range of standard pore sizes and filter formats
- #1 manufacturer for Immunodiagnostics membranes

- 1000+ employees strong
- 100+ Scientists and Engineers on staff
- Global distribution and reseller network

mdi Membrane Technologies

mdi 36 Acre Site-2 Campus

mdi
Membrane Technologies

Expansion of Injection Moulding Facility
5000 sq.m - Operational in January 2020

ISO Class 8 Injection Moulding Facility

Central Warehouse - Operational May 2021

mdi
Membrane Technologies

Expansion Building Unit 5 - 10,000 sq.m
For SUS and Large Filters

US Sales and Distribution Operations

- Incorporated in 2013 in Pennsylvania.
- Office and Warehouse located at Harrisburg, PA
- Finished product stocking and order fulfillment for North American region.
- Pre-Sales and Post Sales technical support, technical sales reps located in different regions providing on-site consultation, testing and troubleshooting support.
- Well established distributor network for Laboratory filtration products (Fisher Scientific, Thomas Scientific, Quartzy)
- MDI products are now qualified into GMP manufacturing by large multinational Biotech and Pharma companies in the US region.

Membrane Technologies

US Office & Warehouse

Leadership Team

NALINI KANT GUPTA (MS EE, USA)
Founder & Managing Director
40+ years experience in membrane tech

ASHAWANT GUPTA (PhD EE, USA)
Executive Director
20+ years experience in membrane tech

JITENDRA JINDAL (BE EE, India)
Associate Director, Sales
20+ years experience in Pharma and Life Sciences sales

VIVEK SHEEL GUPTA (MBA, India)
Associate Director, Marketing
20+ years experience in Pharma and Life Sciences sales and marketing

RAJNI KANT (MS EE, MBA, USA)
Director
40+ years experience leading tech companies

SANTVANA KANSAL (MBA, India)
Head of International Business
20+ years experience in business development

ROHIT SINGHAL (B.Tech, India)
Business Development, US
15+ years experience in Sales and product marketing

RISHI KANT (PhD EE, USA)
Business Operations
4+ years with McKinsey & Co.

Biopharmaceuticals: Segments served

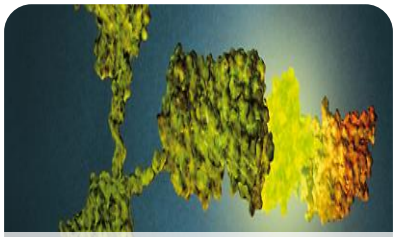
Membrane Technologies

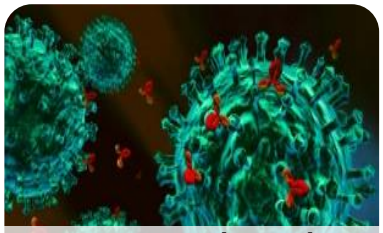
Our products support various areas ...

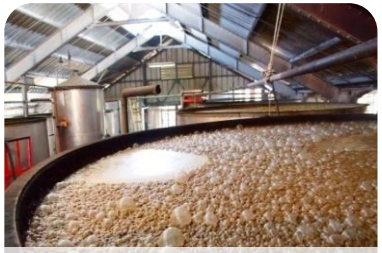
- Development Lab
- Manufacturing
- Fill/Finish
- QC / QA Lab

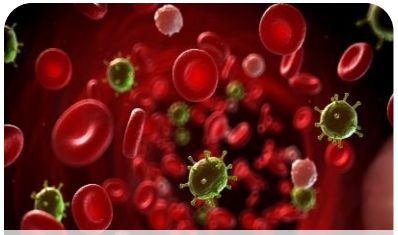
... in multiple segments


Vaccines


Recombinant Proteins


Monoclonal Antibodies


Classical Fermentation


Blood Proteins


Antisera

MDI Single-Use fluid management systems

Membrane Technologies

Bio-Pharmaceutical Manufacturing

MDI manufactures filters for major process steps in biotech manufacturing

Media Filtration	Cell Culture	Harvesting & Clarification	Filtration & Purification	Fill/Finish

Sterilizing filters
- *AseptiVent* Capsules (Gas)
- *AseptiSure* TF Cartridges (Gas)
- *AseptiCap* Capsules (Liquid)
- *AseptiSure* Cartridges (Liquid)

Fine pre-filters
- *ClariPro* GK
  ClariCap GS

Bioburden Reduction filters
- *ClariPro*
- *BioPro*

Secondary clarification
- *ClariPro* GK / GS

Sterilizing filters

Note: MDI offers the complete range of sizes from 25mm to 30” for linear scale up

Linear Scale up of filters

Gamma Compatible Hydrophilic Filters

PES membrane capsule filters (0.1um, 0.2um sterilizing grade)

PVDF membrane capsule filters(0.1um, 0.2um sterilizing grade)

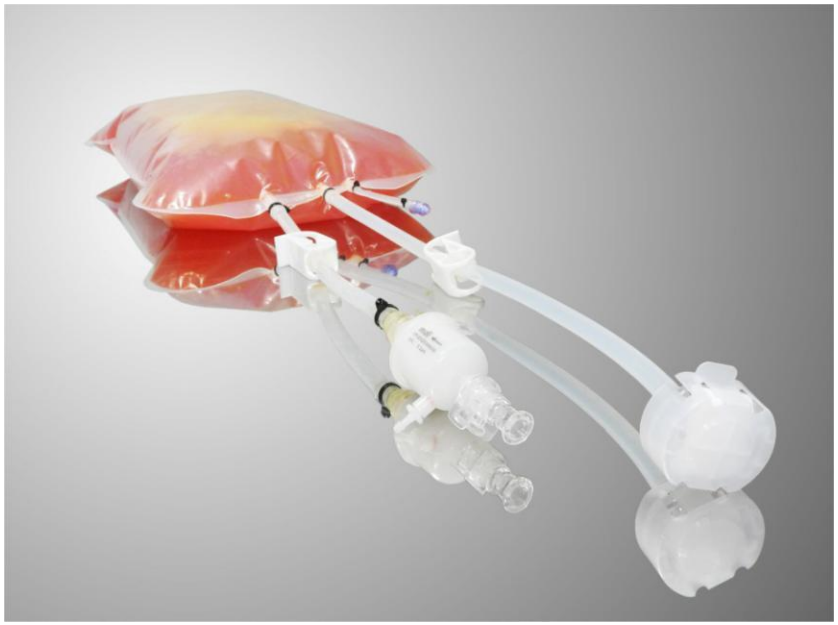
Gamma Compatible Hydrophobic Filters

PVDF membrane capsule filters (0.2um sterilizing grade)

5cm² 20cm² 250cm² 500cm² 1000cm² 2000cm² 6000cm² 12000cm² 18000cm²

MDI *AseptiBag* 2D Storage & Transfer Bags

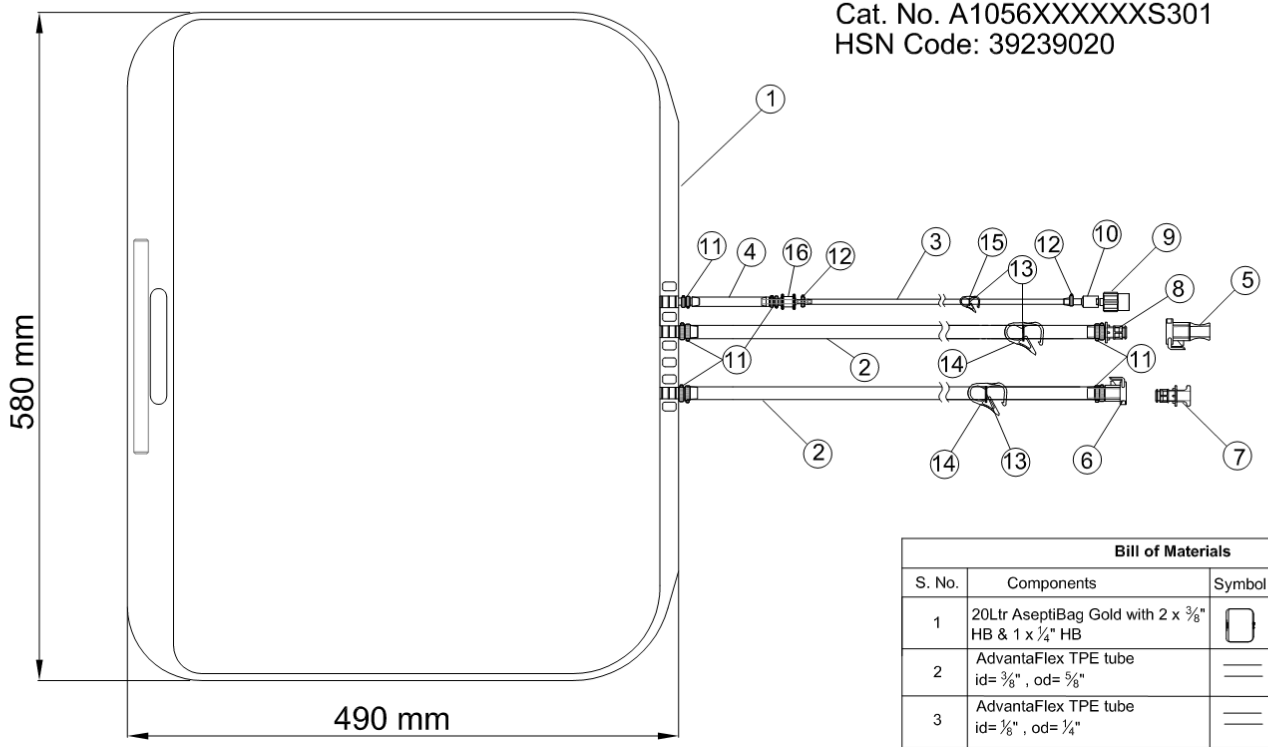
From 3ml to 50L sizes (Standard and Custom configurations)



