

# 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:**

Non-Absorbable surgical suture with or without needle

GMDNSCODES: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.

**STANDARD APPLIED:** ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 14971:2012, EP 9.5- 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** CE<sub>0123</sub>

**(EC) CERTIFICATE(S):** G1 065765 0018 Rev.02



**EUROPEAN REPRESENTATIVE:** MedNet EC-REP GmbH

BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

**START OF CE-MARKING:** 2017.08.25

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

**SIGNATURE:**

**NAME:** ZHIPENGYANG

**POSITION:** GENERAL MANAGER

# 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:** Non-Absorbable surgical suture with or without needle

GMDNSCODES: 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-NusilMed2174Silicone 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 ASSESSMENTROUTE: Annex II.3+ II.4, MDD 93/42/EEC**

We, Foosin Medical Supplies Inc., Ltd. Here with declare that the stated medical devices meet93/42/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.

**STANDARD APPLIED:** ISO 15223-1:2016, EN 1041:2008, EN ISO10993-1:2009/AC:2010, EN ISO 14971:2012,  
EP 9.5- 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** CE<sub>0123</sub>

**(EC)CERTIFICATE(S):** G1 065765 0018 Rev.02

EC REP

**EUROPEAN REPRESENTATIVE:** MedNet EC-REP GmbH

BORKSTRASSE10, 48163 MUENSTER, GERMANY

**START OF CE-MARKING:** 2017.08.25

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

**SIGNATURE:**

**NAME:** ZHIPENGYANG

**POSITION:**GENERAL MANAGER

# 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:**

Non-Absorbable surgical suture with or without needle

GMDNSCODES:38873

Model: WEGO-PVDF

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

Suture length: ≤3.9m

SUTURE Colour: Solvent Blue 104, 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.

**STANDARD APPLIED:** ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 14971:2012,  
EP 9.5- 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** CE<sub>0123</sub>

**(EC) CERTIFICATE(S):** G1 065765 0018 Rev.02



**EUROPEAN REPRESENTATIVE:** MedNet EC-REP GmbH

BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

**START OF CE-MARKING:** 2017.08.25

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

**SIGNATURE:**

**NAME:** ZHIPENGYANG

**POSITION:** GENERAL MANAGER

# 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:** Non-Absorbable surgical suture with or without needle

GMDNSCODES: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.

**STANDARD APPLIED:** ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 14971:2012,  
EP 9.5- 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** CE<sub>0123</sub>

**(EC) CERTIFICATE(S):** G1 065765 0018 Rev.02

**EC REP**

**EUROPEAN REPRESENTATIVE:** MedNet EC-REP GmbH

BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

**START OF CE-MARKING:** 2017.08.25

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

**SIGNATURE:**

**NAME:** ZHIPENGYANG

**POSITION:** GENERAL MANAGER