



<b>PRODUCT TECHNICAL DATA SHEET</b>	
<b>ITEM REFERENCE</b>	<b>011-MC33751</b>
<b>LEGAL MANUFACTURER</b>	ICU Medical, Inc. 951 Calle Amanecer, San Clemente, CA 92673, USA
<b>ASSEMBLY SITE</b>	<ul style="list-style-type: none"> <li>• ICU Medical, Inc., 4455 Atherton Drive Salt Lake City, UT 84123</li> <li>• ICU Medical S. de R.L. de C.V., Avenida Cuarza No. 250 Colonia Rancho, Santa Clara, Maneadero Ensenada, Baja California, Mexico 22790</li> </ul>
<b>ITEM DESCRIPTION</b>	16 cm (6.5") Smallbore Ext Set w/MicroClave® Clear, Clave® Clear, Clamp, Rotating Luer
<b>INTENDED USE</b>	IV Connector and Sets & Intravascular Administration Sets
<b>DEVICE GENERIC INFORMATION</b>	<p>Extension set with smallbore tubing, access by Clear MicroCLAVE®Connector, in line access by Clear Y-CLAVE®Connector and Rotating male Luer Lock at the end.</p> <p>The device is compatible with the common chemotherapy/antiblastic drugs and diluents.</p>
<b>LIST OF COMPONENTS</b>	<p>Clear MicroCLAVE®Connector, needle-free female valve, bi-directional self-sealing (Polycarbonate, Silicone, ABS)</p> <p>Slide clamp, non-removable (Polyethylene)</p> <p>Shunt PVC NO-DEHP, diameter (1.9 x 3.6) mm</p> <p>Clear Y-CLAVE®Connector, needle-free female valve, bi-directional self-sealing (Valox®, ABS, Silicone)</p> <p>Rotating male Luer Lock with breather cap (Polycarbonate, PVC, Polyethylene)</p> <p>PVC Clear NO-DEHP Tubing, diameter (1.2 x 2.1) mm</p> <p>Priming volume: approx. 0.39 ml</p> <p>The MicroCLAVE ® Connector is a neutral pressure needle-free female valve, bi-directional self-sealing and low dead-volume. The CLAVE® Connector can be used for infusion and/or withdrawal and venous/arterial long term access. The seal is automatically opened when it is access by a male Luer. This device, compared to conventional needle free connectors, allows not only to eliminate injuries from needle, thus protecting operators from the risk of infections (AIDS, hepatitis, etc..) and prevents microorganisms to access the system, minimizing the microbial contamination. The MicroCLAVE ® Connector System, if used according to the procedure, is easily disinfected due to its smooth surface. The MicroCLAVE ® Connector maintains a sterile barrier for 7 days and 700 activations. This information is collected in the archive of ICU Medical, Inc.. San Clemente, California 92673, USA. Do not use needles or Luer caps on CLAVE®connectors. The CLAVE® is compatible with Luer connectors with inside diameter between 1.55 mm and 2.8 mm.</p>
<b>PACKING AND PACKAGIN</b>	<p>Individual packaged product using pouch/blister in medical paper and film.</p> <p>Cardboard boxes.</p> <p>Indivisible box composed by: 50 pcs.</p>

	Packing and packaging according to UNI EN ISO 11607/1-2.
<b>STERILIZATION</b>	RADIATION: validated method according to UNI EN ISO 11137
<b>EXPIRY – SHIELD LIFE</b>	5 Year (from sterilization date) if undamaged package and properly stored. Do not re-use  , Reuse negatively impacts performance / sterility potentially resulting in product failure / contamination.
<b>BIOCOMPATIBILITY</b>	All the material are biocompatible according to ISO 10993
<b>LABELS</b>	Labels are applied on the individual bags and on the outside of the cardboard box. Product identification data according to Directive 93/42/EEC point 13.3 and the specific technical standards
<b>INSTRUCTION FOR USE</b>	Contained in each sales package (according to EN 1041 and further modifies and integrations)
<b>PRODUCTION ENVIROMENT</b>	Controlled production environments. Microbiological and particle controls are performed on environmental air and surfaces (UNI EN ISO 14644/1-2).
<b>TRACEABILITY</b>	ICU Medical guarantees full traceability of all the components used in the production of its devices
<b>DISPOSAL</b>	The user must dispose the device according to hospital disposal policy.
<b>STORAGE</b>	Store in a dry and clean place.
<b>WARNINGS</b>	Use aseptic techniques. Single-use only – Do not resterilize.
<b>PRODUCTION CONTROLS</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• During product production and release specific tests are performed according to ICU Medical internal quality procedures.</li> <li>• 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.</li> <li>• At least quarterly Bioburden tests are performed on samples taken from production to verify conformity of the microbial charge on the products.</li> </ul>
<b>QUALITY SYSTEM AND PRODUCT CERTIFICATION</b>	<b>Quality System in compliance with I.S.EN ISO 13485:2012</b> ➤ <b>Certificate</b> Number MD19.4496 <b>Notified body:</b> NSAI (National Standards Authority of Ireland)
	<b>Product certification:</b> in compliance with Directive 93/42/EEC (Annex II) and further modifies and integrations. <b>CE Certificate:</b> Number 252.602  <b>Notified Body:</b> NSAI (National Standards Authority of Ireland) <b>Classification:</b> Class IIa (Annex IX Directive 93/42/EEC).
<b>PATENTS</b>	US. PAT. 5,685,866; 5,928,204; 5,700,248; 6,132,404 Other Patents Pend