2D Storage & Transfer Bag Assembly

MDI *AseptiBag* 2D Standard Bag offering

Gamma Irradiated Single Use Assembly
Cat. No. A1056XXXXXXS301
HSN Code: 39239020



- The assembly will be gamma sterilized. Each pack will have the 'Gamma Irradiated' RED indicator.

Biosafety

- All components of this assembly pass the Biological Reactivity Test *in vivo* for class VI plastics as per USP <88>

Non Animal Origin

- According to declaration from MDI raw material and components suppliers, the materials used to manufacture this assembly do not contain substance of animal origin

Drawing No. A1056	
Revision No. 00	Date: 08-09-2020
Advanced Microdevices Pvt. Ltd. Unit-3, Jawahargarh Road, Tepla Ambala, India	

Approval By Customer	
Customer Code: USA-1258	(For mdi use only)
Approved by:	
Designation:	
Date:	

Bill of Materials

S. No.	Components	Symbol	Size	QTY.
1	20Ltr AseptiBag Gold with 2 x ⅜" HB & 1 x ¼" HB		20Ltr	1
2	AdvantaFlex TPE tube id= ⅜" , od= ⅝"		20"	2
3	AdvantaFlex TPE tube id= ⅛" , od= ¼"		18"	1
4	AdvantaFlex TPE tube id= ¼" , od= 7/16"		2"	1
5	Female Quikonnect plug		--	1
6	Female Quikonnect with ⅜" HB connection		--	1
7	Male Quikonnect plug		--	1
8	Male Quikonnect with ⅜" HB connection		--	1
9	Needle free sampling port		--	1
10	Female luer connection with ⅛" HB		--	1
11	Double Ties		--	12
12	Single Tie		--	2
13	Releasable Tie		--	3
14	Tube clamp C4-190(L4K0343)		--	2
15	Tube clamp C1-068(L4K0308)		--	1
16	Reducer with ¼" to ⅛" HB		--	1

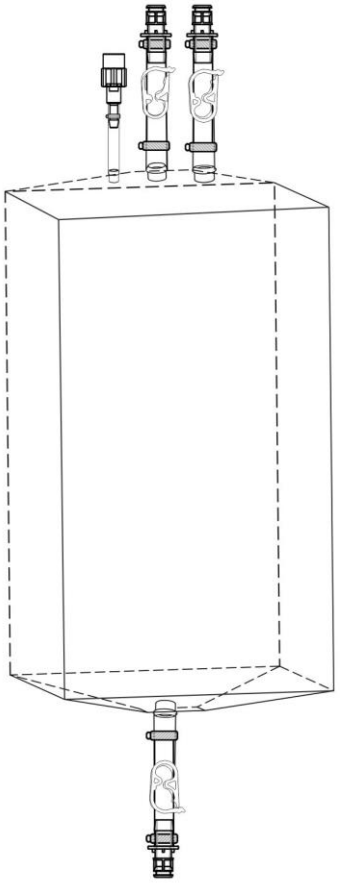
MDI *AseptiBag* 2D Standard Bag offering

Standard 2D Bag assemblies, Gamma irradiated, Sterile			
Description	Ordering info	Pack Size	Unit Price ($)
MDI 1L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1052XXXXXXS301	1	42
MDI 2L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1053XXXXXXS301	1	45
MDI 5L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1054XXXXXXS301	1	61
MDI 10L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1055XXXXXXS301	1	80
MDI 20L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1056XXXXXXS301	1	87
MDI 50L Standard Bag; three ports with TPE tubing, Female and Male Quikconnect and sampling port	A1057XXXXXXS301	1	93.50

MDI *AseptiBag* 3D Storage & Transfer Bags

From 100L to 1000L sizes (Custom configuration for existing hardware)

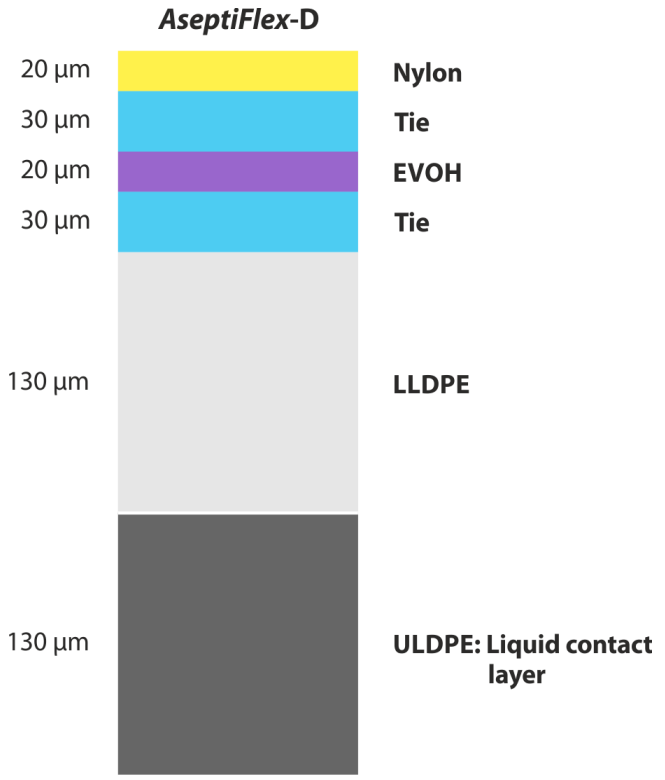
3D Single use bag assemblies for large volume storage and transfer (for Rectangular totes)



3D Single use bag assemblies for large volume storage and transfer (for Round drums)

AseptiFlex-D: Film for MDI *AseptiBags*

- **Multilayered coextruded film with ULDPE fluid contact layer**
- **Physically tough and inert to chemicals and solvents**
- **Excellent barrier to O_2, CO_2 and moisture**
- **ULDPE contact layer without any additives for very low extractables**

