Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 086535 0010 Rev. 04

Holder of Certificate: **Hoshin Medical Instrument Co., Ltd.**
Rm. 3-1421 Wanda Plaza
Xinbei District
213022 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Non-sterile and Sterile Urine Drainage Bag, Sterile Vaginal Speculum**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). 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:Q6 086535 0010 Rev. 04

Report No.: SH2483301

Valid from: 2025-02-19
Valid until: 2026-01-27

Date, 2025-02-19

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 086535 0010 Rev. 04

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Hoshin Medical Instrument Co., Ltd.
Rm. 3-1421 Wanda Plaza, Xinbei District, 213022 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Distribution of Non-sterile and Sterile Urine Drainage Bag, Sterile Vaginal Speculum

Jiangsu Jinwu Medical Instrument Co., Ltd.
No.19, Jingyi Road, Hongze Economic Development Zone, 223100 Huaian, PEOPLE'S REPUBLIC OF CHINA

Production of Non-sterile and Sterile Urine Drainage Bag, Sterile Vaginal Speculum

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TÜV®

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 Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 086535 0016 Rev. 00

Manufacturer:

Hoshin Medical Instrument Co., Ltd.
Rm. 3-1421 Wanda Plaza
Xinbei District
213022 Changzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000003898

Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE NETHERLANDS

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A 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 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 devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X 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:G26 086535 0016 Rev. 00

Report No.: SH2383302
Valid from: 2025-04-16
Valid until: 2030-04-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-04-16

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BS-MDR-099

TÜV SÜD Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 086535 0016 Rev. 00

Classification:	Class I
Device Group:	A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE U089006 - VAGINAL SPECULUM, 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:	N.A

Rev.	Dated	Report	Description
00	2025-04-16	SH2383302	Initial issuance

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