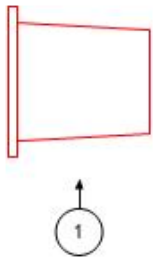
icumedical
human connections

PRODUCT TECHNICAL DATASHEET	
ITEM REFERENCE	**CH-CAP**
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA
ASSEMBLY SITE	**ICU Medical de Mexico**, S.A. de C.**.,** Avenida Cuarza No. 250, Colonia Rancho Santa Clara, Delegacion Manaedero Ensenada, Baja California, Mexico 22790
ITEM DESCRIPTION	CAP, STERILE
PRODUCT CLASS	IV Connector and Sets & Intravascular Administration Sets



Rev. 08
Capacity = 0 ml.
Length = 0 in.

DEVICE GENERIC INFORMATION	STERILE CAP

LIST OF COMPONENTS	1	CAP, RED SPIROS	POLYETHYLENE
	Sterile, non-pyrogenic fluid path in unopened undamaged package. This product is made of non-latex components.		

PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging is according to BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials in 50 unit cartons.
STERILIZATION	Radiation.
EXPIRY – SHELF LIFE	5 year(s).
BIOCOMPATIBILITY	Product has been approved for use and has met the requirements for ISO 10993-1.
LABELS / DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual bags and on the outside of the cardboard box. Each sales package contains a Direction for Use.
PRODUCTION ENVIRONMENT	Product is manufactured in an environmentally controlled room. Floor, surfaces and environment are monitored at defined frequencies to verify the controlled room conditions.
TRACEABILITY	ICU Medical guarantees full traceability of all the components used in the production of its devices.
DISPOSAL	The user must dispose the device according to hospital disposal policy.
STORAGE	Store in a dry and clean place. Product should be retained in provided packaging until ready for use.
WARNINGS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.
PRODUCTION CONTROLS	• Each component is inspected during acceptance (visual inspections, dimensional checks and functional tests) to verify conformity with the requirements according to ICU Medical internal quality procedures. • During product production and release specific tests are performed according to ICU Medical internal quality procedures. • At least once a month a LAL test is performed on samples taken from production to verify conformity of the endotoxin charge on the products. • At least quarterly Bioburden tests are performed on samples taken from production to verify conformity of the microbial charge on the products.

QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Quality System is in compliance to:**	ISO 13485:2016
	Product Certification:	The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.
	CE Certificate Number:	252.602
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class IIa