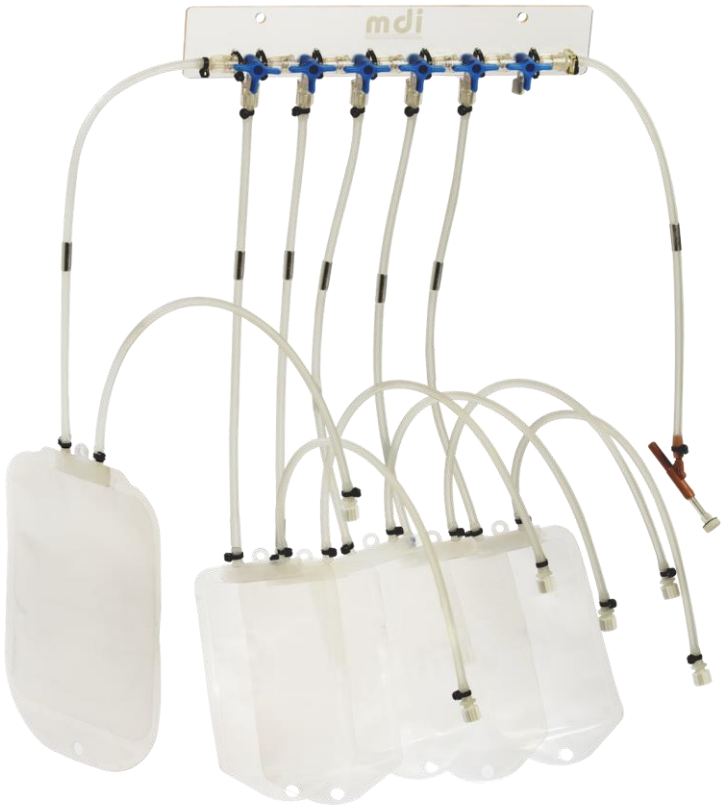


Accessories for Single Use Systems

MDI BioKart - SS Trolleys for 2D Storage Bags

MDI BioSafe – Plastic Rectangular Totes

MDI ASESS Sampling Systems



ASESS Aseptic Sampling Systems

ASESS 50mm Sampling Port Connection for Five Sampling Ports

ASESS Port Blind

ASESS CrimpGard Crimped Tube Cover

ASESS Crimping and Cutting Tool

MDI Bottle/Carboy Assemblies

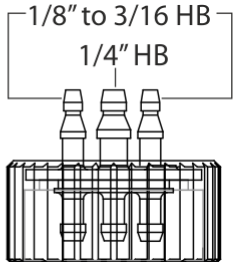
PETG Bottle Assembly

LDPE Bottle Assembly

Polycarbonate Bottle Assembly

PVDF Magnetic Stir bars

Bottle Cap Adapters



Cap Adapter Sizes
2 x 1/8"-1/8" HB and 1 x 1/4"-1/8" HB for 45mm Bottle Cover
2 x 1/8"-1/8" to 3/16"-1/8" HB for 33mm Bottle Cover
1 x 1/8"-1/8" HB and 1 x 1/4"-1/8" HB for 38mm Bottle Cover
2 x 1/8"-1/8" HB and 1 x 1/4"-1/4" HB for 53mm Bottle Cover
1 x 1/4"-1/8" HB and 3 x 1/4"-1/4" HB for 83mm Bottle Cover

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MDI Quick Connectors (Polycarbonate)

1/4″ Hose Barb
Male Connector

1/4″ Hose Barb
Female Connector

3/8″ Hose Barb
Male Connector

3/8″ Hose Barb
Female Connector

Male Plug

1/2″ Hose Barb
Male Connector

1/2″ Hose Barb
Female Connector

Female Plug for 1/2″ Hose Barb
Female Connector

Male Plug for 1/2″ Hose Barb
Female Connector

Female Plug

3/4″ Hose Barb
Male Connector

3/4″ Hose Barb
Female Connector

1″ Hose Barb
Female Connector

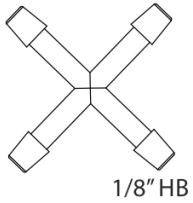
1″ Hose Barb
Male Connector

Male Male Connector

MDI Fluid Management fittings

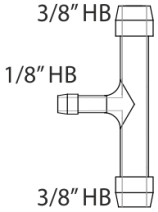
Membrane Technologies

Cross Connection



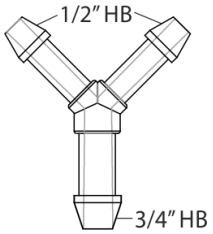
Available Sizes
1/8" HB (5mm nipple)

T Connection



Available Sizes
3 X 1/8" HB
3 X 3/8" HB
2 x 3/8” and 1 x 1/8" HB

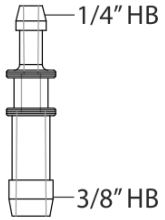
Y Connection



Available Sizes
1/8" HB (5mm nipple Y)
1/4" HB
3/32" HB
2 x 3/32" and 1 x 1/8" HB
2 x 1/2" x 1 x 3/4" HB

USP Class VI Polypropylene material

Reducers



Available Sizes
1/4" to 1/8" HB
3/8” to 1/4" HB
1/2" to 1/4" HB
1/2" to 3/8" HB
3/4" to 1/2" HB
1" to 1/2" HB
3/8" HB to Female Luer lock
1/8" HB to Female Luer lock
Male luer slip nipple with 1/8" HB

MDI Fluid Management fittings

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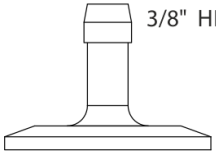
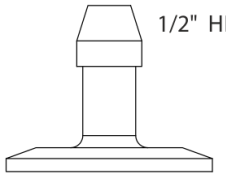
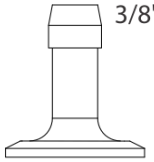
1/2” Sanitary Flannge with Hose Barb Connection

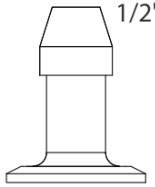




Available Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb
1" Hose Barb

3/4” Sanitary Flannge with Hose Barb Connection

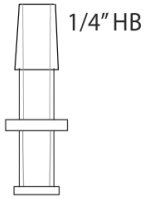




Available Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb

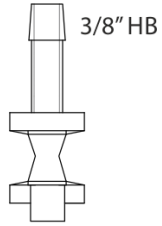
Plugs

Press in Plug



Available Sizes
1/8” Hose Barb
1/4” Hose Barb
3/8” Hose Barb
1/2” Hose Barb

Baxa Spike



Available Sizes
with 3/8” Hose Barb

USP Class VI Polypropylene material

MDI Clamps

Membrane Technologies

Pinch Clamps

Available Sizes
Tube clamp small for 1/8”-1/4" OD tubes
Tube clamp medium for 5/16”-3/8" OD tubes
Tube clamp large for 1/2” OD tubes
Tube clamp extra large for 5/8"- 3/4" OD tubes

Crimp Pipe

Available Sizes
for 5.3mm OD Tube
for 15.8mm OD Tube

Sanitary Flange Clamps

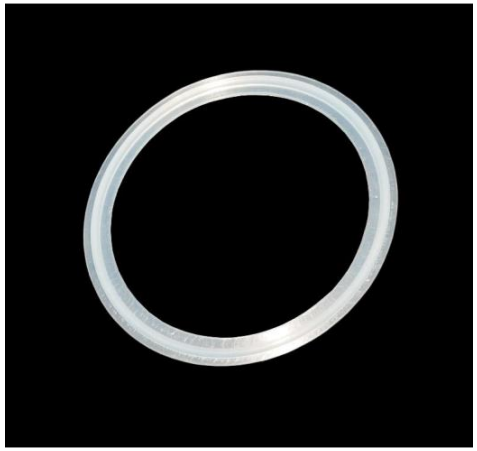
Available Sizes
Clamp for 25 mm Sanitary Flange
Clamp for 50 mm Sanitary Flange
Clamp for 3" Sanitary Flange
Clamp for 4" Sanitary Flange
Clamp for 8" Sanitary Flange

MDI Sanitary Gaskets

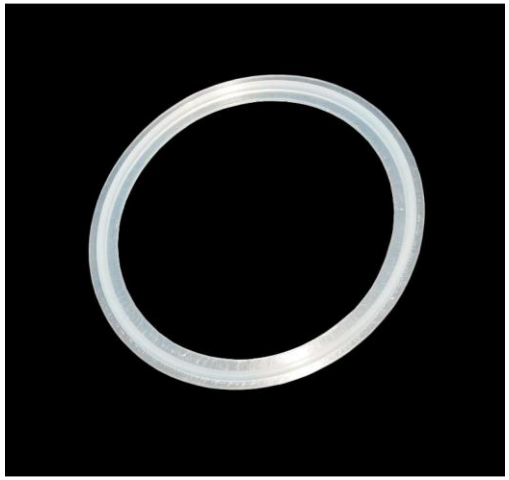
1.5" TC Gasket with 9 ports for Filling lines

50mm TC Gasket

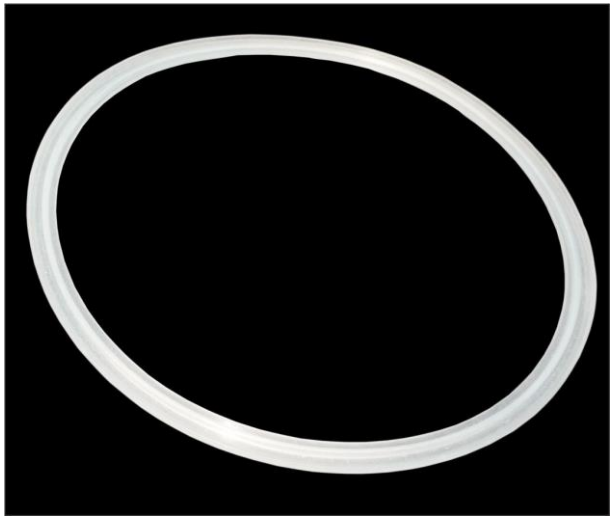
3" TC Gasket



4" TC Gasket



8" TC Gasket



MDI Filling Needles

PEEK
Filling Needles

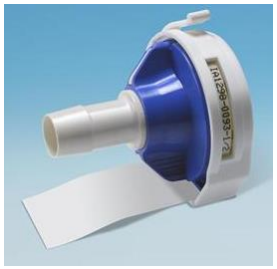
Stainless Steel
Filling Needles

Qualified Sourced components

Membrane Technologies

Valves

Aseptic Connectors



Tubing (TPE and Silicone)

