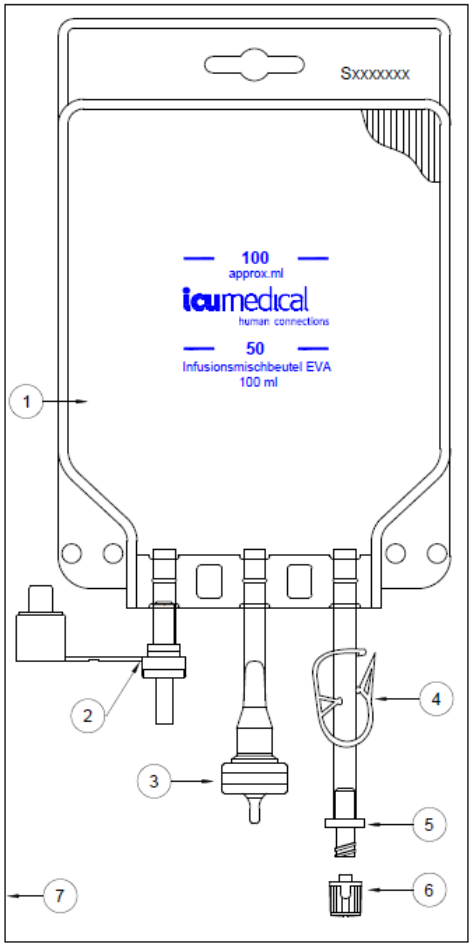
PRODUCT TECHNICAL DATASHEET	
ITEM REFERENCE	**SN2010**
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA
ITEM DESCRIPTION	Infusion bag EVA 100ml
PRODUCT CLASS	*Parenteral / Enteral Solution Bag*



DEVICE GENERIC INFORMATION	Infusion bag EVA		
LIST OF COMPONENTS	1	NPT EVA Bag 100ml Coex tubes	EVA
	2	Infusion point with cap	ABS / POLYPROPYLENE / POLISOPRENE
	3	Infusion closure break open	POLYCARBONATE / CHLOROBUTYL RUBBER LATEX FREE
	4	Medium on/off clamp white	POLYETHYLENE / POLYPROPYLENE
	5	Female luer lock connector	ABS
	6	Male luer lock vented cap	PELD
	7	Envelope	CMED / PET/ PP
	Sterile, non-pyrogenic fluid path in unopened undamaged package.		
PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging is according to BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials in 40 unit cartons.		
STERILIZATION	ETO		
EXPIRY – SHELF LIFE	5 year(s).		
BIOCOMPATIBILITY	Product has been approved for use and has met the requirements for ISO 10993-1.		

LABELS / DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual bags and on the outside of the cardboard box. Each sales package contains a Direction for Use.
PRODUCTION ENVIRONMENT	Product is manufactured in an environmentally controlled room. Floor, surfaces and environment are monitored at defined frequencies to verify the controlled room conditions.
TRACEABILITY	ICU Medical guarantees full traceability of all the components used in the production of its devices.
DISPOSAL	The user must dispose the device according to hospital disposal policy.
STORAGE	Store in a dry and clean place. Product should be retained in provided packaging until ready for use.
WARNINGS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.
PRODUCTION CONTROLS	• Each component is inspected during acceptance (visual inspections, dimensional checks and functional tests) to verify conformity with the requirements according to ICU Medical internal quality procedures. • During product production and release specific tests are performed according to ICU Medical internal quality procedures. • At least once a month a LAL test is performed on samples taken from production to verify conformity of the endotoxin charge on the products. • At least quarterly Bioburden tests are performed on samples taken from production to verify conformity of the microbial charge on the products.
QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Quality System is in compliance to:** ISO 13485:2016 **Product Certification:** The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended. **CE Certificate Number:** 252.884 **Notified Body:** NSAI National Standards Authority of Ireland.

	MDD Device Classification:	Class IIa