



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 094301 0005 Rev. 00

Manufacturer: **Dongguan ZSR Biomedical Technology
Company Limited**

Unit 448, Qingfeng Road, Taihu Village
Sanzhong Village Committee
Qingxi Town
523651 Dongguan City, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000016828

**Authorized
Representative:**

Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, 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.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 094301 0005 Rev. 00

Report No.: GZ2321902

Valid from: 2025-02-27

Valid until: 2030-02-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-27



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Classification: Class IIa
Device Group: H020202 - CIRCULAR STAPLERS FOR OPEN SURGERY
Intended Purpose: /

Classification: Class IIa
Device Group: U020104 - URETERAL CATHETERS WITH OLIVARE TIP
 U020302 - DOUBLE LOOP URETERAL STENTS
 U030102 - URETHRAL AND URETERAL DILATORS
 U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC
 U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC
Intended Purpose: /

Classification: Class IIa
Device Group: U020301 - SINGLE LOOP URETERAL STENTS
 U030101 - SEQUENTIAL DILATORS FOR PERCUTANEOUS
 NEPHROSTOMY
Intended Purpose: /

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

Revision History:

Rev.	Dated	Report	Description
00	2025-02-27	GZ2321902	Initial issuance