

# Certificate of Compliance



## Product Description

**Product Part Number:** MPC30003M                      **Batch Number:** 4719657  
**Product Description:** MPC BODY PLUG, PC              **Date of Manufacture:** 10-MAY-2018

This product was assembled in an ISO 7 clean room, in a Colder Products Company facility certified to ISO9001:2015 and ISO13485:2016 Quality Standards

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## Material Specifications

### **Applicable CPC Specification**

CES21108  
CES21181

### **Specification Description**

Polycarbonate, Lexan HPS1-1H1124 \*  
Silicone Elastomer, LIM6071 \*

### **Statements**

Endotoxins	This product passes USP<85> test for bacterial endotoxins*
Biological Reactivity	This product passes USP<87> in-Vitro testing for biological reactivity* This product passes USP<88> (Class VI) in-Vivo testing for biological reactivity*
Particulates	This product passes USP<788> test for particulate matter in injections*
TSE-BSE Status	All components in the wetted path of this device are manufactured from animal free materials.
Conformance	This statement affirms that the materials and methods used to manufacture the products ordered are in compliance with all applicable CPC engineering, production, dimensional, and test requirements.

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\*Based on previously performed testing.

The shelf life of this item is three years from the date of manufacture.

A handwritten signature in black ink that reads 'Paul Hakamaki'.

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Paul Hakamaki - VP of Quality  
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