# PRODUCT TECHNICAL DATASHEET

| ITEM REF: | 011-CH-12 | REVISION: | 05 |
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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 |

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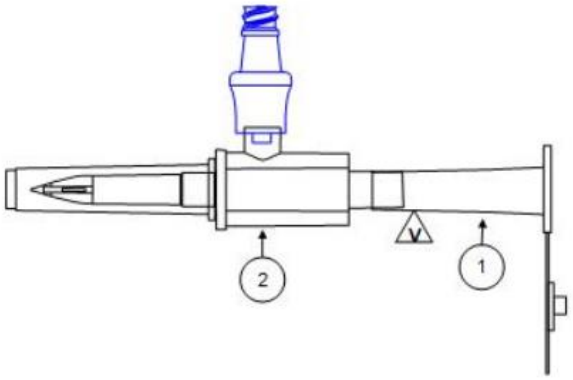
| **PRIMING VOLUME (ml)** | 0.35 | **LENGTH (cm)** | 12.7 | **WEIGHT (g)** | 10 | **CASE QTY** | 50 |

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| **ITEM SPECIFIC DATA** | **MRI Compatibility** | No metal components |
| | **Chemical Compatibility** | Lipids & Common Chemotherapeutics |
| | **Luer Compatibility** | ISO 80369-7 Compliant male luers > 1,55mm Internal diameter |
| | **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 |

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| | **Extended Use** | | 600 repeat activations |
| **LIST OF COMPONENTS** *(Latex and DEHP Free)* | 1 | ADAPTOR, DRY SPIKE | PVC NON-DEHP |
| | 2 | CLAVE® BAG SPIKE WITH ADDITIVE PORT | ABS<br>SILICONE<br>ACRYLIC<br>POLYESTER (PBT) (NON-FLUID PATH)<br>POLYETHYLENE (NON-FLUID PATH)<br>SILICONE LUBRICANT |
| **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.<br>• Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures.<br>• Production and release specific tests are performed according to quality procedures.<br>• Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures.<br>• 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. | |

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| | **MDD Device Classification:** | Class IIa |