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Declaration of Conformity

In accordance with Medical Devices Directive 93/42/EEC

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC as amended by Directive 2007/47/EC.

If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Manufacturer : HUAIAN PINGAN MEDICAL INSTRUMENT CO., LTD

Address No. 128 West Meigao Road, Huaian, Jiangsu, China.

European Representative : CMC Medical Devices & Drugs S.L.

Address C/ Horacio Lengo No 18, CP 29006, Malaga, Spain

Product : Synthetic Absorbable Sutures with/without Needle

Brand name : PI, PAXANONE, PACRYL, PAPRONE

Model name : Polyglycolic acid (PGA), Polydioxanone (PDO),
Polyglactin 910 (PGLA), Poliglecaprone (PGCL).

Classification : Class III by Rule 8 of Annex IX, Council Directive 93/42/EEC

GMDN Code : Polyglycolic acid (PGA)(13908), Polydioxanone (PDO) (16584),
Polyglactin(PGLA) (17471), Poliglecaprone (PGCL) (45814)

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards: (Appendix 1)

This Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II (+ section 4) under the supervision of Notified body, UDEM (NB No. 2292).

Notified body:

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. LTD. ŞTİ.

EC Certificate No.: M.2019.106.11953, M.2019.106.11953-1

Issue date: 14. 05. 2019 **Valid until:** 13.05. 2024


 President on behalf of
 HUAIAN PINGAN MEDICAL
 INSTRUMENT CO., LTD

Place: Huaian Jiangsu, China

Date: April 29, 2020

(name and signature or equivalent making of authorized person)

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(Appendix 1)

Applied Standards:

No	Standard identification	Issued date	Standard name
1	EN ISO 15223-1	2016	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
2	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
3	EN ISO 10993-3	2014	Biological evaluation of medical devices -Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO10993-3:2014)
4	EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
5	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
7	EN ISO 10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
8	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
9	EN ISO 10993-11	2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
10	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
11	EN ISO 11138-2	2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)
12	EN ISO 11607-1	2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)
13	EN ISO 11607-2	2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006, including Amd 1:2014)
14	EN ISO 11737-1	2006	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
15	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 (ISO 11737-2:2009)
16	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
17	EN ISO14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO14644-1:2015)
18	EN ISO14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
19	EN ISO14644-3	2005	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2005)
20	EN ISO14644-4	2001	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001)
21	EN ISO14644-5	2004	Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)
22	EN ISO14644-7	2004	Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) (ISO 14644-7:2004)
23	EN ISO14644-8	2013	Cleanrooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC) (ISO 14644-8:2013)

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24	EN ISO14698-1	2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods (ISO 14698-1:2003)
25	EN ISO14698-2	2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)
26	EN ISO 14971	2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
27	ASTM F1980-16	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for medical device
28	MEDDEV 2.12_2 Rev.2	2012	Post Market Clinical Follow-up Studies
29	MEDDEV 2.12_1 Rev.8	2013	Guidelines on a medical device vigilance system
30	MEDDEV 2.7.1 Rev.4	2016	Guidelines on a medical device – Clinical evaluation
32	EN 1041:2008+A1	2013	Information supplied by the manufacturer of medical devices
33	EP(European Pharmacopoeia) 9.0	2017	Sutures (sterile synthetic absorbable monofilament) - length, diameter, breaking load, needle attachment
34	YY1116	2020	Absorbable Surgical Suture
35	YY0166	2002	Surgical Suture Needles with threads
36	YY0043	2005	Medical Suture Needle
37	YY0033	2000	Management Criterion for the Sterile Medical Devices Production,
38	YY1116	2020	Absorbable Sutures

no.	product name	reference	model
1	Sterile, Absorbable Sutures with/without Needles Brand: PASORB, Polyglycolic acid (PGA)	USP 8/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 7/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 6/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 5/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 1	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
2	Sterile, Absorbable Sutures with/without Needles Brand:	USP 8/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;

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	PAXANONE, Polydioxanone (PDO)	USP 7/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 6/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 5/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 1	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
3	Sterile, Absorbable Sutures with/without Needles Brand: PACRYL, Polyglactin 910 (PGLA)	USP 8/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 7/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 6/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 5/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 1	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
4	Sterile, Absorbable Sutures with/without Needles Brand:	USP 8/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;

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	PAPRONE, Poliglecaprone (PGCL)	USP 7/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 6/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 5/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 1	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 2	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 3	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
		USP 4	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;