

DECLARATION OF CONFORMITY (APPROVED) TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER: Foosin Medical Supplies Inc., Ltd.

No.20 Xingshan Road, Weihai Torch Hi-tech Science Park, Shandong, China

MEDICAL DEVICE: Non-absorbable surgical suture with or without needle

UMDNS CODES:13910

Model:WEGO-SILK

Suture diameter gauge: European pharmacopeia (EP) standard 0.2~7(USP10-0~5#)

Suture length:≤3.9m

Suture Colour: blue, black or undyed.

Structured diagrams: Braided

Needle length:4mm~90mm

Needle type: Taper, cutting, spatula, blunt, taper cut, diamond, premium cutting and square.

Needle quantity: 0~20, Suture quantity:1~50

CLASSIFICATION-ANNEX IX:Class II b Rule 8

CONFORMITY ASSESSMENT ROUTE :Annex II.3, MDD 93/42/EEC

We, Foosin Medical Supplies Inc., Ltd. Here with declare that the stated medical devices meet 93/42/EEC directive concerning medical devices; all supporting documentation is retained at the premises of the manufacturer. We, as the manufacturer, are exclusively responsible for the declaration of conformity.

STANDARDS APPLIED :

1	MDD 93/42/EEC	21	EN ISO 11138-2:2017	41	USP36-<861>
2	EN 556-2:2015	22	EN ISO 11135:2014	42	USP36-<871>
3	MEDDEV 2.7-1 rev.4	23	EN ISO 11737-1:2006/AC:2009	43	USP36-<881>
4	MEDDEV 2.12-1 rev 8	24	EN ISO 11737-2:2009	44	EN ISO 14937: 2009
5	MEDDEV 2.12-2 rev 2	25	ISO 13485: 2016	45	EN 1422:2014
6	ISO10993-1:2009/AC: 2010	26	EN ISO 14971:2012	46	YY0167:2005
7	ISO10993-3:2014	27	ISO 14644-1:2015	47	YY0043:2016
8	ISO 10993-4:2017	28	ISO 14644-2:2015	48	ISO 11138-1:2017
9	ISO 10993-5:2009	29	ISO 14644-3:2005	49	ISO14161: 2009
10	ISO 10993-6:2016	30	ISO 14644-4:2001	50	ISO 11140-1:2014
11	ISO 10993-7: 2008	31	ISO 14644-5:2004	51	ISO 11137-1:2006
12	ISO 10993-9:2009	32	ISO 14644-7:2004		
13	ISO 10993-10:2010	33	ISO 14644-8:2013		
14	ISO 10993-11:2006	34	ISO 14698-1:2003		
15	ISO 10993-12:2012	35	ISO 14698-2:2003		
16	ISO 10993-16:2017	36	EN 62366-1:2015		
17	ISO 10993-18:2005	37	ISO 15223-1:2016		
18	ISO/TR 10993-33: 2015(E)	38	EN ISO 14630:2012		
19	EN ISO 11607-1: 2009+A1: 2014	39	EP 9.0- 0324		
20	EN ISO 11607-2: 2006+A1: 2014	40	USP 36		

NOTIFIED BODY:TÜV SÜD Product Service GmbH.,
Ridlerstrasse 65, 80339 München, Germany

Identification NumberCE₀₁₂₃

(EC) CERTIFICATE(S): No. G1 065765 0023 Rev.02

EC REP

EUROPEAN REPRESENTATIVE : MEDNET EC-REP GMBH

BORKSTRASSE10, 48163 MUENSTER, GERMANY

START OF CE-MARKING: 2015.11.17

PLACE,DATE OF DECLARATION :WEIHAI ,P,R,CHINA

SIGNATURE:



NAME:ZHIPENG YANG

POSITION:GENERAL MANAGER

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No.20 Xingshan Road, Weihai Torch Hi-tech Science Park, Shandong, China

MEDICAL DEVICE: Non-absorbable surgical suture with or without needle

UMDNS CODES:38000

Model:WEGO-NYLON

Suture diameter gauge: European pharmacopeia (EP)standard 0.2~7(USP10-0~5#)

Suture length:≤3.9m

Suture Colour: blue or Logwood black

Structure diagrams: Monofilament

Needle length:4mm~90mm

Needle type: Taper, cutting, spatula, blunt ,taper cut, diamond, premium cutting and square.

Needle quantity: 0~20,Suture quantity:1~50

CLASSIFICATION-ANNEX IX: Class II bRule 8

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