ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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 041808 0060 Rev. 02

Manufacturer:

Shanghai Kindly Enterprise Development Group Co., Ltd.
No 658 Gaochao Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005652

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 041808 0060 Rev. 02

Report No.:	BJ22081703
Preceding Certificate No.:	G11 041808 0060 Rev. 01
Valid from:	2023-07-19
Valid until:	2026-02-10
Date of Initial Issuance:	2021-02-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-07-19

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class I
Device Group:	A020108 - ENTERAL FEEDING SYRINGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A070502 - CAPS OR OBTURATORS, PERFORABLE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A020199 - SYRINGES, SINGLE-USE - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A030499 - ADMINISTRATION KITS - OTHER
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	2021-02-11	BJ20081703	-	
01	2022-08-04	BJ21081703	-	
02	2023-07-19	BJ22081703	Supplemented: Other	Scope Expansion

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