

# Certificate of Quality

The PTFE membrane syringe filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

## **PTFE Membrane Syringe Filters**

Catalog No.	: SYTF0602MNXX104
Туре	: SY25TF
Pore Size	: 0.45 µm
Lot Number	: ST9227G

#### **SPECIFICATION**

Membrane	: PTFE
Housing	: Polypropylene
Filter Diameter	: 25 mm
Filtration Area	: 4.15 cm <sup>2</sup>
Burst pressure	: > 14 Kg/cm <sup>2</sup>
Hold up volume	: < 50 µl

### **QUALITY ASSURANCE LOT RELEASE CRITERIA**

Each lot has been sampled, tested and released by the Quality Assurance Department for the following characteristics:

- o Integrity
- Flow Rate Performance
- o Burst Pressure
- Leakage Test
- HPLC Certified
- o Retention: Microbial Challenge test

: Passes as per FDA 21CFR 177.1520(a)1(i).

**Biosafety** 

**EXPIRY** 

: Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

Indirect Food Additives

: Non degradable polymeric materials of construction with no expiry when stored at room temperature in a dry place.

#### PRECAUTIONS

1. During handling, avoid contamination of outlet.

2. If pressure required to maintain the required flow becomes too high, the filter unit should be changed.

#### **CUSTOMER SUPPORT**

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

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Head of Quality Assurance Issue Date: 24-Jul-17

#### Advanced Microdevices Pvt. Ltd.

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## An ISO 9001 Company