

**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.

Structure 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: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,

EP - 0324 <suture, sterile non-absorbable> ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.,

Ridlerstrasse 65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC) CERTIFICATE(S): No. G1150565765010



EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,

NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

BORKSTRASSE10, 48163 MUENSTER, GERMANY

TEL: +49251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING: 2015.11.17

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

SIGNATURE:

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Digitally signed by Guțan Ghenadie
Date: 2022.05.26 15:29:10 EEST
Reason: MoldSign Signature
Location: Moldova



Revision :B/3

**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: 38000

Model: WEGO-NYLON

Suture diameter gauge: European pharmacopeia (EP) standard 0.2~7 (USP 10-0~5#)

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 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: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,

EP - 0324 <suture, sterile non-absorbable >. ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.,

Ridlerstrasse 65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC) CERTIFICATE(S): No. G1150565765010

EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,

NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

TEL: +49 251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING: 2015.11.17

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

SIGNATURE:

 2015.11.17

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision : B/3



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Design-Examination Certificate

No. 13 0685 CN/NB

issued for 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**

in accordance with requirements of

Directive 93/42/EEC
on medical devices, Annex II (4)

for the following product category(ies):

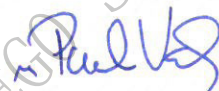
Synthetic Absorbable Suture

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2018-07-31
Valid until: 2023-07-30
First Issued: 2013-08-05
Revision: a

Date: 2018-07-31




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 13 0685 CN/NB

issued for 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:

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PDO

Model(s): EP 0.5~5 [USP 7-0~2]; with or without needles

Class: III

GMDN: 16584

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PGA

Model(s): EP 0.4~6 Braided suture / EP 0.2~0.3 Monofilament
[USP 10-0~3 or 4]; with or without needles

Class: III

GMDN: 13908

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PGLA

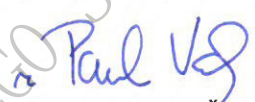
Model(s): EP 0.4~6 [USP 8-0~3 or 4]; with or without needles

Class: III

GMDN: 17471



Date: 2018-07-31
Revision: a


RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 13 0685 CN/NB

issued for 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

Certificate History:

Revision	Date	Reference Number	Action
	2013-08-05	803602002	Certification
a	2018-07-31	803602667	Re-certification process

Date: 2018-07-31
Revision: a




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 13 0684 QS/NB

The quality system of 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**

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Synthetic Absorbable Suture

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2018-07-31
Valid until: 2023-07-30
First Issued: 2013-08-05
Revision: a

Date: 2018-07-31




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 13 0684 QS/NB

issued for 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(s):

Name: **Synthetic Absorbable Sutures**

Trade name(s): WEGO-PDO

Model(s): EP 0.5~5 [USP 7-0~2]; with or without needles

Class: III

GMDN: 16584

Name: **Synthetic Absorbable Sutures**

Trade name(s): WEGO-PGA

Model(s): EP 0.4~6 Braided suture / EP 0.2~0.3 Monofilament
[USP 10-0~3 or 4]; with or without needles

Class: III

GMDN: 13908

Name: **Synthetic Absorbable Sutures**

Trade name(s): WEGO-PGLA

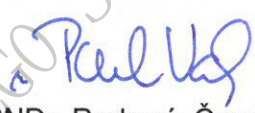
Model(s): EP 0.4~6 [USP 8-0~3 or 4]; with or without needles

Class: III

GMDN: 17471



Date: 2018-07-31
Revision: a


RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 13 0684 QS/NB
issued for manufacturer:

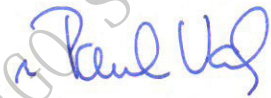
Foosin Medical Supplies Inc., Ltd.
No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park,
264210 Weihai, Shandong Province, People's Republic of China

Facility(ies):

Foosin Medical Supplies Inc., Ltd.
No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park, 264210 Weihai,
Shandong Province, People's Republic of China



Date: 2018-07-31
Revision: a


RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 13 0684 QS/NB

issued for manufacturer:

Foosin Medical Supplies Inc., Ltd.

