ISO 80369

**Connectors** 

Caps O-Rina:

Stopcocks Filter

Injection Sites & Sampling Port

Clamps, Clips & Cable Tie

Tubino

Extension Line

Guide Wire Accessorie

Needle

Dilators & Introducer Sheath

Spike

Baa

Chambers

Ports & Flange

Syringe

Sterilization Supplie

Applicators, Swabs & Brushe

Containers

Scoops & Spoons

Dispenser

Drapes, Towels & Bandage

Clothing

CONNECTORS

Metals

Chrome-Plated

Brass - CDA 360

Polymers

ABS

Acetal

LDPE

Nylon

Polycarbonate

Polypropylene

Polysulfone

Elastomers

Nitrile/Buna-N

Silicone

EPR/EPDM

FKM/Viton®

Quick Disconnect Couplings

CPC® Recommended Sterilization Methods

Formalin

Ν

**Disinfectants** 

Isopropyl

Alcohol

N/A

Υ

Ν

Υ

Ethyl

Alcohol

Ν

Gamma

Irradiation

50

Kilograys

Υ

Ν

Ν

Υ

Ν

E-Beam

Irradiation

50

Kilogravs

Ν

Ν

Ν

Method

**Autoclave** 

Ν

Ν

Ν

Ethylene

Oxide

Dry

Heat

250° F

Ν

Ν

Ν

Disinfectants: 70°F (20°C), Formalin, ethyl alcohol, etc.

Ethylene Oxide, EtO: Four hours, 100% EtO @ 110°F

Polycarbonate: 250°F (121°C), 30 minutes, up to

Polysulfone: 270°F (132°C) for 60 minutes, up to

Steam-Thru Connection: 265°F (129°C) for 30 minutes,

HFC39: 270°F (132°C) for 60 minutes, up to

25 repetitions for uncoupled units and up to one repetition

Electron Beam (E-Beam): Maximum cumulative exposure

Gamma: Maximum cumulative exposure of 50 kilograys.

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

ISO 13485:2003 is recognized by regulators around

the world as a good basis for addressing medical

device design and manufacturing regulatory

requirements. It allows us to enhance product safety

by proactively identifying and managing product and

project risks. Becoming ISO 13485:2003 certified has

allowed CPC® to better control the consistency of

of 50 kilograys. Sterilize coupled or uncoupled.

Sterilize coupled or uncoupled.

SIP (Steam In Place) Process:

(Steam-Thru Connection)

(Steam-Thru II Connection)

Regulatory and Compliance

ISO 13485:2003 Certification

Up to 266°F (130°C) for 60 minutes

Up to 275°F (135°C) for 60 minutes

(43°C), up to five repetitions, coupled or uncoupled.

Sterilization Methods

for coupled units.

uncoupled only.

Sterilize coupled or uncoupled.

10 repetitions. Sterilize uncoupled only.

25 repetitions. Sterilize uncoupled only.

up to two cycles. (part number specific)

**CONNECTORS** 

Quick Disconnect Couplings CPC® Recommended Sterilization Methods

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 CPC® products are made

using resins that comply with applicable FDA or USDA

standards. When necessary, the standard O-Ring seals

CPC® 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 provided upon request.

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)

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. CPC® 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.

are replaced with specific, recognized materials.

FDA and USDA

Cleanroom Manufacturing

flame retardants.

NSF

Regulation of Hazardous Substances

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njection Sites & Sampling Ports

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Dilators & Introducer Sheaths

Spikes

Chambers

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Ports & Flanges

Syringes

Tools

Sterilization Supplies

Applicators, Swabs & Brushes

Containers

Scoops & Spoons

Dispensers

Drapes, Towels & Bandages

Clothing

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Australian Distributor
Importers & Manufacurers
www.chromfech.net.au **Manufacurers** 

ISO 9001:2008 Certification

manufactured products.

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. CPC® Quality Management System has been approved and certified under the ISO 9001:2008 standard.

2034 in AUSTRALIA

## In AUSTRALIA +61(03)9762-2034

N = No, not recommended

N/A = Not applicable

Y = Excellent, recommended material for this sterilization method

Ν