Bottles

PETG

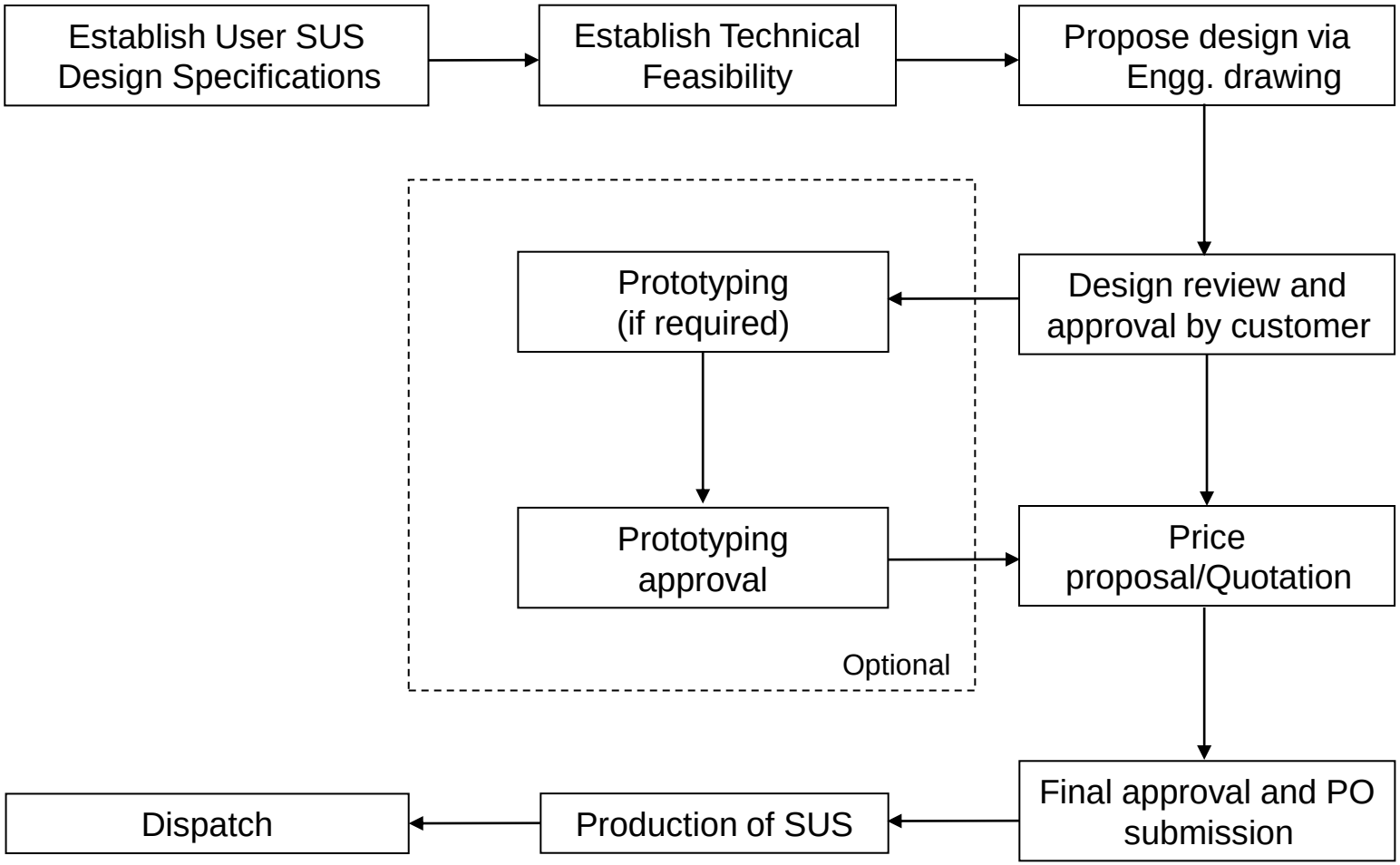
LDPE/HDPE

Polycarbonate

Oetiker clamps

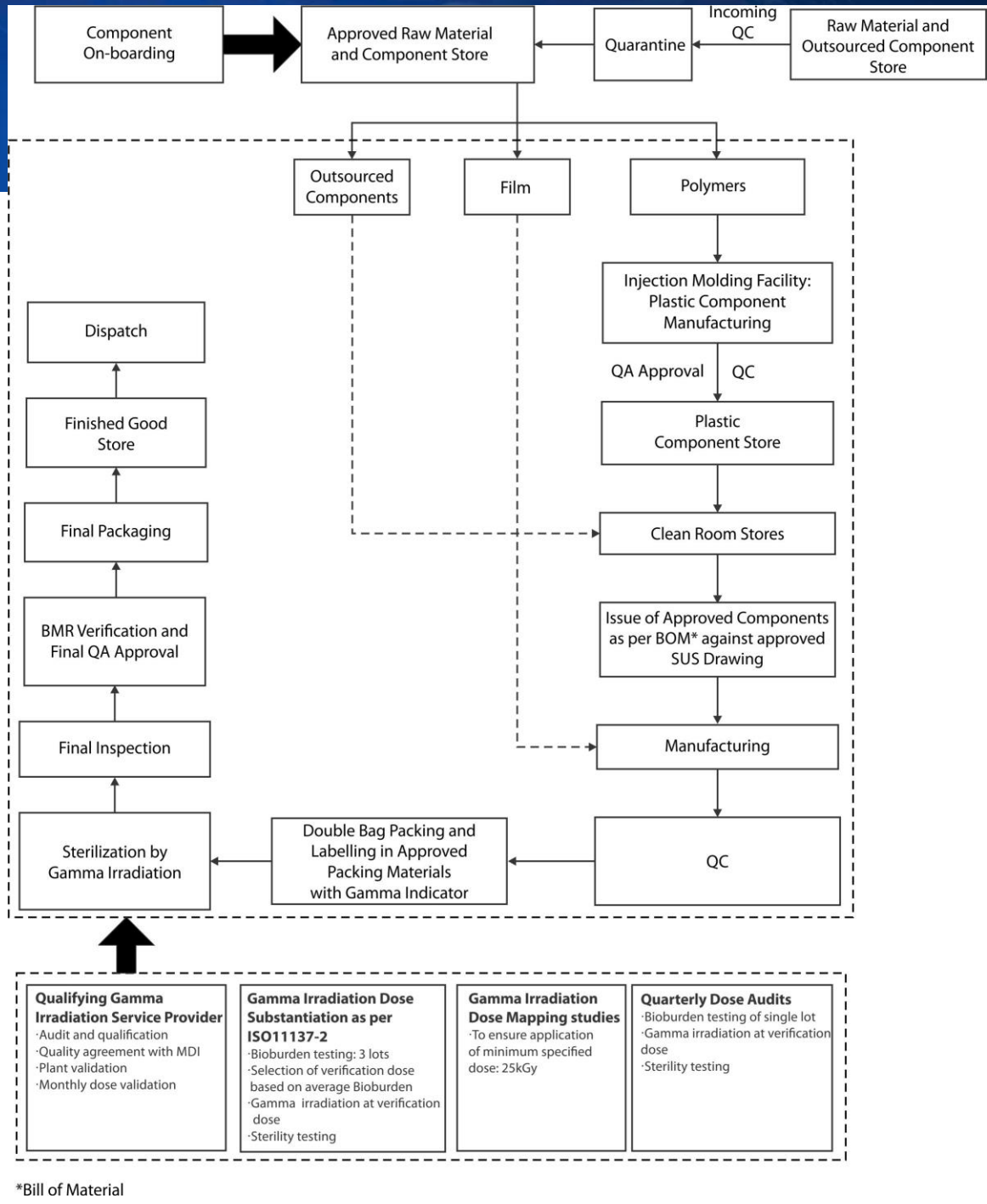
Membrane Technologies

Process Flow : Single Use Systems



Membrane Technologies

Process Flow Chart: Single Use Systems

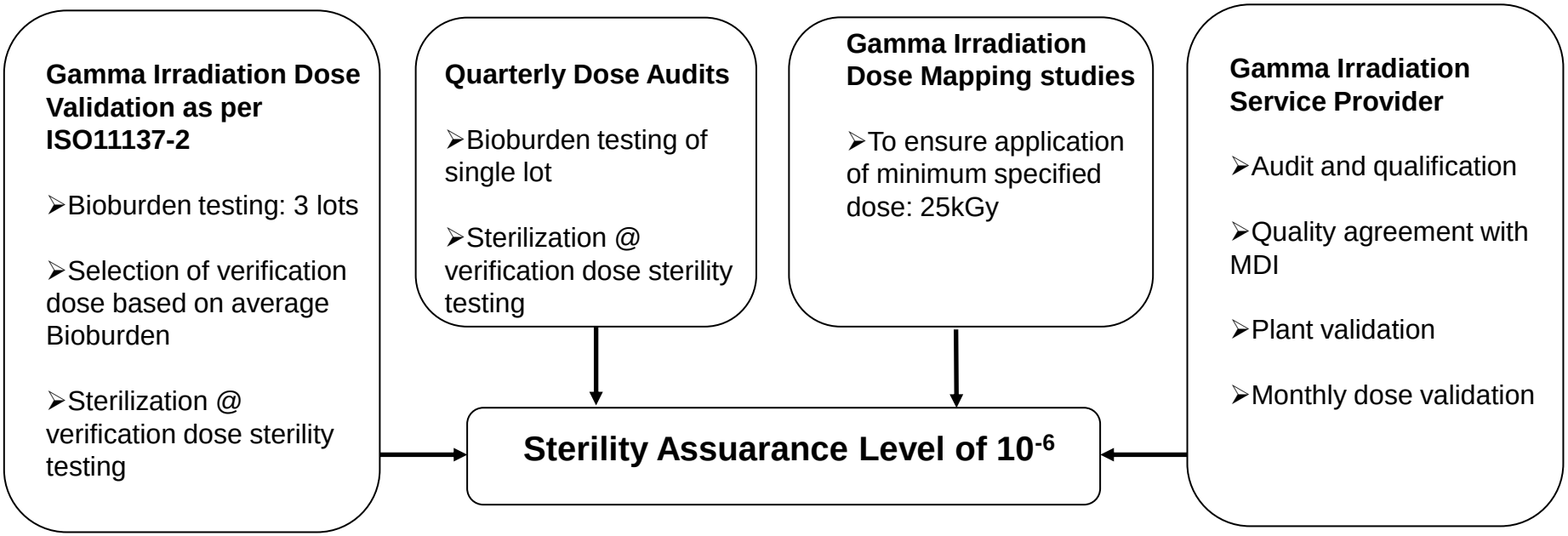


*Bill of Material

Quality Certification for Single Use Assemblies

Parameters	Testing
Integrity Testing	100 %
Conformance to approved drawing	100 %
Visual Inspection	100 %
Bioburden	Quarterly monitoring
Sterilization	≥ 25 kGy
Sterility Assurance Level (SAL)	10^{-6} through quarterly dose audits
Bacterial Endotoxin	Quarterly monitoring
Particle Release	Quarterly monitoring
Shelf Life	2 years

Validation Program for Gamma Sterilization



ISO - 9001 : 2015 certification

CERTIFICATE

This is to certify that

Advanced Microdevices Pvt. Ltd.
(Corporate Office)
SITE - I
20-21, Industrial Area
Ambala Cantt-133006
Haryana
India

