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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

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

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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No. G11 097364 0014 Rev. 01

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

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

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No. G11 097364 0014 Rev. 01

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

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