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

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 041808 0065 Rev. 01

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 quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective 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.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 041808 0065 Rev. 01

Report No.: BJ25081704
Preceding Certificate No.: G15 041808 0065 Rev. 00

Valid from: 2026-02-11
Valid until: 2031-02-10
Date of Initial Issuance: 2025-04-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-12-18

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

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

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 041808 0065 Rev. 01

Classification:	Class I
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A020108 - ENTERAL FEEDING SYRINGES
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A020199 - SYRINGES, SINGLE-USE - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition 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 - Devices in sterile condition
Classification:	Class I
Device Group:	A030499 - ADMINISTRATION KITS - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A070502 - CAPS OR OBTURATORS, PERFORABLE
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A0399 - TUBULAR DEVICES - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A0401 - INFUSION AND WITHDRAWL FILTERS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A060301 - COLLECTION BAGS AND OTHER CONTAINERS FOR DRAINAGES AND FISTULAS, SINGLE USE
Device Properties:	MDS 1005 - Devices in sterile condition
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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

TÜV®

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

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 041808 0065 Rev. 01

Revision History:

Rev.	Dated	Report	Description
00	2025-04-09	BJ24081701	Supplemented: Device(s)/group of device(s) added
01	2026-02-11	BJ25081704	Renewal of certificate

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

TÜV®