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development and Manufacture of Microporous Membranes and Membrane based Products, Single Use Systems, Components and Assemblies.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	20000048 QM15
Date of original certification	2018-10-24
Date of certification	2021-10-24
Valid until	2024-10-23

DQS Inc.

Brad McGuire
Managing Director

Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA
Administrative Office: Deutsch Quality Systems (India) Pvt. Ltd., 5th Floor, Anjaneya Techno Park, 147, HAL Airport Road, Kodihalli, Bangalore- 560 017 - India

1 / 2

Validation guides

Include:

Physical Tests

Chemical Tests

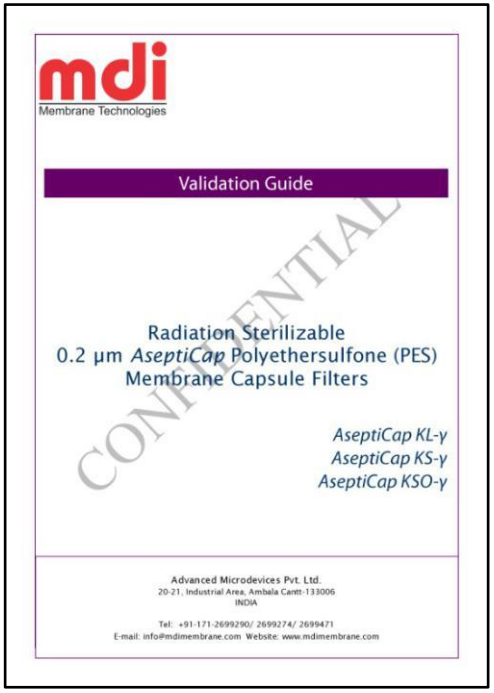
Biological Tests

Bio-safety Tests

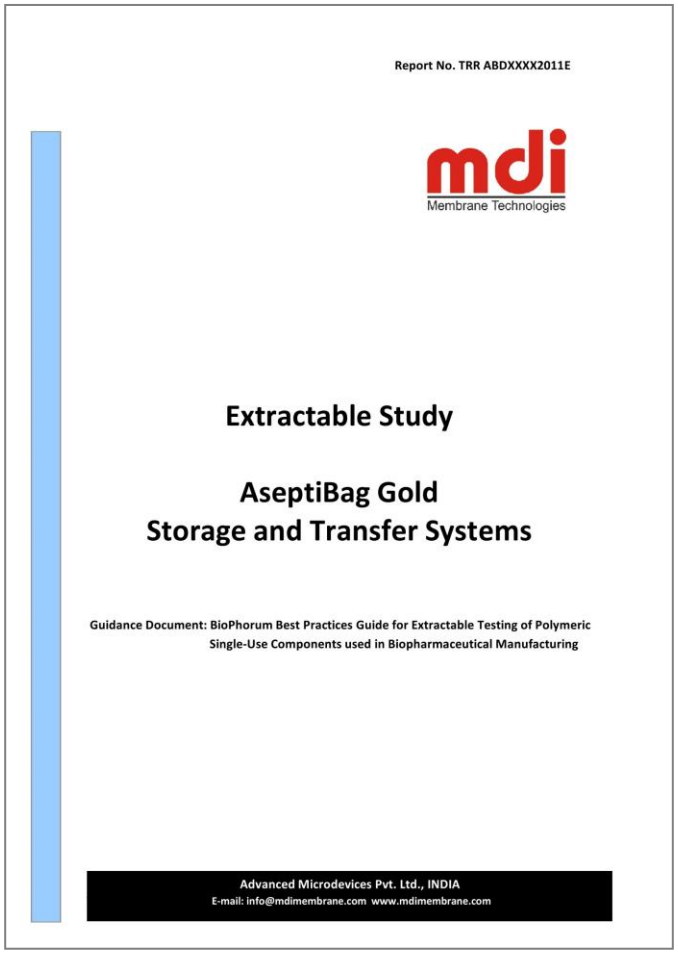
Functional Tests

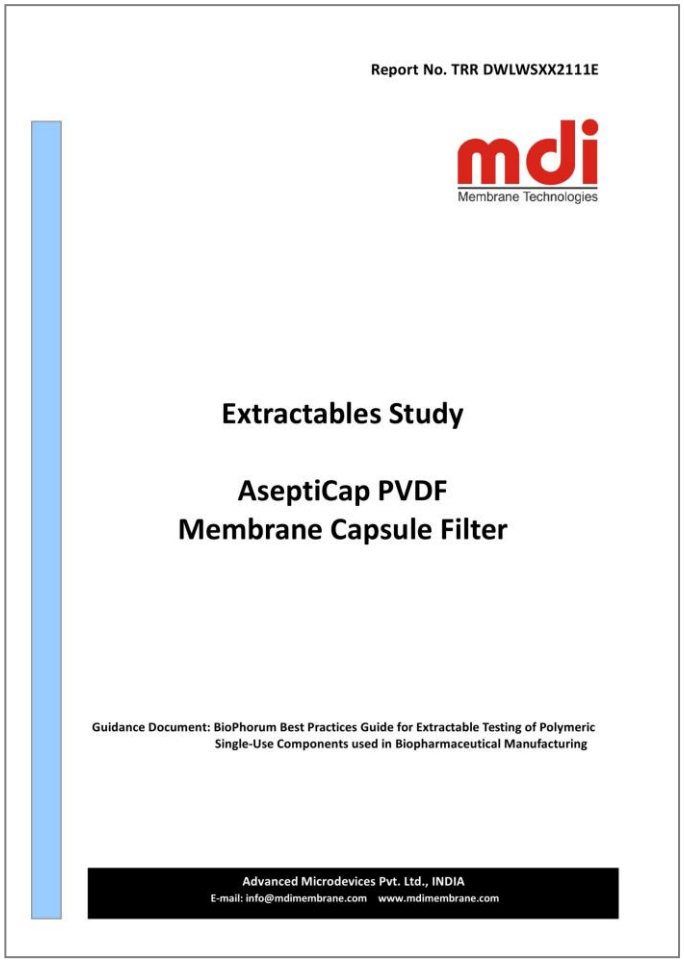
Shelf Life

Certifications and Declarations



Extractables Guides as per Standardized Testing Protocol for Single Use Systems in Bio manufacturing as per BPOG Extractables Work Group



