PRODUCT TECHNICAL DATASHEET

ITEM REF:	CH-12	REVISION:	17

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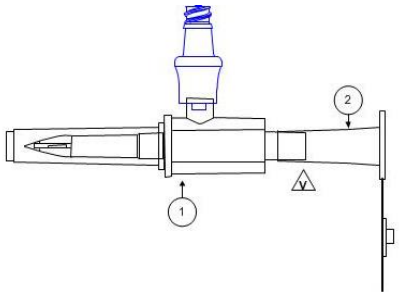
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA						
IMPORTER	**ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands						
EU AUTHORISED REPRESENTATIVE (EUAR)	**Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany						
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: 43324						
INTENDED USE	Fluid transfer set, general-purpose A collection of sterile devices and supplies designed to transfer several types of medical fluids (e.g., drugs, vaccines, blood, and solutions) between a first container(s) [e.g., a vial(s)] and a second container [e.g., an intravenous (IV) bag]; it is not dedicated to a particular type of fluid or clinical procedure. It is available in a variety of configurations and typically includes tubulures, connectors, spike(s), syringes, and caps. This is a single-use device.						
ITEM DESCRIPTION	ChemoClave® Bag Spike with Additive Port Dry Spike						
PRIMING VOLUME (ml)	0.35	**LENGTH (cm)**	12	**WEIGHT (g)**	10	**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
CLAVE SPECIFIC DATA	**Backpressure Rating**	60 psig / 3103 mmHG (Unactivated)
	Microbial Ingress and Disinfection Compatibility	Microbial barrier for seven days utilizing a 70% IPA disinfection
	Extended Use	600 repeat activations
	Luer Compatability	ISO 80369-7 Compliant male luers > 1,55mm Internal diameter

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LIST OF COMPONENTS	1	CLAVE® BAG SPIKE WITH ADDITIVE PORT	ABS SILICONE ACRYLIC POLYESTER (PBT) SILICONE LUBRICANT
	2	ADAPTOR, DRY SPIKE	PVC

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