SHENYUN
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TECHNICAL DATA SHEET

Silicone Urinary Catheters

1. GENERAL INFORMATION

Types	2-way Foley · 3-way Foley · Nelaton
Intended use	Urinary drainage through the urethra; 3-way Foley also for bladder irrigation
Material	100% silicone, latex-free
Material properties (typical)	Density approx. 1.1–1.2 g/cm³
Sterility	Sterile, ethylene oxide (EO)
Use	Single use

2. TECHNICAL SPECIFICATIONS

Type	Models	Sizes	Balloon / length
2-way Foley	SY03-08 – SY03-26	8–26 Fr	3–5 mL (8–12 Fr) · 5–10 mL (14–24 Fr) · 30 mL (26 Fr)
3-way Foley	SY03-18T – SY03-30T	18–30 Fr	5–10 mL / 30 mL
Nelaton	SY04-06 – SY04-24	6–24 Fr	Length 250 mm (paediatric) / 400 mm (standard)

3. PACKAGING

Carton	56 × 56 × 45 cm

See the Packaging Specification for packaging details, freight and customization options.

4. REGULATORY INFORMATION

Quality management system	ISO 13485:2016, certificate CN25/00005189, SGS United Kingdom Ltd, valid until 2028-07-30
EU MDR	Class IIa, EU quality assurance certificate CN25/00007163, SGS Belgium NV (NB 1639), valid until 2030-10-22 · Basic UDI-DI 6975573320099D6

5. MANUFACTURER

Manufacturer	Suzhou Shenyun Medical Equipment Co., Ltd. Building 11, No. 666 Yinzang Road, Linhu Town, Wuzhong District, Suzhou, Jiangsu, P.R. China
EU SRN	CN-MF-000026847
EU authorised representative	MedPath GmbH, Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany (SRN DE-AR-000000087)

Specifications are subject to change without notice. Contact info@symedical.com.cn for the latest version.