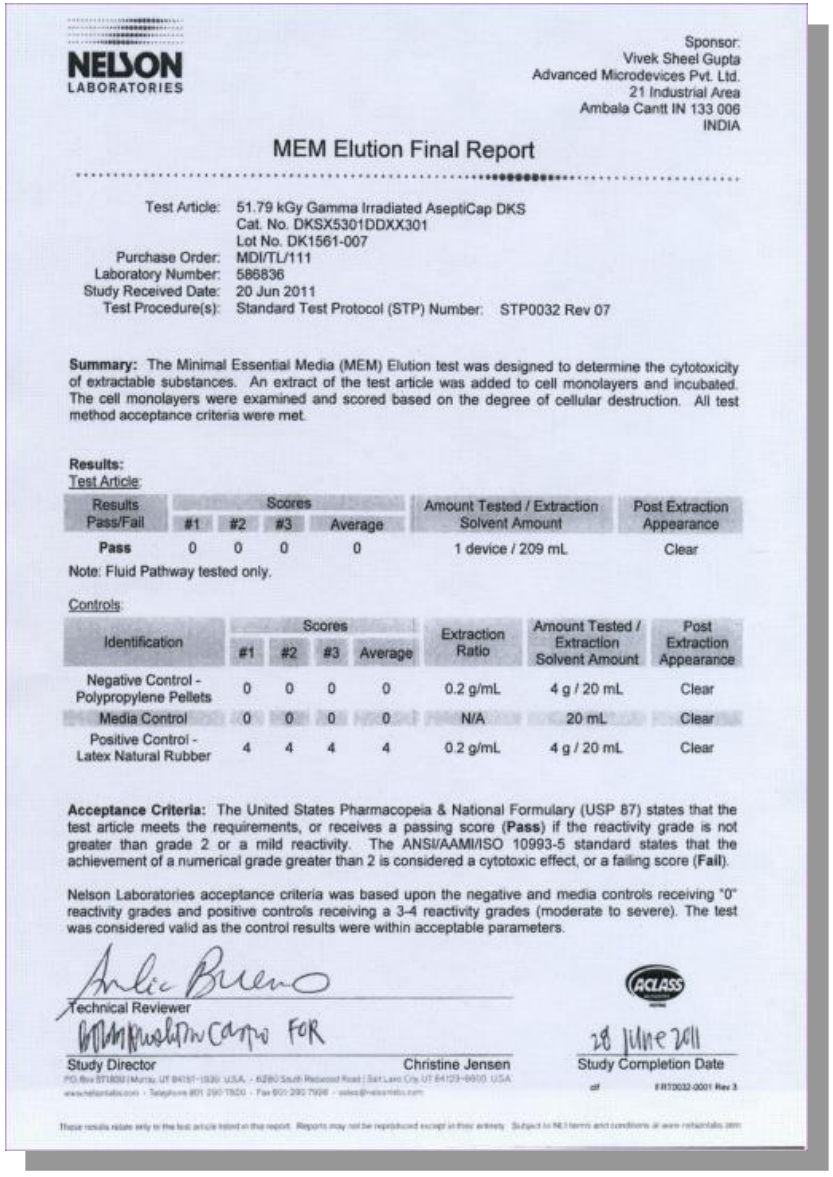


Membrane Technologies

MDI Products Comply with Regulatory as well as Functional Requirements

Tests	Standards complied to
Particulate Matter	USP <788> and ICH Q4B Annex 3
Bacterial Endotoxin Testing	USP<85> and ICH Q4B Annex 14
Biological Reactivity Tests	USP<88> for Class VI Plastics USP<87> for Cytotoxicity
Bioburden	ISO 117 37-1
Gamma Sterilization Dose Substantiation and Validation	ISO 11137-2
Bacterial Retention	ASTM F838-05
Physical Tests of Films	
• Tensile Strength	ASTM D-882
• Tear Strength	ASTM D-1938
• Gelbo Flex Test (Flex Durability Test)	ASTM F-392
• Puncture resistance Test	EN 14477
• Oxygen Transmission Rate Test	ASTM D-3985-05
• Carbon Dioxide Transmission RateTest	ASTM F 2476-05
• Water Vapour Transmission Rate Test	ASTM F-1249-13

Testing for Cytotoxicity as per USP <87>



NELSON LABORATORIES

Sponsor:
Vivek Sheel Gupta
Advanced Microdevices Pvt. Ltd.
21 Industrial Area
Ambala Cantt IN 133 006
INDIA

MEM Elution Final Report

Test Article: 51.79 kGy Gamma Irradiated AseptiCap DKS
Cat. No. DKSX5301DDXX301
Lot No. DK1561-007
Purchase Order: MDI/TL/111
Laboratory Number: 586836
Study Received Date: 20 Jun 2011
Test Procedure(s): Standard Test Protocol (STP) Number: STP0032 Rev 07

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:
Test Article:

Results Pass/Fail	Scores #1	#2	#3	Average	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
Pass	0	0	0	0	1 device / 209 mL	Clear

Note: Fluid Pathway tested only.

Controls:

Identification	Scores #1	#2	#3	Average	Extraction Ratio	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL	Clear
Media Control	0	0	0	0	N/A	20 mL	Clear
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL	Clear

Acceptance Criteria: The United States Pharmacopeia & National Formulary (USP 87) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

Technical Reviewer

Study Director Christine Jensen

28 June 2011
Study Completion Date

Testing for USP Class VI Plastics as per USP <88>

Membrane Technologies

WuXi AppTec

TO
Ms. Tarika Onishi
Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123
tonishi@nelsonlabs.com

Certificate of Compliance

USP Biological Reactivity Tests, *In Vivo*

FOR SAMPLE(S) RECEIVED: 06/30/11

Test Article: 51.57 kGy Gamma Irradiated Polyethersulfone Membrane
Lot Number: M931

Name of Study	**Intracutaneous Irritation Test (USP)**	PROJECT # 156307
Extracts	Normal Saline, 5% Ethanol in Saline, Polyethylene Glycol 400, Cottonseed Oil	**RESULTS:**
Test Code / Study Director	900600 / Brianna Carlson	**Met the requirements of the test.**

Name of Study	**Acute Systemic Injection Test (USP)**	PROJECT # 156306
Extracts	Normal Saline, 5% Ethanol in Saline, Polyethylene Glycol 400, Cottonseed Oil	**RESULTS:**
Test Code / Study Director	9007AST / Michelle Dietzel	**Met the requirements of the test.**

Name of Study	**Intramuscular Implantation Test (USP) - 1 week**	PROJECT # 156308
		RESULTS:
Test Code / Study Director	9001IM / Michelle Dietzel	**Met the requirements of the test.**

