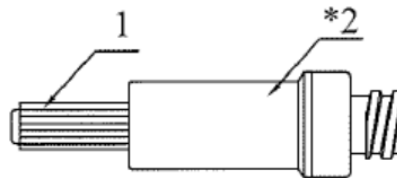


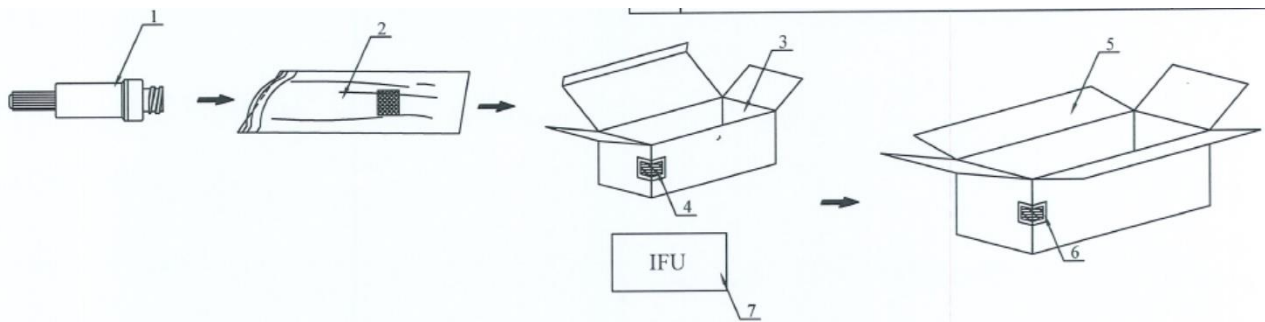
PRODUCT TECHNICAL DATA SHEET

| | | | |
|---------------------------|---|----------------|----|
| TITLE | TECHNICAL DATA SHEET: Sure-Lok™ Needle-Free Connector | | |
| CATEGORY | Sure-Lok™ Needle-Free Connector | Version | 02 |
| LEGAL MANUFACTURER | Amsino International Inc | | |

| DESCRIPTION | No. | New Item # | Description |
|-----------------------|---|------------|--|
| | 1 | AY0200 | Sure-Lok™ Needle-Free Connector, EO-sterile, 100pcs/box, 4boxes/case |
| USE/INDICATION | The AMSafe® Needleless connector, also known as sure-lok Connector is a negative Needleless connector intended for single patient use, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids which using a vascular access device. The Needleless connector is a closed, Luer activated device that eliminates the risk of needle stick injuries. | | |
| DRAWING | Refer to the below drawing | | |



| | | | | |
|-------------|---------------|---------------------------------|------------|----------------|
| *2 | KL1069 | 无针注射阀/Needleless injection site | 1 | PC/Silicone |
| 1 | KL0161 | 护帽/Protective cap | 1 | PP |
| 序号 Index | 零件编号 Part# | 描述 Description | 数量 Qty. | 原料 Material |



PRODUCT TECHNICAL DATA SHEET

| | | | |
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| TITLE | TECHNICAL DATA SHEET: Sure-Lok™ Needle-Free Connector | | |
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| | | | | |
|-------------|---------------|---------------------------------|------------|--------------------------|
| * 7 | SM387 | 说明书/IFU | 1 | Paper |
| * 6 | KB044327 | 外箱标签/Case label | 1 | Pressure sensitive paper |
| 5 | KB01035 | 外箱/Case | 1 | Corrugated Kraft |
| 4 | KB04530 | 中盒标签/Inner box label | 4 | Pressure sensitive paper |
| 3 | KB01050 | 中盒/Inner box | 4 | Corrugated Kraft |
| 2 | KB03530 | 小包装袋/PE pouch | 400 | PE |
| 1 | AY0200_AS | 无针加药阀/Needleless injection site | 400 | See drawing |
| 序号 Index | 零件编号 Part# | 描述 Description | 数量 Qty. | 原料 Material |

1. AY0200_AS

| | |
|----------------------------------|---|
| MATERIALS OF CONSTRUCTION | The product is consisting of components: Needleless injection site made of PC/Silicone, Protective cap made of PP. |
| PACKAGING | Individually packed in poly pouch with breathing paper patch, 100pcs per inner box. 4 inner boxes per case. |
| STERILIZATION METHOD | EO-sterile |
| SHELF LIFE | 5 years |
| BIOCOMPATIBILITY | Cytotoxicity ISO 10993-5 Intracutaneous reactivity ISO 10993-10 Sensitization ISO 10993-10 Acute systemic toxicity ISO 10993-11 Hemolysis ISO 10993-4 Pyrogen ISO 10993-11 |
| LABELING | Labelling is developed in accordance with ISO 20417 (Applicable ISO Standard version per product design inputs), ISO 15223 (Applicable ISO Standard version per product design inputs). |
| INSTRUCTIONS FOR USE | Label/Enclosure contains information for proper use including any warnings or contraindications. |
| MANUFACTURING ENVIRONMENT | Products are manufactured in a clean room. |

PRODUCT TECHNICAL DATA SHEET

| | | | |
|---------------------------|---|----------------|----|
| TITLE | TECHNICAL DATA SHEET: Sure-Lok™ Needle-Free Connector | | |
| CATEGORY | Sure-Lok™ Needle-Free Connector | Version | 02 |
| LEGAL MANUFACTURER | Amsino International Inc | | |

| | |
|---|--|
| TRACKING | Each product is identified by a unique list number assigned to a finished product batch record number, and tracked through all the stages of the production process including release to market. |
| STORAGE CONDITION | Avoid freezing and excessive heat. |
| QUALITY TESTS | Product is tested per Amsino quality guidelines at manufacturing plant. |
| QUALITY SYSTEM AND PRODUCT CERTIFICATION | Quality System is in compliance to: EN ISO 13485: 2016 Quality System Certificate Number: Q5 0551960063 Notified Body: TÜV SUD Product Service GmbH |
| | Product Certification: The products are manufactured in compliance to Regulations (EU) 2017/745 CE Certificate Number: CL 055196 0074 Rev. 01 Notified Body: TÜV SUD Product Service GmbH |