

PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-CL4162	REVISION:	03
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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: 41222						
INTENDED USE	<p>Medication transfer set</p> <p>A collection of sterile devices and supplies designed to transfer parenteral medications [e.g., intravenous (IV) fluids, drugs] between a first container(s) [e.g., a vial(s)] and a second container/administration line [e.g., an IV bag/line] in a non-powered closed system; it may also be used to compound and/or reconstitute medication for its preparation and administration. It is available in a variety of configurations and typically includes vials, tubulures, connectors, spikes, syringes, and caps. This is a single-use device.</p>						
ITEM DESCRIPTION	Ext Set w/ChemoLock™, ChemoLock Port™						
PRIMING VOLUME (ml)	4	LENGTH (cm)	25	WEIGHT (g)	20	CASE QTY	50
ITEM SPECIFIC DATA	Chemical Compatibility		Lipids & Common Chemotherapeutics				
	Luer Compatibility		ISO 80369-7 Compliant.				
	Sterilization and Shelf Life		Radiation; 5-Year Expiration				
CHEMOLOCK SPECIFIC DATA	Connected Pressure Rating		45 psig / 2327 mmHG				
	Activations		10 Activations				
	Needlefree Connector Compatibility		ChemoLock Port compatible with all known Needlefree Connectors				
	Pressure Rating		ChemoLock Injector = 45 psig / 2327 mmHG; ChemoLock Port = 20 psig / 1034 mmHG				
	Microbial Ingress and Disinfection Compatibility		Microbial barrier for seven days utilizing a 70% IPA disinfection				

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LIST OF COMPONENTS	1	CLAMP, PINCH, RED	POLYPROPYLENE (NON-FLUID PATH)
	2	TUBING, .090 X .141 , FROSTED	PVC
	3	FILTER, 0.2 MICRON	PES ACRYLIC PTFE
	4	CHEMOLOCK, AND MALE LOCKING LUER	POLYCARBONATE SILICONE STAINLESS STEEL POLYETHYLENE
	5	CHEMOLOCK™ PORT	SILICONE SILICONE LUBRICANT STAINLESS STEEL (NON-FLUID PATH) POLYCARBONATE POLYETHYLENE
	6	FEMALE ADAPTER, LUER LOCK	COPOLYESTER
	7	BANDING TAPE	TAPE (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.		
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	<ul style="list-style-type: none"> • 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 amoebocyte 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. 		

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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:	252.602
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class IIa