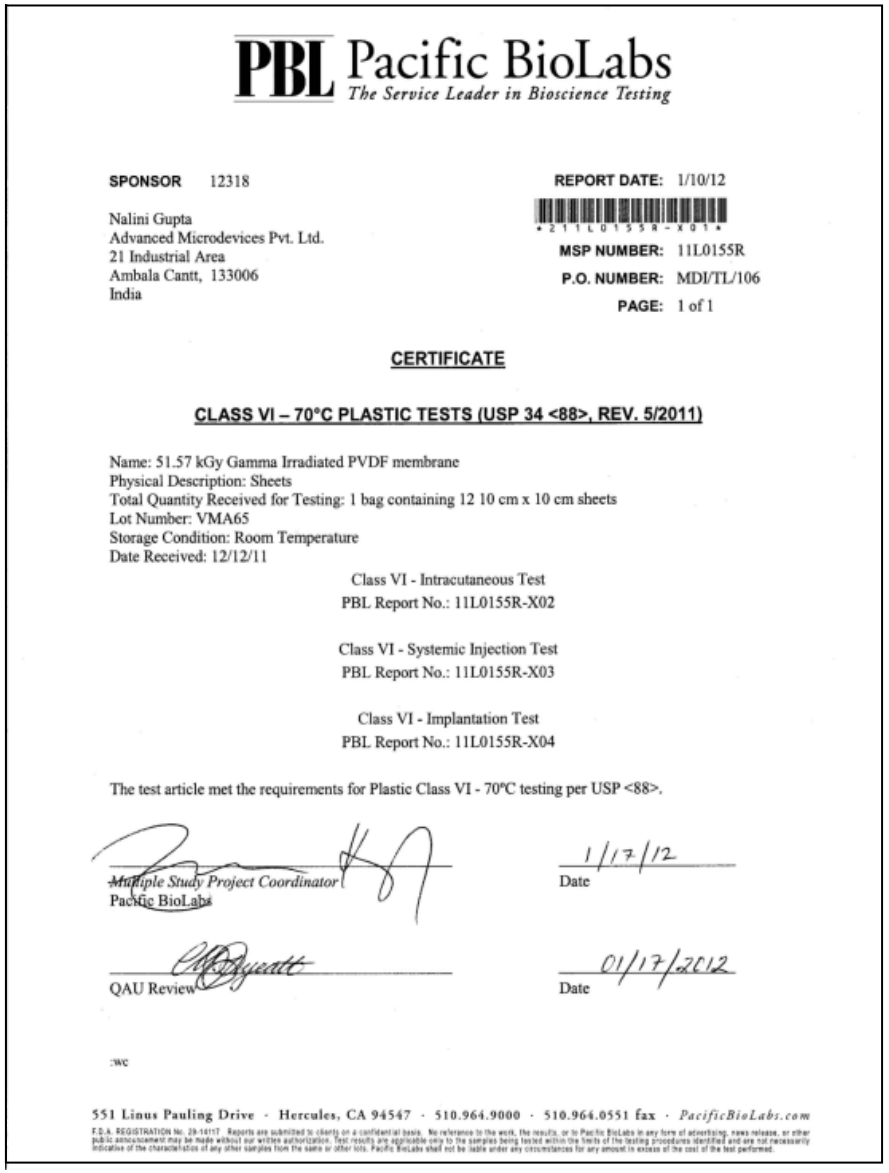
The test article MET the requirements of a USP Plastic Class VI.

Quality Assurance Auditor: Melissa Ellers Date: 8/4/11

Study Director: [signature] Date: 8/4/11

Study Director: Michelle Dietzel Date: 8/4/11

Testing for USP Class VI Plastics as per USP <88>



PBL Pacific BioLabs
The Service Leader in Bioscience Testing

SPONSOR 12318

Nalini Gupta
Advanced Microdevices Pvt. Ltd.
21 Industrial Area
Ambala Cantt, 133006
India

REPORT DATE: 1/10/12
211L0155R-X01
MSP NUMBER: 11L0155R
P.O. NUMBER: MDI/TL/106
PAGE: 1 of 1

CERTIFICATE

CLASS VI – 70°C PLASTIC TESTS (USP 34 <88>, REV. 5/2011)

Name: 51.57 kGy Gamma Irradiated PVDF membrane
Physical Description: Sheets
Total Quantity Received for Testing: 1 bag containing 12 10 cm x 10 cm sheets
Lot Number: VMA65
Storage Condition: Room Temperature
Date Received: 12/12/11

Class VI - Intracutaneous Test
PBL Report No.: 11L0155R-X02

Class VI - Systemic Injection Test
PBL Report No.: 11L0155R-X03

Class VI - Implantation Test
PBL Report No.: 11L0155R-X04

The test article met the requirements for Plastic Class VI - 70°C testing per USP <88>.

Multiple Study Project Coordinator
Pacific BioLabs

1/17/12
Date

QAU Review

01/17/2012
Date

:wc

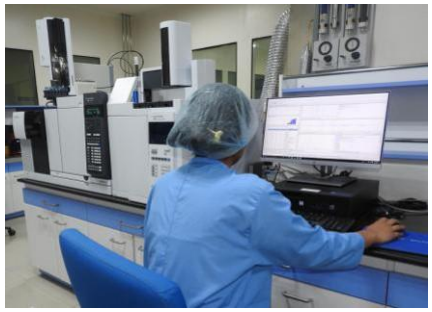
551 Linus Pauling Drive · Hercules, CA 94547 · 510.964.9000 · 510.964.0551 fax · *PacificBioLabs.com*

F.D.A. REGISTRATION No. 29-14117 Reports are submitted to clients on a confidential basis. No reference to the work, the results, or to Pacific BioLabs in any form of advertising, news release, or other public announcement may be made without our written authorization. Test results are applicable only to the samples being tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples from the same or other lots. Pacific BioLabs shall not be liable under any circumstances for any amount in excess of the cost of the test performed.

All Quality Control tests and most of Validation tests are carried out in-house

Analytical Labs

- Physico chemical tests
- Extractable Studies



- Microbiology Labs
  - Sterility Testing
  - Microbial Load Test
  - Bacterial Challenge Test
  - Bacterial Endotoxin Test

- Physical Test Labs

Only a few Validation tests such as Biological Reactivity Tests, in-vivo for Class VI Plastics as per USP <88>, Biological Reactivity Tests, in-vitro for Cytotoxicity as USP <87> and some of the physical test for the films are outsourced

Filter Validation Lab

(for specific drug product validation services)

- HPLC
- GC-MS-MS
- LC-UV-MS-TOF
- HS-GC-MS
- FTIR
- TOC Analyzer
- UV Spectrophotometer
- Integrity Test Equipment
- Air Particle Counter
- Digital Mass Flow Meter
- Digital Pressure Gauges
- pH Meter
- Conductivity Meter
- Viscometer
- Laboratory Water System
- Weighing Balance
- Liquid Particle Counter

Technical Support with Strong Analytical Abilities

GC-MS

LC-MS

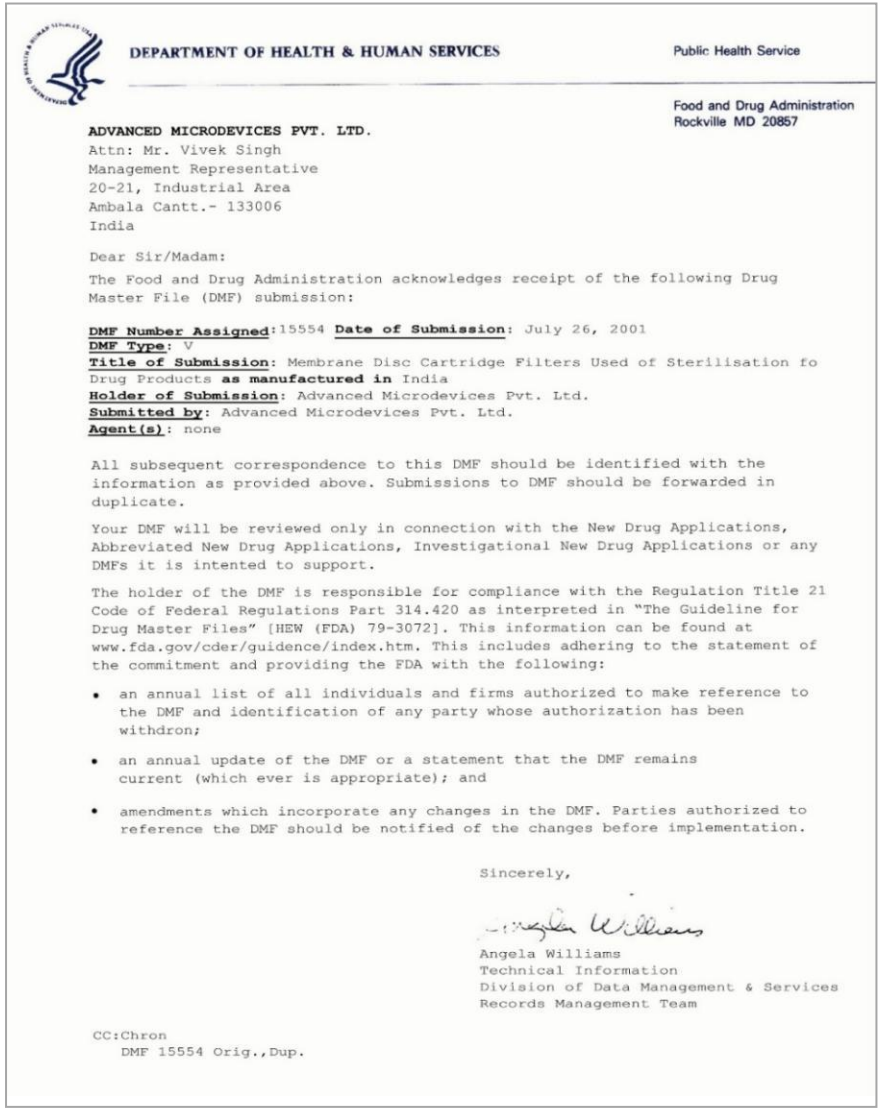
Analytical Lab

Scanning Electron Microscope

USFDA DMF # 015554

DMF for MDI Filter Products

"Membrane Disc, Capsule and Cartridge Filters used for Sterilization of Drug Products". Drug Master File No. 015554.



