

DECLARATION OF CONFORMITY TO MEDICAL DEVICE REGULATION (EU) 2017/745



MANUFACTURER: Foosin Medical Supplies Inc., Ltd.

No.8-1, Weigao West Road, Chucun Town, Torch Hi-Tech
Science Park, 264200 Weihai, Shandong Province, PEOPLE'S
REPUBLIC OF CHINA



MEDICAL DEVICE: Non-Absorbable Surgical Suture With or Without Needle

EMDN CODES: H0102010101

Model Name: WEGO-NYLON

Suture Diameter:

EP 0.2-7 (USP 10-0 through 5)

Suture length: ≤3.9m

Suture Colour: Blue; Black

Structure Diagrams:

Monofilament

Needle Length: 3mm~90mm

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

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

Basic UDI-DI: 69418136NA-suturesIIbN7R

Unique Device Identifier (UDI): UDI-DI of
all devices will be distributed in actual
production in the future

Suture Specification: For details see
Annex Model Number

CLASSIFICATION: Non-absorbable
Sutures are classified to Class II b
according to Rule 8, Annex VIII of
REGULATION (EU) 2017/745

“ All implantable devices and long-term
surgically invasive devices are classified as
class II b” .

INTENDED PURPOSE:

WEGO-NYLON suture is used to suture and
ligate general soft tissues.

CONFORMITY ASSESSMENT ROUTE

ANNEX IX Conformity assessment based on a quality management system and on
assessment of technical documentation of MEDICAL DEVICE REGULATION (EU) 2017/745

DECLARATION

We, Foosin Medical Supplies Inc., Ltd. Here with declare that the stated medical devices meet
MEDICAL DEVICE REGULATION (EU) 2017/745; 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:

ISO 15223-1:2021, ISO 20417:2021, EN ISO10993-1:2020, ISO 14971:2019, EP
10-0324<suture, sterile non-absorbable >, USP 43 Nonabsorbable Surgical Suture, ASTM F
3014-14, ASTM F1874-98.

The device does not currently refer to any common specifications.

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

IDENTIFICATION NUMBER: 0123

(EC)CERTIFICATE(S) NUMBER: G10 065765 0031 Rev. 00

EC	REP
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EUROPEAN REPRESENTATIVE:

MedNet EC-REP CIII GmbH
BORKSTRASSE10, 48163 MUENSTER, GERMANY

START OF CE-MARKING: 2024-02-19

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

SIGNATURE:


NAME: Ma Bo



2024.03.01

POSITION: TECHNICAL DIRECTOR

PROCURATION ENDORSEMENT SIGNATURE



2024.03.01

NAME: Zhou Caijie

POSITION: TECHNICAL MANAGER

Rev. No.: A/0

Issued date: 2024.03.01

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MEDICAL DEVICE: Non-Absorbable Surgical Suture With or Without Needle

EMDN CODES: H0102020203

Model Name: WEGO-SILK

Suture Diameter:

EP 0.2-7 (USP 10-0 through 5)

Suture length: ≤3.9m

Suture Colour: Black; Natural Ivory

Structure Diagrams: Braided

Needle Length: 3mm~90mm

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

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

Basic UDI-DI: 69418136NA-suturesIIbS83

Unique Device Identifier (UDI): UDI-DI of
all devices will be distributed in actual
production in the future

Suture Specification: For details see
Annex Model Number

CLASSIFICATION: Non-absorbable
Surgical Sutures are classified to Class II b
according to Rule 8, Annex VIII of
REGULATION (EU) 2017/745

“ All implantable devices and long-term
surgically invasive devices are classified as
class II b” .

INTENDED PURPOSE:

WEGO-SILK suture is used to suture and
ligate general soft tissues.

CONFORMITY ASSESSMENT ROUTE

ANNEX IX Conformity assessment based on a quality management system and on assessment of technical documentation of MEDICAL DEVICE REGULATION (EU) 2017/745

DECLARATION

We, Foosin Medical Supplies Inc., Ltd. Here with declare that the stated medical devices meet MEDICAL DEVICE REGULATION (EU) 2017/745; 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:

ISO 15223-1:2021, ISO 20417:2021, EN ISO10993-1:2020, ISO 14971:2019, EP 11-0667<SUTURES, STERILE NON-ABSORBABLE>, USP <Nonabsorbable Surgical Suture>, ASTM F 3014-14, ASTM F1874-98.

The device does not currently refer to any common specifications.

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