

PRODUCT TECHNICAL DATASHEET

ITEM REF: 011-46112-28 REVISION: 09



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 Manadero Ensenada, Baja California, Mexico 22790						
CLASSIFICATION CODE	GMDN Code: 45275						
INTENDED USE	A collection of devices that includes the necessary tubing, pressure transducer(s) and other items [e.g., connectors, stopcock(s), clamps and filters] used for an invasive blood pressure measurement. This set will typically connect directly to the applied invasive catheter and the transducer will provide the electrical signals for display by a patient monitoring system. This device will have physical characteristics appropriate for preserving, to the extent possible, the waveform and fidelity of the measured pressure. This is a single-use device.						
ITEM DESCRIPTION	Transpac® IT w/91 INCH (232 CM), 3 ML/HR Macro drip						
PRIMING VOLUME (ml)	15.72	LENGTH (cm)	454.91	WEIGHT (g)	73.63	CASE QTY	25

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	3	TRANSDUCERS	SILICONE SANTOPRENE POLYPROPYLENE SENSOR ADHESIVE HDPE POLYCARBONATE COPPER PVC SILICONE RUBBER
	4	CONNECTORS	POLYCARBONATE
	5	TUBING	PVC
	6	CONNECTORS	POLYCARBONATE
	7	STOPCOCKS	POLYCARBONATE HDPE POLYPROPYLENE SILICONE OIL
	8	MALE LUERS	POLYETHYLENE POLYCARBONATE
	9	CAPS	POLYETHYLENE ABS
	10	LABEL, PATIENT LINE	CAST GLOSS ADHERIVE
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	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.		

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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 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	<table border="1"><tr><td>Quality System complies to:</td><td>ISO 13485:2016</td></tr><tr><td>Product Certification:</td><td>The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.</td></tr><tr><td>CE Certificate Number:</td><td>252.702</td></tr><tr><td>Notified Body:</td><td>NSAI National Standards Authority of Ireland.</td></tr><tr><td>MDD Device Classification:</td><td>Class IIa</td></tr></table>	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:	252.702	Notified Body:	NSAI National Standards Authority of Ireland.	MDD Device Classification:
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