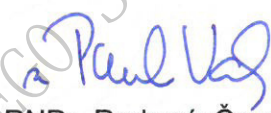
**No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park,
264210 Weihai, Shandong Province, People's Republic of China**

Certificate History:

Revision	Date	Reference Number	Action
	2013-08-05	803602002	Certification
a	2018-07-31	803602667	Re-certification process



Date: 2018-07-31
Revision: a

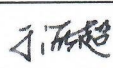
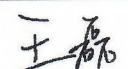

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

CE technical documents

<According to MDD (93/42/EEC as amended by 2007/47/EC) authorized>

EC Declaration of Conformity (WEGO-PDO)

Edition/Revision No. B/6

Audited By/Date	 Yv HC/2018.07.07	Approved By/Date	 Zhipeng Yang /2018.07.08
Issuing Department	Technical Department	Drafted By/Date	 Wang Lei/2018.07.07
Date of Implementation	2018.07.09		

DECLARATION OF CONFORMITY 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,264210 Weihai,
Shandong Province, People's Republic of China

MEDICAL DEVICE: Synthetic Absorbable Suture

GMDN CODES: 16584

Model: WEGO-PDO

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.5-5

Suture length: ≤3.9m

Suture Colour: Violet; Natural White (undyed colour).

Coated: None

Structure Diagrams: Monofilament

Sutures are available with or without stainless steel needles of varying types and sizes

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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 fulfill the obligations imposed by the quality system and to keep the quality system adequate and efficacious. The medical device is not intended for use in combination with other devices or pharmaceutical. The device doesn't contain derivatives of human blood, animal origin material, phthalate and latex. If we have plan for change product, we will give notice to Notification Body. We, as the manufacturer, are exclusively responsible for the declaration of conformity.

STANDARDS APPLIED:

No	Standard No.	No.	Standard No.	No.	Standard No.
1	MDD 93/42/EEC	26	ISO 14644-2:2015	51	ASTM F3014-14
2	EN 556-2:2015	27	ISO 14644-3:2005	52	ASTM F1874-98
3	EN 1041:2008	28	ISO 14644-4:2001	53	ASTM F1980-07(2011)
4	MEDDEV 2.7-1 rev.4	29	ISO 14644-5:2004	54	ASTM F1929 - 15
5	MEDDEV 2.12-1 rev 8	30	ISO 14644-7:2004	55	ASTM D5276 – 98(2009)
6	MEDDEV 2.12-2 rev 2	31	ISO 14644-8:2013	56	ASTM D642 – 2000(2010)
7	ISO10993-1:2009/AC: 2010	32	ISO 14698-1:2003	57	ASTM D999 - 08(2015)
8	ISO10993-3:2014	33	ISO 14698-2:2003	58	ASTM D6653 / D6653M - 13
9	ISO 10993-4:2002/ Amdl:2006	34	EN 62366-1:2015	59	ASTM D4728 – 06(2012)
10	ISO 10993-5:2009	35	ISO 15223-1:2012	60	ASTM D6344 - 04(2009)
11	ISO 10993-6:2007	36	EN ISO 14630:2012	61	ISO 11138-1:2017
12	ISO 10993-7: 2008	37	EP 8.0-01/2008: 0666	62	ISO14161: 2009
13	ISO 10993-10:2010	38	USP 36	63	ISO 11140-1:2014
14	ISO 10993-11:2006	39	USP36-<861>	64	ASTM D4169-14
15	ISO 10993-12:2012	40	USP36-<871>	65	ASTM F88 / F88M - 15
16	ISO/TR 10993-33: 2015(E)	41	USP36-<881>	66	ASTM F1886 / F1886M - 2009
17	EN ISO 11607-1: 2009+A1: 2014	42	USP36<231>	67	ASTM D3078 - 02(2013)
18	EN ISO 11607-2: 2006+A1: 2014	43	USP36<921>	68	ASTM F1140 / F1140M - 13
19	EN ISO 11138-2:2017	44	USP39<151>		

20	EN ISO 11135:2014	45	ISO/TR 15499: 2012		
21	ISO 11737-1:2006/Cor 1:2007	46	EN ISO 14937: 2009		
22	EN ISO 11737-2:2009	47	ISO 13781: 1997		
23	EN ISO 13485:2012	48	EN 1422:2014		
24	EN ISO 14971:2012	49	YY1116:2010		
25	ISO 14644-1:2015	50	YY0043:2005		

