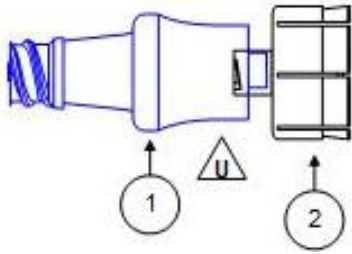


PRODUCT TECHNICAL DATASHEET

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| ITEM REF: | CH-62 | REVISION: | 12 |
|-----------|-------|-----------|----|

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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 Maneadero Ensenada, Baja California, Mexico 22790 | | | | | | |
| CLASSIFICATION CODE | GMDN Code: 60539 | | | | | | |
| INTENDED USE | The ChemoClave is a needle - free CSTD that mechanically prohibits the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system during drug preparation and administration, thereby minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs. | | | | | | |
| ITEM DESCRIPTION | ChemoClave® Vial Spike, 13mm | | | | | | |
| PRIMING VOLUME (ml) | 0.07 | LENGTH (cm) | 4.3 | WEIGHT (g) | 3.8 | CASE QTY | 50 |
|  | | | | | | | |
| ITEM SPECIFIC DATA | MRI Compatibility | | No metal components | | | | |
| | Chemical Compatibility | | Lipids & Common Chemotherapeutics | | | | |
| | Luer Compatibility | | ISO 80369-7 Compliant. | | | | |
| | 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 | | | | |
| | Extended Use | | 600 repeat activations | | | | |
| | Luer Compatability | | ISO 80369-7 Compliant male luers > 1,55mm Internal diameter | | | | |

PRODUCT TECHNICAL DATASHEET

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| LIST OF COMPONENTS | 1 | CLAVE | SILICONE SILICONE LUBRICANT VALOX COPOLYESTER |
| | 2 | VIAL ADAPTER, 13MM TRITAN | COPOLYESTER |
| 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 | <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 amoebocyte 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 | 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: | 252.1002 | |
| | Notified Body: | NSAI National Standards Authority of Ireland. | |
| | MDD Device Classification: | Class I Sterile | |