

# Certificate of Quality

The filling needle for transfer of processing fluids have been manufactured in **mdi** facility in compliance with ISO 9001 regulations.

These are produced using validated production processes in classified clean rooms.

The quality management system complies with ISO 9001 standards

## 1.6 mm Filling Needle

Part No. : L1K0080

Lot Number : US00570

### LOT RELEASE CRITERIA:

The above lot of filling needle was released based on following criteria:

**100% Visual Inspection** : Passes

**Dimensional Testing on sample basis** : Passes

**Leakage Testing on sample basis** : Passes

### VALIDATED FOR

**Bio burden Level** : The bio burden level has been tested as per ISO 11737

**Endotoxin Level** : < 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test

**Particle release** : Passes test as per USP<788> Particulate matter in Injections

**Biosafety** : Passes Biological Reactivity tests , *In Vivo* for Class VI plastic as per USP<88>

**TSE/BSE** : Free from TSE/BSE causing agents in compliance with EMEA/ 410/01 Rev.03

### 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**