Certificate of Compliance



Product Description

Product Part Number: AQG17006HT Batch Number: 9674415

Product Description: 3/8HB ASEPTIQUIK G Date of Manufacture: 22-APR-2025

CONNECTOR, HT

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 SpecificationSpecification DescriptionCES211195Polycarbonate (white)CES211202Silicone ElastomerCES270002PolyethersulfoneCES280001PTFE (Gamma Stable)

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.

Ben Schultze - Senior Director of Quality

Colder Products Company

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25-APR-2025
Date of Release

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^{*}Based on previously performed testing.