NOTIFIED BODY: INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Identification Number CE₁₀₂₃

(EC) CERTIFICATE(S):

120684 QS/N13

EUROPEAN REPRESENTATIVE:

MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

TEL: +49 251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

2018.7.31

SIGNATURE:

NAME: ZHIPENG YANG



2018.8.9

POSITION: GENERAL MANAGER

PLACE, DATE OF DECLARATION:

Weihai

Revision: B/6

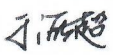
WEGO-SUTURE Foosin Medical Supplies Inc., Ltd

CE technical documents

<According to MDD (93/42/EEC as amended by 2007/47/EC) authorized>

EC Declaration of Conformity (WEGO-PGA)

Edition/Revision No. B/6

Audited By/Date	 Yv HC/2018.07.07	Approved By/Date	 Zhipeng Yang /2018.07.08
Issuing Department	Technical Department	Drafted By/Date	 Wang Lei/2018.07.07
Date of Implementation	2018.07.09		

DECLARATION OF CONFORMITY 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,264210 Weihai,
Shandong Province, People's Republic of China

MEDICAL DEVICE: Synthetic Absorbable Suture

GMDN CODES: 13908

Model: WEGO-PGA

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.2~6(USP10-0 through 3 or 4)

Suture length: ≤3.9m

Suture Colour: Violet; Natural White (undyed colour).

Coated: Polycaprolactone and calcium stearate; Uncoated.

Structure Diagrams: Braided (EP sizes 0.4-6 (USP sizes 8-0 through 3 or 4)),

Monofilament (EP sizes 0.2-0.3 (USP size 10-0 through 9-0))

Sutures are available with or without stainless steel needles of varying types and sizes

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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 fulfill the obligations imposed by the quality system and to keep the quality system adequate and efficacious. The medical device is not intended for use in combination with other devices or pharmaceutical. The device doesn't contain derivatives of human blood, animal origin material, phthalate and latex. If we have plan for change product, we will give notice to Notification Body. We, as the manufacturer, are exclusively responsible for the declaration of conformity

STANDARDS APPLIED:

No	Standard No.	No.	Standard No.	No.	Standard No.
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3	EN 1041:2008	28	ISO 14644-4:2001	53	ASTM F1980-07(2011)
4	MEDDEV 2.7-1 rev.4	29	ISO 14644-5:2004	54	ASTM F1929 - 15
5	MEDDEV 2.12-1 rev 8	30	ISO 14644-7:2004	55	ASTM D5276 - 98(2009)
6	MEDDEV 2.12-2 rev 2	31	ISO 14644-8:2013	56	ASTM D642 - 2000(2010)
7	ISO10993-1:2009/AC: 2010	32	ISO 14698-1:2003	57	ASTM D999 - 08(2015)
8	ISO10993-3:2014	33	ISO 14698-2:2003	58	ASTM D6653 / D6653M - 13
9	ISO 10993-4:2002/ Amdl:2006	34	EN 62366-1:2015	59	ASTM D4728 - 06(2012)
10	ISO 10993-5:2009	35	ISO 15223-1:2012	60	ASTM D6344 - 04(2009)
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12	ISO 10993-7: 2008	37	EP 8.0-01/2008: 0667	62	ISO14161: 2009
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14	ISO 10993-11:2006	39	USP36-<861>	64	ASTM D4169-14
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18	EN ISO 11607-2: 2006+A1: 2014	43	USP36<921>	68	ASTM F1140 / F1140M - 13

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20	EN ISO 11135:2014	45	ISO/TR 15499: 2012		
21	ISO 11737-1:2006/Cor 1:2007	46	EN ISO 14937: 2009		
22	EN ISO 11737-2:2009	47	ISO 13781: 1997		
23	EN ISO 13485:2012	48	EN 1422:2014		
24	EN ISO 14971:2012	49	YY1116:2010		
25	ISO 14644-1:2015	50	YY0043:2005		

NOTIFIED BODY: INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Identification Number CE₁₀₂₃

(EC) CERTIFICATE(S):

EC REP

13 0684 QS/NB

EUROPEAN REPRESENTATIVE: MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

TEL: +49 251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

2018.7.31

SIGNATURE:

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

[Signature] 2018.8.9

PLACE, DATE OF DECLARATION:

Weihai

Revision: B/6

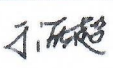
WEGO-SUTURE Foosin Medical Supplies Inc., Ltd

CE technical documents

<According to MDD (93/42/EEC as amended by 2007/47/EC) authorized>

EC Declaration of Conformity (WEGO-PGLA)

Edition/Revision No. B/6

Audited By/Date	 Yv HC/2018.07.07	Approved By/Date	 Zhipeng Yang /2018.07.08
Issuing Department	Technical Department	Drafted By/Date	 Wang Lei/2018.07.07
Date of Implementation	2018.07.09		

DECLARATION OF CONFORMITY 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,264210 Weihai,

Shandong Province, People's Republic of China

MEDICAL DEVICE: Synthetic Absorbable Suture

GMDN CODES: 17471

Model: WEGO-PGLA

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.4~6(USP 8-0 through 3 or 4)

Suture length: $\leq 3.9m$

Suture Colour: Violet; Natural White (undyed colour).

Coated: Poly(glycolide-co-lactide) (30/70) and calcium stearate.

Structure Diagrams: Braided

Sutures are available with or without stainless steel needles of varying types and sizes

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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 fulfill the obligations imposed by the quality system and to keep the quality system adequate and efficacious. The medical device is not intended for use in combination with other devices or pharmaceutical. The device doesn't contain derivatives of human blood, animal origin material, phthalate and latex. If we have plan for change product, we will give notice to Notification Body. We, as the manufacturer, are exclusively responsible for the declaration of conformity.

STANDARD APPLIED:

No	Standard No.	No.	Standard No.	No.	Standard No.
1	MDD 93/42/EEC	26	ISO 14644-2:2015	51	ASTM F3014-14
2	EN 556-2:2015	27	ISO 14644-3:2005	52	ASTM F1874-98
3	EN 1041:2008	28	ISO 14644-4:2001	53	ASTM F1980-07(2011)
4	MEDDEV 2.7-1 rev.4	29	ISO 14644-5:2004	54	ASTM F1929 - 15
5	MEDDEV 2.12-1 rev 8	30	ISO 14644-7:2004	55	ASTM D5276 - 98(2009)
6	MEDDEV 2.12-2 rev 2	31	ISO 14644-8:2013	56	ASTM D642 - 2000(2010)
7	ISO10993-1:2009/AC: 2010	32	ISO 14698-1:2003	57	ASTM D999 - 08(2015)
8	ISO10993-3:2014	33	ISO 14698-2:2003	58	ASTM D6653 / D6653M - 13
9	ISO 10993-4:2002/ Amdl:2006	34	EN 62366-1:2015	59	ASTM D4728 - 06(2012)
10	ISO 10993-5:2009	35	ISO 15223-1:2012	60	ASTM D6344 - 04(2009)
11	ISO 10993-6:2007	36	EN ISO 14630:2012	61	ISO 11138-1:2017
12	ISO 10993-7: 2008	37	EP 8.0-01/2008: 0667	62	ISO14161: 2009
13	ISO 10993-10:2010	38	USP 36	63	ISO 11140-1:2014
14	ISO 10993-11:2006	39	USP36-<861>	64	ASTM D4169-14
15	ISO 10993-12:2012	40	USP36-<871>	65	ASTM F88 / F88M - 15
16	ISO/TR 10993-33: 2015(E)	41	USP36-<881>	66	ASTM F1886 / F1886M - 2009
17	EN ISO 11607-1: 2009+A1: 2014	42	USP36<231>	67	ASTM D3078 - 02(2013)
18	EN ISO 11607-2: 2006+A1: 2014	43	USP36<921>	68	ASTM F1140 / F1140M - 13

19	EN ISO 11138-2:2017	44	USP39<151>		
20	EN ISO 11135:2014	45	ISO/TR 15499: 2012		
21	ISO 11737-1:2006/Cor 1:2007	46	EN ISO 14937: 2009		
22	EN ISO 11737-2:2009	47	ISO 13781: 1997		
23	EN ISO 13485:2012	48	EN 1422:2014		
24	EN ISO 14971:2012	49	YY1116:2010		
25	ISO 14644-1:2015	50	YY0043:2005		

NOTIFIED BODY: INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Identification Number CE₁₀₂₃

(EC) CERTIFICATE(S):

13 0684 QS/NB

EUROPEAN REPRESENTATIVE: MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

TEL: +49 251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

2018.7.31

SIGNATURE:

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

PLACE, DATE OF DECLARATION:

[Signature] 2018.8.9
Weihai

Revision: B/6

WEGOSUTURES

威海威高富森医用材料有限公司

Foosin Medical Supplies Inc., Ltd.

