

## Ethylene oxide sterilization records

No. : JL(7.5.1)-012 Version: B/0

|                                         |                                                                                                    |                                        |                                                                                            |                                    |                              |
|-----------------------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------|------------------------------|
| Procedure Name                          | Sterilization process                                                                              |                                        | Sterilization date                                                                         | Dec. 25, 2023                      |                              |
| Device number                           | SCSB-06                                                                                            |                                        | Sterilization lot number<br>(Sterilization lot)                                            | CJ24040-C, 2023. 12. 18            |                              |
| destroy bacteria production product     | Product name                                                                                       |                                        | Model specifications                                                                       | Production lot number              | quantity                     |
|                                         | Scalp vein set                                                                                     |                                        | 19G, 23G                                                                                   | CJ24040-C                          | 470, 000pcs                  |
| Preparation                             | Water check: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal          |                                        | Device check: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> abnormal |                                    |                              |
| Sterilization operation parameters      | Tank temperature<br>60 ± 3 °C                                                                      | Sterilization temperature<br>45 ± 3 °C | Sterilizing humidity<br>30 to 80%                                                          | Heat retention time<br>60min       | Vacuum degree<br>-20 ± 2 Kpa |
|                                         | 59.2°C                                                                                             | 47.6°C                                 | 69%                                                                                        | 60                                 | -20 Kpa                      |
|                                         | Pressure holding time<br>20min                                                                     | Sterilization time<br>480 min          | Air exchange vacuum<br>-5Kpa                                                               | Number of air changes<br>3 breaths | Ventilation time<br>20 min   |
|                                         | 20                                                                                                 | 480                                    | -5 Kpa                                                                                     | 3                                  | 20                           |
| Dosing time<br>30 to 45min              | 16:45-17:40~                                                                                       |                                        | Sterilization start time                                                                   | 17:45                              |                              |
| Dosage: 16 ± 0.3Kg (concentration: 80%) |                                                                                                    | Ethylene oxide supply unit             |                                                                                            | Production lot number              |                              |
| Initial weight                          | End weight                                                                                         | Actual dosing                          | Changyuan, Henan                                                                           |                                    | CJ24040-C                    |
| 41.7kg                                  | 25.8kg                                                                                             | 15.9kg                                 |                                                                                            |                                    |                              |
| Sterilization equipment                 | HMG-A (20m <sup>3</sup> ) ethylene oxide sterilization cabinet Jiangyin Huaqing Machinery Co., LTD |                                        |                                                                                            |                                    |                              |
| Equipment operation                     | <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal: _____                |                                        |                                                                                            |                                    |                              |
| Sterilization completion time           | Dec. 25, 2023                                                                                      |                                        | Coming out time                                                                            | Dec. 26, 2023                      |                              |

上海昌军进出口贸易有限公司

SHANGHAI CHANNELMED IMPORT & EXPORT CO.,LTD

地址: 上海浦东张扬路 707 号生命人寿大厦 1402 室 邮编: 200120.

Tel: +8621-58354015/16/17 Fax: +8621-58354018 E-mail: [info@channelmed.com](mailto:info@channelmed.com) [Http://www.channelmed.com](http://www.channelmed.com)

|                       |                                                                                                                                 |                                     |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Sterilizing<br>effect | <input type="checkbox"/> √ Passed <input type="checkbox"/> failed<br><br>Sterilization card color: from<br>red to blue to pass. | Operator:<br><br><div>Xulicun</div> |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|

Review:Guoguangzhen

上海昌军进出口贸易有限公司  
SHANGHAI CHANNELMED IMPORT & EXPORT CO., LTD.

钟明军