



EU Quality Assurance Certificate CN25/00007163

The management system of

# Suzhou Shenyun Medical Equipment Co., Ltd.

Building 11, No. 666, Yinzang Road, Linhu Town, Wuzhong District, Suzhou City, Jiangsu  
Province, P.R. China  
SRN Number: CN-MF-000026847

has been assessed and certified as meeting the requirements of  
**MDR EU Quality Assurance certificate (Annex XI Part A)**

For the following products  
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 22 October 2025 until 22 October 2030 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 22 April 2030

Issue 1. Certified since 22 October 2025

Authorised by

Virginie Siloret

Global Medical Device  
Certification Manager

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# Suzhou Shenyun Medical Equipment Co., Ltd.

## MDR EU Quality Assurance certificate (Annex XI Part A)

Class IIa devices:

MDN1202, MDS1005

Sterile Single Use Gastric Calibration Tube  
Basic UDI-DI: 6975573320097D2

Sterile Single Use Drainage Tube  
Basic UDI-DI: 6975573320098D4

Sterile Single Use Urinary Catheter  
Basic UDI-DI: 6975573320099D6

Conditions for & limitation to the validity of the certificate:

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability, or measurement function).

For placing on the market of Class IIb or Class III devices covered by this certificate an EU Type Examination Certificate according to Annex X is required.

List of examinations and tests performed, which may include reference to relevant CS and harmonized standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to [NB1639@sgs.com](mailto:NB1639@sgs.com).

Limitation: N/A

Certification is based on following reports: - CN/SZH/277550 - S2A 1.1 + TFR 1.2

Authorized representative name and address (if relevant): MedPath GmbH; Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