Add: 20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Weihai City, Shandong Province, P.R. China Tel:0631-5661991 Fax:0631-5661996 Http://www.wegosuture.com

Power of attorney

We, FOOSIN MEDICAL SUPPLIES INC., LTD.,

based in 20 Xingshan Road ,Weihai Torch Hi-Tech Science Park Shandong Province P.R. China,

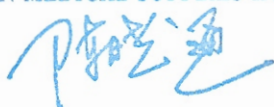
assign ICS Farmina s.r.l., based in Str. Ciocana 8/1, Chisinau MD -2044, Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Sincerely



威海威高富森医用材料有限公司
FOOSIN MEDICAL SUPPLIES INC.,LTD.



3710000033407

Foosin Medical Supplies Inc., Ltd.

**NO.20 Xingshan Road ,Weihai Torch
Hi-Tech Science Park Shandong Province
P.R. China**

Date: Sep 30.2018



Product Service

EC Certificate

Full Quality Assurance System

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

No. **G1 17 09 65765 018**

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

**EC-Representative:****MedNet GmbH**

Borkstrasse 10
48163 Muenster
GERMANY

Product**Category(ies):**

non-absorbable surgical suture with or without needle
(PVDF,PTFE,polyester,polypropylene).

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ1792607

Valid from:

2017-11-15

Valid until:

2022-08-24

Date, 2017-11-15

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**Full Quality Assurance System**

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

No. G1 17 09 65765 018

Facility(ies):

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

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



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

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

GMDNS CODES: 13909

Model: WEGO-Polypropylene

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.2~4(USP10-0~1)

Suture length: ≤3.9m

Suture Colour: Blue; Natural White (undyed colour).

Coated: NONE

Structure Diagrams: Monofilament

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting, Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,

EP 8.0- 0324 <suture, sterile non-absorbable >. ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.

Ridlerstrasse65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC)CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,

NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

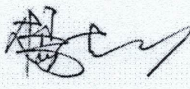
BORKSTRASSE10, 48163 MUENSTER, GERMANY

TEL: +49251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

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

SIGNATURE:

 2017.9.1

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision: B/5

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



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

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

GMDNS CODES: 13906

MODE: WEGO-POLYESTER

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

Suture length: ≤3.9m

Suture with or without needle

Suture Colour: Green (D. & C. No. 6); Natural White (undyed colour).

Coated: Silicone-Nusil Med 2174Silicone Elastomer; NONE

Structure Diagrams: Braided (EP sizes 0.3-7 (USP sizes 9-0 through 5))
Monofilament (EP size 0.2 (USP size 10-0))

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting, Blunt
Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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.

STANDARDSAPPLIED: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,
EP 8.0- 0324 <suture, sterile non-absorbable >, ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.

Ridlerstrasse65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC)CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,

NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

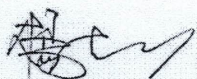
BORKSTRASSE10, 48163 MUENSTER, GERMANY

TEL: +49251 32266-0, FAX: +49 251 32266-22

STARTOFCE-MARKING:

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

SIGNATURE:

 2017.9.1

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

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



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

MEDICAL DEVICE:

Non-Absorbable surgical suture with or without needle

GMDNS CODES: 38873

Model: WEGO-PVDF

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.2~5(USP10-0~2)

Suture length: ≤3.9m

SUTURE Colour: Solvent Blue104, Phthalocyanine blue and Natural White (undyed colour).

Coated: NONE

Structure Diagrams: Monofilament

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting, Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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.

STANDARDSAPPLIED: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,
EP 8.0- 0324 <suture, sterile non-absorbable >. ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.

