## PRODUCT TECHNICAL DATASHEET

ITEM REF: 011-MC3322 REVISION: 08



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	<b>GMDN</b> Code: 12170							
INTENDED USE	Intravenous administration tubing extension set  A collection of tubing and connectors intended to establish an extension of tubing where the standard length of the tubing in an intravenous (IV) administration set is insufficient. This is a single-use device.							
ITEM DESCRIPTION	15 cm (6") Appx 0.35 ml, Smallbore Bifuse Ext Set w/2 MicroClave™ Clear, 2 Clamps, Rotating Luer							
PRIMING VOLUME (ml)	0.35 <b>LENGTH (cm)</b> 15 <b>WI</b>	EIGHT (g)	6	CASE QTY	50			
5	2.5" 1 2.5" 3 1 1							
ITEM SPECIFIC DATA	MRI Compatibilit	y No metal	No metal components					
	Chemical Compatibilit	Lipids &	Lipids & Common Chemotherapeutics					
	Luer Compatibilit	y ISO 8036	ISO 80369-7 Compliant.					
	Sterilization and Shelf Lif	e Radiation	Radiation; 5-Year Expiration					
CLAVE SPECIFIC DATA	Backpressure Ratin	<b>g</b> 45 psig /	45 psig / 2327 mmHG (Unactivated)					
	Disinfection Compatibilit	y 70% Isop	70% Isopropyl Alcohol					
	Luer Compatabilit	ISO 8036 1,55mm		npliant male luers liameter	>			

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1 CLAMP, SLIDE		Microbial Ingress and Disinfection Compatibility			Microbial barrier for seven days utilizing a 70% IPA disinfection		
LIST OF COMPONENTS  4 ROTATING MALE LOCKING LUER POLYCARBONATE (NON-FLUID PATH) PVC  5 MICROCLAVE®, CLEAR ABS POLYCARBONATE (NON-FLUID PATH) PVC  6 TUBING, NON-DEHP, .047 X .083 X PVC  MATERIAL COMPLIANCE AND BIOCOMPATIBILITY requirements of ISO 10993-1 and related standards for biocompatibility.  PRECAUTIONS  LABELS AND DIRECTIONS FOR USE  PACKING AND PACKAGING  The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging met the requirements of SD 10910 and release bit it most item is bilister packed or pouched individually using medical grade materials.  TRACEABILITY  PRODUCTION AND The user must dispose of the device according to quality procedures.  DISPOSAL  PRODUCTION AND ENVIRONMENT CONTROLS  Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Production and release specific tests are performed according to quality procedures.  Bioburden tests are performed on production samples to verify conformity of the endotion charge according to applity procedures.  Bioburden tests are performed on production samples to verify conformity of the endotion charge according to applity procedures.  Bioburden tests are performed on production samples to verify conformity of the endotion charge according to applity procedures.  Bioburden tests are performed on production samples to verify conformity of the endotion charge according to applity procedures.  Bioburden tests are performed on production sam		1	CLAMP, SLIDE		POLYETHYLENE (NON-FLUID PATH)		
LIST OF COMPONENTS  4 ROTATING MALE LOCKING LUER POLYCARBONATE (NON-FLUID PATH) PVC ABS POLYCARBONATE (NON-FLUID PATH) SILICONE SILICONE SILICONE SILICONE SILICONE LUBRICANT  6 TUBING, NON-DEHP047 X .083 X PVC  MATERIAL COMPLIANCE AND BIOCOMPATIBILITY PRECAUTIONS LABELS AND DIRECTIONS FOR USE  PACKING AND PACKAGING The non-unit packaging is biodegradable as defined by Directive Materials of BS EN ISO 11607. The packaging for this product is Lates Free. This item is bilister 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.  PRODUCTION AND ENVIRONMENT CONTROLS  Limilus amebocyte lysate (LAL) testing is performed on production samples to verify conformity with the requirements according to quality procedures.  Limilus amebocyte lysate (LAL) testing is performed on production samples to verify conformity with the requirements according to quality procedures.  Product Certification:  The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.	LIST OF COMPONENTS	2	BIFURACATED CON	IN MINIBORE	PVC		
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Solution   Polycarbonate (Non-Fluid Path)		4	ROTATING MALE LO	OCKING LUER	POLYCARBONATE (NON-FLUID PATH)		
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY  PRECAUTIONS  PRECAUTIONS  LABELS AND DIRECTIONS FOR USE  PACKING AND PACKAGING  The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging met the requirements of SE SEN 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  PRODUCTION AND ENVIRONMENT CONTROLS  PRODUCTION AND ENVIRONMENT CONTROLS  QUALITY SYSTEM AND  QUALITY SYSTEM AND  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.  The product is 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.  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.  Lot number provides full traceability of all components and manufacturing processes.  Store in a dry and clean place. Product should be retained in packaging until ready for use.  Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures.  Production and release specific tests are performed on production samples to verify conformity of the endotoxin charge according to quality procedures.  Product certification:  Product Certification:  The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.		5	MICROCLAVE®, CL	EAR	POLYCARBONATE (NON-FLUID PATH) SILICONE		
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  PRODUCTION AND ENVIRONMENT CONTROLS  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.  Each component is inspected during acceptance (example visual; dimensional; functional) to verify conformity of the endotoxin charge according to quality procedures.  Each component is inspected during acceptance (example visual; dimensional; functional) to verify conformity of the endotoxin charge according to quality procedures.  Each component is inspected during acceptance (example visual; dimensional; functional) to verify conformity of the endotoxin charge according to quality procedures.  Each component is performed on production samples to verify conformity of the endotoxin charge according to quality procedures.  Qu		6	•	P, .047 X .083 X	PVC		
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		Pı	roduct Certification:				
		CE	Certificate Number:	252.602			
Notified Body: NSAI National Standards Authority of Ireland.			Notified Body:	NSAI National S	Standards Authority of Ireland.		
MDD Device Classification: Class IIa		MDD De	evice Classification:	Class IIa	Class IIa		

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