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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 065765 0014 Rev. 02

Manufacturer:

Foosin Medical Supplies Inc., Ltd.

No.20, Xingshan Road
Weihai Torch Hi-tech Science Park
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Product:

Sutures

**Non-absorbable Surgical Suture
with or without Needle**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.:

713174356

Valid from:

2020-03-04

Valid until:

2024-05-26

Date,

2020-03-04

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

**WEGO-POLYPROPYLENE
WEGO-POLYESTER
WEGO-PVDF
WEGO-PTFE**

Parameters:

- **WEGO-POLYPROPYLENE sutures:**

- Suture diameter: European standard 0.2 to 4 (USP 10-0 to USP 1)
- Suture length: $\leq 390\text{cm}$
- Suture with or without needle
- Needle Description:
 - Tip Shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
 - Length: 3mm to 90mm
 - Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape
- Colour: Dyed (blue) / Undyed (natural white)
- None coated
- Structure diagrams: Monofilament
- Suture Quantity: 1-50

- **WEGO-POLYESTER sutures:**

- Suture diameter: European standard 0.2 to 7 (USP 10-0 to USP 5)
- Suture length: $\leq 390\text{cm}$
- Suture with or without needle
- Needle Description:
 - Tip Shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
 - Length: 3mm to 90mm
 - Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape
- Colour: Dyed (green) / Undyed (natural white)
- Coating: Silicone or Uncoated
- Structure diagrams:
 - Braided (EP Sizes 0.3 to 7 (USP Sizes 9-0 to USP 5))
 - Monofilament (EP size 0.2 (USP size 10-0))
- Suture Quantity: 1-50

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- **WEGO-PVDF sutures:**

- Suture diameter: European standard 0.2 to 5 (USP 10-0 to USP 2)
- Suture length: ≤390cm
- Suture with or without needle
- Needle Description:
 - Tip Shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
 - Length: 3mm to 90mm
 - Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape
- Colour: Dyed (blue) / Undyed (natural white)
- None coated
- Structure diagrams: monofilament
- Suture Quantity: 1-50

- **WEGO-PTFE sutures**

- Suture diameter: European standard 0.2 to 5 (USP 10-0 to USP 2)
- Suture length: ≤390cm
- Suture with or without needle
- Needle Description:
 - Tip Shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
 - Length: 3mm to 90mm
 - Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape
- Colour: Undyed (natural white)
- None coated
- Structure diagrams: monofilament
- Suture Quantity: 1-50



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Suture Coding System:

XX (1)	X (2)	X (3)	XX (4)	X (5)	XXXXX (6)	-	XXX (7)	x	XX (8)	X (9)							
(1)	Suture Material	(2)	USP	(3)	Needle type	(4)	Needle Length/mm (3-90mm)	(5)	Needle Curve	(6)	Subsidiary	(7)	Suture Length/cm (0-390cm)	(8)	Suture Quantity (1-50) Note: Suture Quantity > 1 marking	(9)	Packaging Configuration
P	PP	1	0	None	No Needle	None	None	None	No Needle	D	Double Needle	5	5	None	1	None	paper card + aluminum-plasticsachet + dialyzing paper bags (dialyzing paper +PEfilm)
E	PE	2	2-0	1	Taper	03	3	2	1/2 circle	U	Un-dyed Suture	15	15	2	2		
Z	PTFE	3	3-0	2	Blunt	04	4	3	3/8 circle	B	Blue Suture	30	30	3	3		
PV	PVDF	4	4-0	3	Reverse Cutting	05	5	4	1/4 circle	G	Green Suture	45	45	4	4		
		5	5-0	4	Cutting	06	6	5	5/8 circle	H	Heavy Needle	60	60	5	5		
		6	6-0	5	Diamond	07	7	6	Compound Curve	P	Loop	75	75	6	6		
		7	7-0	6	Premium Cutting	08	8	0	Straight	N	Uncoated	90	90	7	7	H	Paper card +Tyvekbags (Tyvek + PEfilm)
		8	8-0	7	Taper Cutting	09	9	J	J Shape	S	Slim Needle	100	100	8	8		
		9	9-0	8	Spatula	10	10			None	None	120	120	9	9		
		A	10-0	9	Square	20	20					150	150	10	10	T	Paper card + Tyvekbags (Tyvek + PETG)
		B	1			40	40					180	180	15	15		
		C	2			50	50					200	200	20	20		
		D	3			60	60					250	250	30	30		
		E	4			70	70					300	300	40	40		
		F	5			80	80					390	390	50	50		
						90	90										

Note: 1. The needle length shown in table is general specification. The other specifications within the recommended limit (3-90mm) also can be manufactured.
2. The suture length shown in table is general specification. The other specifications within the recommended limit (0-390cm) also can be manufactured.
3. The suture quantity shown in table is general specification. The other specifications within the recommended limit (1-50) also can be manufactured.
4. The situation that character 6 is 'None': Polypropylene suture: Blue colour, none coated;
Polyester suture: Green colour, coated;
PVDF suture: Blue colour, none coated;
PTFE suture: Un-dyed, none coated.