



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

**No. G11 097364 0014 Rev. 01**

### Manufacturer:

**Kingstar Medical (Xianning) Co., LTD**

No. 79 Yong'andong Road  
Xian'an District  
437100 Xianning City, Hubei Province  
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000006015

### Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11 097364 0014 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G11 097364 0014 Rev. 01)

**Report No.:** SH2393901

**Preceding Certificate No.:** G11 097364 0014 Rev. 00

**Valid from:** 2024-09-11

**Valid until:** 2028-01-29

**Date of Initial Issuance:** 2023-02-10

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-09-11



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|                           |                                                                                      |
|---------------------------|--------------------------------------------------------------------------------------|
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M010102 - PURE COTTON                                                                |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0201010101 - COTTON GAUZE, CUT, WITHOUT X-RAY<br>DETECTABLE THREAD, STERILE         |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0201020101 - COTTON GAUZES, FOLDED, WITHOUT X-RAY<br>DETECTABLE THREAD, STERILE     |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0201030101 - LAPAROTOMY COTTON GAUZES, WITHOUT X-<br>RAY DETECTABLE THREAD, STERILE |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0201050101 - COTTON GAUZE PADS, WITHOUT X-RAY<br>DETECTABLE THREAD, STERILE         |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0202010101 - NON-WOVEN FOLDED GAUZES, WITHOUT X-<br>RAY DETECTABLE THREAD, STERILE  |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M0202030101 - NON-WOVEN GAUZE PADS, WITHOUT X-RAY<br>DETECTABLE THREAD, STERILE      |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M020204 - NON-WOVEN GAUZES IN PIECES                                                 |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                                            |
| <b>Classification:</b>    | Class I                                                                              |
| <b>Device Group:</b>      | M03030101 - ELASTIC FIXING BANDAGES, NON-ADHESIVE                                    |



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|---------------------------|----------------------------------------------------------------|
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M03040101 - ELASTIC COMPRESSION BANDAGES, NON-ADHESIVE         |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M03040202 - ELASTIC SUPPORT BANDAGES, COHESIVE (SELF-ADHESIVE) |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M0401 - PREPARED DRESSINGS                                     |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M04010101 - NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD   |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M040204 - NON-ADHERENT ABSORBENT DRESSINGS                     |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M040299 - NON-ADHESIVE ABSORBENT DRESSINGS - OTHER             |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS              |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |
| <b>Device Group:</b>      | T0201 - SURGICAL DRAPES                                        |
| <b>Device Properties:</b> | MDS 1005.1 - Ethylene Oxide sterilization                      |
| <b>Classification:</b>    | Class I                                                        |



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**Device Group:** T020401 - STANDARD SURGICAL GOWNS  
**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**Classification:** Class I  
**Device Group:** T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)  
**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**Classification:** Class I  
**Device Group:** T020699 - MEDICAL USE FACE MASKS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) - OTHER  
**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**Classification:** Class I  
**Device Group:** V9001 - TONGUE DEPRESSORS, SINGLE-USE  
**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**The validity of this certificate depends on conditions and/or is limited to the following:** -none-

### Revision History:

| Rev. | Dated      | Report    | Description                                      |
|------|------------|-----------|--------------------------------------------------|
| 00   | 2023-02-10 | SH2193901 | -                                                |
| 01   | 2024-09-11 | SH2393901 | Supplemented: Device(s)/group of device(s) added |