Certificate of Compliance



Product Description

Product Part Number: MPC22006T03M Batch Number: 4167357

Product Description: 3/8 HB NV INSERT Date of Manufacture: 16-NOV-2017

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

Material Specifications

Applicable CPC Specification Specification Description

CES21108 Polycarbonate, Lexan HPS1-1H1124 *
CES21181 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.

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

Paul Hakamaki - VP of Quality Colder Products Company

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17-NOV-2017 Date of Release

^{*}Based on previously performed testing.