



Colder Recommended Sterilization Methods

		Method							
		Disinfectants			Ethylene Oxide	Autoclave	E-Beam Irradiation	Gamma Irradiation	Dry Heat
		Formalin	Isopropyl Alcohol	Ethyl Alcohol			50 Kilograys	50 Kilograys	250° F
Materials	Metals								
	Chrome-Plated Brass - CDA 360	N	Y	Y	Y	Y	Y	Y	Y
	Polymers								
	ABS	N	N/A	Y	Y	N	Y	Y	N
	Acetal	Y	Y	Y	Y	Y	N	N	N
	LDPE	Y	Y	Y	Y	N	Y	Y	N
	Nylon*	Y	N	N	Y	N	N	N	N
	Polycarbonate	Y	Y	Y	Y	Y	Y	Y	Y
	Polypropylene*	Y	Y	Y	Y	N	Y	Y	N
	Polysulfone	Y	Y	Y	Y	Y	Y	Y	Y
	Elastomers								
	Nitrile/Buna-N	Y	Y	Y	N	N	Y	Y	Y
	Silicone	Y	Y	Y	Y	Y	Y	Y	Y
	Kalrez®	Y	Y	Y	Y	Y	N	N	Y
	EPR/EPDM	Y	Y	Y	Y	Y	Y	Y	Y
FKM/Viton®	Y	Y	Y	N	N	N	N	Y	

Key:

Y = Excellent, recommended material for this sterilization method

N = No, not recommended

N/A = Not Applicable

* = For FitQuik Connector Sterilization Methods please contact Customer Service at Qosina.com



Sterilization Methods

Disinfectants: 70°F (20°C), Formalin, ethyl alcohol, etc. Sterilize coupled or uncoupled.

Ethylene Oxide, EtO: Four hours, 100% EtO @ 110°F (43°C), up to five repetitions, coupled or uncoupled.

Autoclave:

Polycarbonate: 250°F (121°C), 30 minutes, up to 10 repetitions. Sterilize uncoupled only.

Polysulfone: 270°F (132°C) for 60 minutes, up to 25 repetitions. Sterilize uncoupled only.

Steam-Thru Connection: 265°F (129°C) for 30 minutes, up to two cycles. (part number specific)

HFC39: 270°F (132°C) for 60 minutes, up to 25 repetitions for uncoupled units and up to one repetition for coupled units.

Electron Beam (E-Beam): Maximum cumulative exposure of 50 kilograys. Sterilize coupled or uncoupled.

Gamma: Maximum cumulative exposure of 50 kilograys. Sterilize coupled or uncoupled.

Dry Heat: 250°F (121°C), 12 hours, no pressure. Sterilize uncoupled only.

Sip Process:

Up to 266°F (130°C) for 60 minutes (Steam-Thru Connection).

Up to 275°F (135°C) for 60 minutes (Steam-Thru II Connection)

Regulatory and Compliance

FDA and USDA

The U.S. Food and Drug Administration publishes, through the Code of Federal Regulations, standardized criteria which govern the acceptability of materials used in food contact. The U.S. Department of Agriculture publishes similar standards that mirror FDA criteria. Neither agency approves or disapproves products for particular applications. Most of Colder's products are made using resins that comply with applicable FDA or USDA standards. When necessary, the standard o-ring seals are replaced with specific, recognized materials.

NSF

NSF International, based in Ann Arbor, Michigan, develops and publishes consensual criteria that govern the acceptability of materials and equipment used in food and beverage processing. They also do testing to verify the performance of materials or devices to their published criteria. Colder lists many of its product lines under the criteria of NSF/ANSI Standard 169 (formerly C-2), which governs components used in food and beverage contact applications.

ISO 9001:2008 Certification

ISO 9001:2008 is a standard which assures consistency of a product ordered by customers. Organizations having ISO 9001:2008 certification have demonstrated compliance to the ISO 9001:2008 requirements by an independent registration authority. Colder Products Company's Quality Management System has been approved and certified under the ISO 9001:2008 standard.

Regulation of Hazardous Substances

The RoHS Directive stands for "the restriction of the use of certain hazardous substances in electrical and electronic equipment". This Directive bans the placing on the EU market of new electrical and electronic equipment containing more than agreed levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants.

Cleanroom Manufacturing

Colder Products Company manufactures certain Life Sciences and Chemical Management product lines in a cleanroom certified by an external testing service to meet or exceed ISO Class 7 (10,000) at 0.5 mm per ISO 14644 and the former Federal Standard 209E. Certification data can be provided upon request.