

# Certificate of Quality

The Polycarbonate Quick Connector has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

## Polycarbonate Quick Connector (Plug Body)

Catalog No. : QCCXXXPBXXX304  
Lot Number : PC0208I  
Ster. No. : R126  
Date of Sterilization : 2018 - 11  
Expiry Date : 2020 - 11

### SPECIFICATION

Material of Construction : Polycarbonate  
Operating Pressure : Vacuum at 60 psi  
Operating Temperature : - 60 to 150 °C  
Sterilization : Pre sterilized by Gamma Irradiation at  $\geq 25$  kGy

### LOT RELEASE CRITERIA

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

- Visual inspection
- Pressure test

### VALIDATED FOR

**Sterility** : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of  $10^{-6}$  in accordance with ISO 11137.  
**Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.  
**Cytotoxicity** : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.  
**Fiber Release** : Complies with USFDA 21CFR 211.72.

### CUSTOMER SUPPORT

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



Head of Quality Assurance

Issue Date: 27-Nov-18

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**An ISO 9001 Company**