

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name and address of the manufacturer Name: Suzhou Anying Medical Equipment Co.Ltd.
Address: Building 3, No. 58 Suwei Road, Weitang Town, Xiangcheng District, Suzhou City, Jiangsu Province, China

SRN CN-MF-000047126

Trademark /

Name and address European Representative Name: Llins Service&Consulting GmbH
Address: Prankhstrasse 47, 67061 Ludwigshafen am Rhein, Germany

SRN DE-AR-000009077

Product name Single Use Sterile Gastric Calibration Tube

Product model 34FR,36FR,38FR,40FR

Product specification	Specification	Model			
		34FR	36FR	38FR	40FR
	Outer Diameter(mm)	11.3 ± 0.3	12.0 ± 0.3	12.4 ± 0.3	13.2 ± 0.3
	Inner Diameter(mm)	7.1 ± 0.3	8 ± 0.3	8.4 ± 0.3	8.3 ± 0.3
	X-ray Line Colour	Red	Blue	Green	Yellow
	Tip Colour	Red	Blue	Green	Yellow
	Tube length(mm)	1260 ± 50	1260 ± 50	1260 ± 50	1260 ± 50

Intended purpose/use The Single Use Sterile Gastric Calibration Tube is intended to be used during bariatric or gastric surgical procedures, such as sleeve gastrectomy, gastric bypass and fundoplication, to:

- provide a physical template for the visual and tactile delineation and calibration of stomach size during resection or suturing;
- decompress the stomach and remove gastric waste fluids, gas or stomach contents through suction;
- facilitate gastric flushing/suction with clinically appropriate flushing fluid, such as sterile normal saline, during the surgical procedure;
- support intraoperative leak testing with clinically appropriate diagnostic fluid, such as methylene blue solution, where required by the clinical procedure;
- provide visual orientation and positioning reference markings to assist the clinician in identifying the tube position during use.

The device is not intended for routine drug delivery or general administration of medicinal products. No broad medicinal product

compatibility claim is made.

The graduation marks / scale markings are visual reference markings only for orientation and positioning of the tube during use. They do not provide quantitative measurement results, are not linked to an accuracy claim, and shall not be used to determine insertion depth, anatomical dimensions, resection length, gastric pouch size, dose, volume, or any other quantitative clinical parameter. Therefore, the device does not have a measuring function in accordance with MDCG 2021-24 Rev.1, Section 3.1.6.

Basic UDI-DI 697849452WG23042538

EMDN G020502

Classification acc. to MDR Ax. VIII

- Sterile Single Use Sterile Gastric Calibration Tube: Class II a, Rule 5, Indent 2.
- Universal Connector (Accessory): Class II a, Rule 5, Indent 4.

Conformity assessment procedure Annex XI of MDR Regulation (EU) 2017 /745 on medical devices

CE certificate no. /

Name, address and ID of the Notified Body SGS Belgium NV
Noorderlaan 87 BE-2030 Antwerpen, Belgium



We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Suzhou, July 1, 2026

Hongjie Liu, Quality manager

Hongjie Liu

SUZHOU

Place, date

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Name and function