Ridlerstrasse65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC)CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE:

MEDNET GMBH, NICOLE BOEHNISCH,
NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

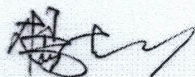
BORKSTRASSE10, 48163 MUENSTER, GERMANY

TEL: +49251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

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

SIGNATURE:

 2017.9.1

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

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



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

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

GMDNS CODES: 17467

Model: WEGO-PTFE

Suture diameter gauge: European pharmacopeia (EP) standard 0.2~5(USP10-0~2)

Suture length: 3.9m

Suture colour: Natural White (undyed colour).

Coated: NONE

Structure: Monofilament

Needle length: 3mm~90mm

Needle type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting, Blunt
Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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: EN 980:2008, EN 1041:2008, EN ISO10993-1: 2009/AC: 2010, EN ISO 14971:2012,
EP 8.0- 0324 <suture, sterile non-absorbable >.. ASTM F1874-98(2011), ASTM F3014-14(2014).

NOTIFIED BODY: TÜV SÜD Product Service GmbH.

Ridlerstrasse65, 80339 München, Germany

Identification Number CE₀₁₂₃

(EC)CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,
NICOLE.BOEHNISCH@MEDNETEUROPE.COM,

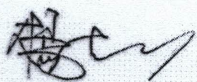
BORKSTRASSE10, 48163 MUENSTER, GERMANY

TEL: +49251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

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

SIGNATURE:

 2017.9.1

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision: B/5

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



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

MEDICAL DEVICE: Absorbable Surgical Suture

GMDN CODES: 13908

Model: WEGO-PGA RAPID

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.7-5 (USP 6-0 through 2)

Suture length: ≤3.9m

Suture Colour: Violet; Natural White (undyed colour).

Coated: polycaprolactone and calcium stearate

Structure Diagrams: Braided

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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:

MDD 93/42/EEC
EN 556-2:2003
EN 980:2008
EN 1041:2008
EN 15986:2011
MEDDEV 2.7-1 rev.4
MEDDEV 2.12-1 rev 8
MEDDEV 2.12-2 rev 2
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-3:2014
EN ISO 10993-4:2009
EN ISO 10993-5:2009
EN ISO 10993-6:2009
EN ISO 10993-7: 2008
EN ISO 10993-9:2009
EN ISO 10993-10:2013
EN ISO 10993-11:2009
EN ISO 10993-13:2010
EN ISO 10993-18:2005
ISO 15814:1999
ISO 13781:1997
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN ISO 11138-2:2009
EN ISO 11135:2014
EN ISO 11737-1:2006/AC:2009
EN ISO 11737-2:2009
EN ISO 13485:2012/AC:2012
EN ISO 14971:2012
ISO 14644-1:2015
ISO 14644-2:2015

ISO 14644-3:2005
ISO 14644-4:2001
ISO 14644-5:2004
ISO 14644-7:2004
ISO 14644-8:2013
ISO 14698-1:2003
ISO 14698-2:2003
EN 62366
ISO 15223-1:2012
ISO 15223-2:2010
ISO 16142-1:2016
EN ISO 14630
EP 9.0- 0667

NOTIFIEDBODY:

Name of the NB: UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi ve Ticaret Limited Şirketi

Country: Turkey

Website: www.udemltd.com.tr

Notified Body number: 2292

Identification No.CE2292

(EC)CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,
NICOLE.BOEHNISCH@MEDNETEUROPE.COM,
BORKSTRASSE10, 48163 MUENSTER, GERMANY
TEL: +49251 32266-0, FAX: +49 251 32266-22

START OF CE-MARKING:

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

SIGNATURE:

 2017.9.25

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision: B/3

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



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

MEDICAL DEVICE: Absorbable Surgical Suture

GMDN CODES: 17471

Model: WEGO-PGLA RAPID

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.7-5 (USP6-0 through 2)

Suture length: ≤3.9m

Suture Colour: Violet; Natural White (undyed colour).

