PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-CH2000S-C	REVISION:	02

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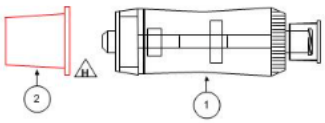
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA							
IMPORTER	**ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands							
EU AUTHORISED REPRESENTATIVE (EUAR)	**Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany							
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							
CLASSIFICATION CODE	**GMDN** Code: 42750							
INTENDED USE	Neutral-pressure needleless valve-connector A small, sterile, stand-alone, Luer-activated needleless plastic valve intended to mate two related intravenous (IV) line devices [e.g., hypodermic syringe and catheter port or tubing from an IV administration set] and hold them in a secured, sealed, locked position until disconnection, at which point there is minimal fluid flow into or out of the catheter/tubing. It is intended to eliminate the use of needles for IV administration of medications. This is a single-use device.							
ITEM DESCRIPTION	Spinning Spiros™ Closed Male Luer, Red Cap							
PRIMING VOLUME (ml)	0.1	**LENGTH (cm)**	3.63	**WEIGHT (g)**	3.63	**CASE QTY**	50	



ITEM SPECIFIC DATA		**MRI Compatibility**	No metal components
		Chemical Compatibility	Lipids & Common Chemotherapeutics
		Luer Compatibility	ISO 80369-7 Compliant.
		Sterilization and Shelf Life	Radiation; 5-Year Expiration
LIST OF COMPONENTS	1	SPINNING SPIROS	SILICONE SILICONE LUBRICANT POLYCARBONATE
	2	CAP	POLYETHYLENE (NON-FLUID PATH)
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	This product is made of non-latex, and non-DEHP components. Product has met the requirements of ISO 10993-1 and related standards for biocompatibility.		
PRECAUTIONS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.		

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LABELS AND DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual package and on the outside of the cardboard box. Each sales package contains a Direction for Use where applicable.	
PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging met the requirements of BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials.	
TRACEABILITY	Lot number provides full traceability of all components and manufacturing processes.	
STORAGE	Store in a dry and clean place. Product should be retained in packaging until ready for use.	
DISPOSAL	The user must dispose of the device according to hospital disposal policy.	
PRODUCTION AND ENVIRONMENT CONTROLS	• Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures. • Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures. • Production and release specific tests are performed according to quality procedures. • Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures. • Bioburden tests are performed on production samples to verify conformity of the microbial charge according to quality procedures.	
QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Quality System complies to:**	ISO 13485:2016
	Product Certification:	The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.
	CE Certificate Number:	252.714
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class IIa