CE technical documents

<According to MDD (93/42/EEC as amended by2007/47/EC) authorized>

EC Declaration of Conformity (WEGO-PGA&WEGO-PGLA)

Edition/Revision No. B/5

Audited By/Date	Yv HC/2019.11.29	Approved By/Date	Zhipeng Yang /2019.11.29
Issuing Department	Technical Department	Drafted By/Date	Wang Lei/2019.11.28
Date of Implementation	2019.11.29		

EC Declaration of Conformity

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

Synthetic Absorbable Suture

GMDN CODES: 17471

Model: WEGO-PGLA

Suture Diameter Gauge: European pharmacopeia (EP) standard 0.4~6(USP 8-0 through3 or 4)
Suture length: ≤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

Product Catalogue sees Annex Product Catalogue.

CLASSIFICATION-ANNEX IX: Class Ⅲ Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II(including section 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 pharmaceutical, derivatives of human blood , animal origin, origin of the material or the presence of phthalate content. 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 SAPPLIED:

No.	Standard No.	Content
1	MDD 93/42/EEC	Council Directive Concerning Medical Devices
2	EN 556-2:2015	Sterilization of medical devices--Requirements for medical devices to be designated "STERILE"-Part 2: Requirements for aseptically processed medical devices

3	EN 1041:2008	Information supplied by the manufacturer of medical devices
4	MEDDEV 2.7-1 rev.4	Evaluation of clinical data: a guide for manufacturers and notified bodies
5	MEDDEV 2.12-1 rev 8	Guidelines on a medical devices vigilance system
6	MEDDEV 2.12-2 rev 2	Post market clinical follow-up studier-a guide for manufacturers and notified bodies
7	ISO10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
8	ISO10993-3:2014	Biological evaluation of medical devices--Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
9	ISO 10993-4:2017	Biological evaluation of medical devices --Part 4: Selection of tests for interactions with blood
10	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
11	ISO 10993-6:2016	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
12	ISO 10993-7:2008/Cor 1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
13	ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
14	ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
15	ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
16	ISO/TR 10993-33: 2015(E)	Biological evaluation of medical devices -- Part 33: Guidance on tests to evaluate genotoxicity -- Supplement to ISO 10993-3
17	EN ISO 11607-1：2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
18	EN ISO 11607-2：2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
19	EN ISO 11138-2:2017	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
20	EN ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
21	ISO 11737-1:2018	Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
22	EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
23	ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
24	EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices
25	ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1：Classification of air cleanliness
26	ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2：Specifications for testing and monitoring to prove continued compliance with
27	ISO 14644-3:2019	Cleanrooms and associated controlled environments -- Part 3：Test methods
28	ISO 14644-4:2001	Cleanrooms and associated controlled environments -- Part 4：Design, construction and startup
29	ISO 14644-5:2004	Cleanrooms and associated controlled environments -- Part 5：Operations

30	ISO 14644-7:2004	Cleanrooms and associated controlled environments -- Part 7：Separative devices (clean air hoods, gloveboxes, isolators and
31	ISO 14644-8:2013	Cleanrooms and associated controlled environments -- Part 8：Classification of airborne molecular contamination
32	ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
33	ISO 14698-2:2003/Cor 1:2004	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
34	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
35	EN ISO 14630:2012	Non-active surgical implants-General requirements
36	EP 9.0-01/2008: 0666	Sutures, sterile synthetic absorbable braided
37	USP 39	Absorbable Surgical Suture
38	USP39-<861>	Sutures-diameter
39	USP39-<871>	Sutures-needle attachment
40	USP39-<881>	Tensile strength
41	USP39<231>	Heavy Metals
42	USP39<921>	Water Determination
43	USP39<151>	Pyrogen Test
44	EN ISO 14937：2009	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
45	ISO 13781：2017	Implants for surgery -- Homopolymers, copolymers and blends on poly(lactide) -- In vitro degradation testing
46	EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
47	YY1116:2010	Absorbable Surgical Suture
48	YY0043:2016	Medical Suture Needle
49	ASTM F3014-14	Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures
50	ASTM F1874-98(2011)	Standard Test Method for Bend Testing of Needles Used in Surgical Sutures
51	ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
52	ASTM F1929 - 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
53	ASTM D5276 – 19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
54	ASTM D642 – 15	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
55	ASTM D999 - 08(2015)	Standard Test Methods for Vibration Testing of Shipping Containers
56	ASTM D6653 / D6653M - 13	Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
57	ASTM D4728 – 17	Standard Test Method for Random Vibration Testing of Shipping Containers
58	ASTM D6344 - 04(2017)	Standard Test Method for Concentrated Impacts to Transport Packages
59	ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
60	ISO14161：2009	Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results
61	ISO 11140-1:2014	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements
62	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
63	ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials

64	ASTM F1886 / F1886M - 16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
65	ASTM D3078 - 02(2013)	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
66	ASTM F1140 / F1140M - 13	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

NOTIFIED BODY: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi Sanayi ve Ticaret Limited Sirketi

Address: Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya - ANKARA

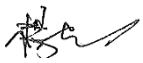
Identification Number CE_{2292}

(EC)CERTIFICATE(S):/

EC REP

EUROPEAN REPRESENTATIVE: MedNet GmbH
Borkstrasse10,48163 Muenster, Germany

START OF CE-MARKING:/

SIGNATURE: 

NAME: ZHIPENG YANG

POSITION: GENERAL MANAGER

PLACE, DATEOF DECLARATION: WEIHAI, 2019.11.30