Coated: poly(glycolide-co-lactide) (30/70) and calcium stearate

Structure Diagrams: Braided

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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:

MDD 93/42/EEC
EN 556-2:2003
EN 980:2008
EN 1041:2008
EN 15986:2011
MEDDEV 2.7-1 rev.4
MEDDEV 2.12-1 rev 8
MEDDEV 2.12-2 rev 2
EN ISO 10993-1:2009/AC:2010
EN ISO10993-3:2014
EN ISO 10993-4:2009
EN ISO 10993-5:2009
EN ISO 10993-6:2009
EN ISO 10993-7: 2008
EN ISO 10993-9:2009
EN ISO 10993-10:2013
EN ISO 10993-11:2009
EN ISO 10993-13:2010
EN ISO 10993-18:2005
ISO 15814:1999
ISO 13781:1997
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN ISO 11138-2:2009
EN ISO 11135:2014
EN ISO 11737-1:2006/AC:2009
EN ISO 11737-2:2009
EN ISO 13485:2012/AC:2012
EN ISO 14971:2012
ISO 14644-1:2015
ISO 14644-2:2015
ISO 14644-3:2005

ISO 14644-4:2001
ISO 14644-5:2004
ISO 14644-7:2004
ISO 14644-8:2013
ISO 14698-1:2003
ISO 14698-2:2003
EN 62366
ISO 15223-1:2012
ISO 15223-2:2010
ISO 16142-1:2016
EN ISO 14630
EP 9.0- 0667

NOTIFIEDBODY:

Name of the NB: UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi ve Ticaret Limited Şirketi

Country: Turkey

Website: www.udemltd.com.tr

Notified Body number: 2292

Identification No.CE2292

(EC)CERTIFICATE(S):

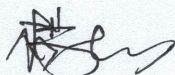
EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,
NICOLE.BOEHNISCH@MEDNETEUROPE.COM,
BORKSTRASSE10, 48163 MUENSTER, GERMANY
TEL: +49251 32266-0, FAX: +49 251 32266-22

STARTOFCE-MARKING:

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

SIGNATURE:

 2017.9.25

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision: B/3

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



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

MEDICAL DEVICE: Sterile Synthetic Absorbable Suture

GMDN CODES: 45814

Model: WEGO-PGCL

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.7-5

Suture length: ≤3.9m

Suture Colour: Violet; Natural White (undyed colour).

Coated: None

Structure Diagrams: Monofilament

Needle Length: 3mm~90mm

Needle Type: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting,
Blunt Point, Square and Spatula

Needle Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

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

Foosin Product Codes Explanation see Annex I

CLASSIFICATION-ANNEX IX: Class III Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II.3+ II.4, 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:

MDD 93/42/EEC
EN 556-2:2003
EN 980:2008
EN 1041:2008
EN 15986:2011
MEDDEV 2.7-1 rev.4
MEDDEV 2.12-1 rev 8
MEDDEV 2.12-2 rev 2
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-3:2014
EN ISO 10993-4:2009
EN ISO 10993-5:2009
EN ISO 10993-6:2009
EN ISO 10993-7: 2008
EN ISO 10993-9:2009
EN ISO 10993-10:2013
EN ISO 10993-11:2009
EN ISO 10993-13:2010
EN ISO 10993-18:2005
ISO 15814:1999
ISO 13781:1997
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN ISO 11138-2:2009
EN ISO 11135:2014
EN ISO 11737-1:2006/AC:2009
EN ISO 11737-2:2009
EN ISO 13485:2012/AC:2012
EN ISO 14971:2012
ISO 14644-1:2015
ISO 14644-2:2015

ISO 14644-3:2005
ISO 14644-4:2001
ISO 14644-5:2004
ISO 14644-7:2004
ISO 14644-8:2013
ISO 14698-1:2003
ISO 14698-2:2003
EN 62366
ISO 15223-1:2012
ISO 15223-2:2010
ISO 16142-1:2016
EN ISO 14630 EP
9.0- 0666

NOTIFIEDBODY:

Name of the NB: UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi ve Ticaret Limited Şirketi

Country: Turkey

Website: www.udemltd.com.tr

Notified Body number: 2292

Identification No.CE2292

(EC)CERTIFICATE(S):

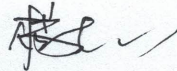
EC REP

EUROPEAN REPRESENTATIVE: MEDNET GMBH, NICOLE BOEHNISCH,
NICOLE.BOEHNISCH@MEDNETEUROPE.COM,
BORKSTRASSE10, 48163 MUENSTER, GERMANY
TEL: +49251 32266-0, FAX: +49 251 32266-22

STARTOFCE-MARKING:

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

SIGNATURE:

 2017.9.25

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

Revision: B/3