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

ADVANCED MICRODEVICES PVT. LTD.
Attn: Mr. Vivek Singh
Management Representative
20-21, Industrial Area
Ambala Cantt.- 133006
India

Dear Sir/Madam:

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF Number Assigned:15554 **Date of Submission**: July 26, 2001
DMF Type: V
Title of Submission: Membrane Disc Cartridge Filters Used of Sterilisation fo Drug Products **as manufactured in** India
Holder of Submission: Advanced Microdevices Pvt. Ltd.
Submitted by: Advanced Microdevices Pvt. Ltd.
Agent(s): none

All subsequent correspondence to this DMF should be identified with the information as provided above. Submissions to DMF should be forwarded in duplicate.

Your DMF will be reviewed only in connection with the New Drug Applications, Abbreviated New Drug Applications, Investigational New Drug Applications or any DMFs it is intented to support.

The holder of the DMF is responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072]. This information can be found at www.fda.gov/cder/guidence/index.htm. This includes adhering to the statement of the commitment and providing the FDA with the following:

- an annual list of all individuals and firms authorized to make reference to the DMF and identification of any party whose authorization has been withdron;
- an annual update of the DMF or a statement that the DMF remains current (which ever is appropriate); and
- amendments which incorporate any changes in the DMF. Parties authorized to reference the DMF should be notified of the changes before implementation.

Sincerely,

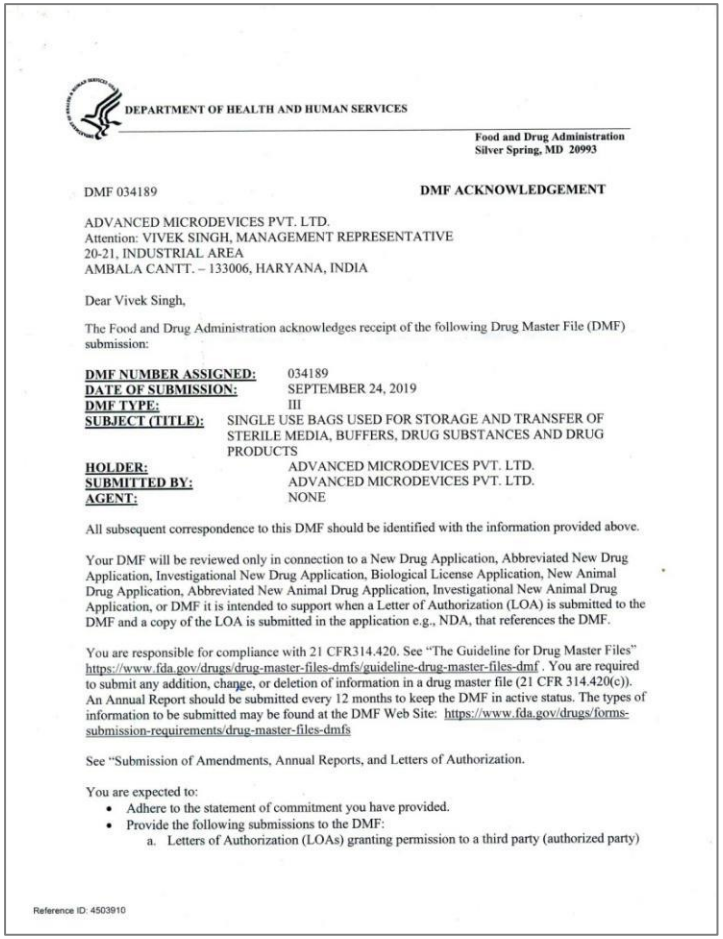
Angela Williams
Technical Information
Division of Data Management & Services
Records Management Team

CC:Chron
DMF 15554 Orig.,Dup.

USFDA DMF # 034189

DMF for MDI Single Use Bags

"Single use bags used for storage and transfer of sterile media, buffers, drug substances and drug products". Drug Master File No.034189.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DMF 034189

DMF ACKNOWLEDGEMENT

ADVANCED MICRODEVICES PVT. LTD.
Attention: VIVEK SINGH, MANAGEMENT REPRESENTATIVE
20-21, INDUSTRIAL AREA
AMBALA CANTT. – 133006, HARYANA, INDIA

Dear Vivek Singh,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED:	034189
DATE OF SUBMISSION:	SEPTEMBER 24, 2019
DMF TYPE:	III
SUBJECT (TITLE):	SINGLE USE BAGS USED FOR STORAGE AND TRANSFER OF STERILE MEDIA, BUFFERS, DRUG SUBSTANCES AND DRUG PRODUCTS
HOLDER:	ADVANCED MICRODEVICES PVT. LTD.
SUBMITTED BY:	ADVANCED MICRODEVICES PVT. LTD.
AGENT:	NONE

All subsequent correspondence to this DMF should be identified with the information provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

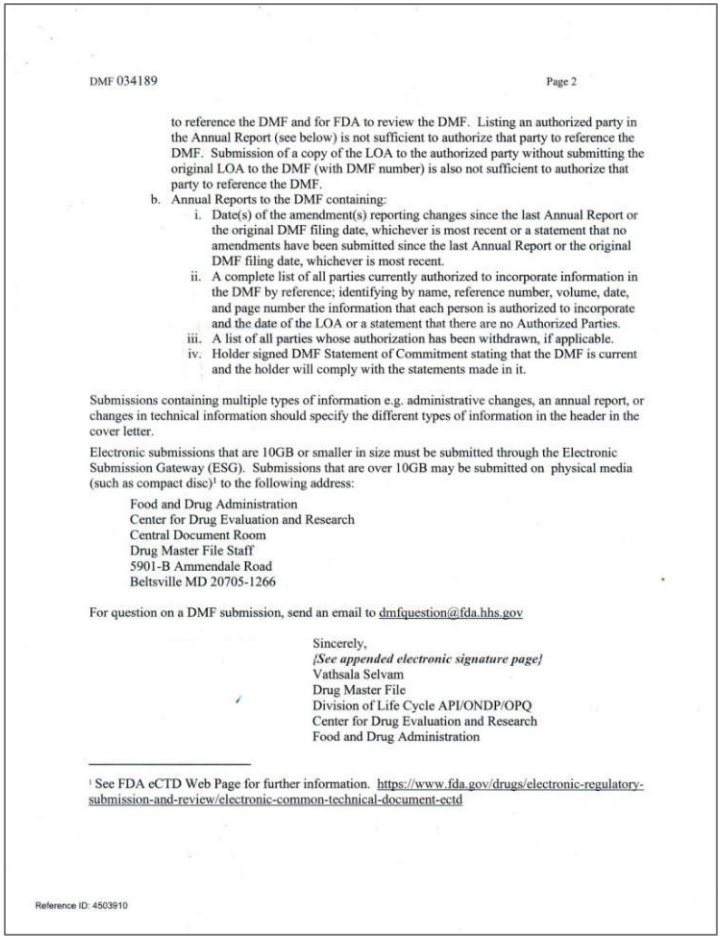
You are responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf . You are required to submit any addition, change, or deletion of information in a drug master file (21 CFR 314.420(c)). An Annual Report should be submitted every 12 months to keep the DMF in active status. The types of information to be submitted may be found at the DMF Web Site: https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs

See "Submission of Amendments, Annual Reports, and Letters of Authorization.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
  a. Letters of Authorization (LOAs) granting permission to a third party (authorized party)

Reference ID: 4503910



DMF 034189 Page 2

to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF (with DMF number) is also not sufficient to authorize that party to reference the DMF.

b. Annual Reports to the DMF containing:
   i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
   ii. A complete list of all parties currently authorized to incorporate information in the DMF by reference; identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
   iii. A list of all parties whose authorization has been withdrawn, if applicable.
   iv. Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Submissions that are over 10GB may be submitted on physical media (such as compact disc)[1] to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

For question on a DMF submission, send an email to dmfquestion@fda.hhs.gov

Sincerely,
{See appended electronic signature page}
Vathsala Selvam
Drug Master File
Division of Life Cycle API/ONDP/OPQ
Center for Drug Evaluation and Research
Food and Drug Administration

[1] See FDA eCTD Web Page for further information. https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

Reference ID: 4503910

Membrane Technologies

THANK YOU