

Certificate of Compliance



Product Description

Product Part Number: AQG17006HT

Batch Number: 9721798

Product Description: 3/8HB ASEPTIQUIK G
CONNECTOR, HT

Date of Manufacture: 05-MAY-2025

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

CES211195
CES211202
CES270002
CES280001
CES280002

Specification Description

Polycarbonate (white)
Silicone Elastomer
Polyethersulfone
PTFE (Gamma Stable)
PTFE (POLYTETRAFLUOROETHYLENE)

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.

*Based on previously performed testing.

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

Per change notification BCN1057, AseptiQuik high temp slider sticker is changing to a new PTFE material (non-product contact component). The running change transition will occur between June and July of 2025. Prior to the change, the applicable CES number for this component part is CES280001; this is specific to the PTFE slider that is white in appearance. After the change, the applicable CES number for this component will be CES280002; this is specific to the new PTFE slider that is gray in appearance. During this transition, one or both of these CES material specifications may be detailed on this CoC. For a copy of BCN1057 please contact laura.schweitz@cpcworldwide.com.

Ben Schultze - Senior Director of Quality
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21-MAY-2025
Date of Release

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