CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2019.106.11953-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Huaian Pingan Medical Instrument Co., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile, Absorbable Polyglactin 910 (PGLA) suture with or without needle - Class III - Sterile, Absorbable Polyglycolic Acid (PGA) suture with or without needle - Class III - Sterile, Absorbable Polydioxanone (PDO) suture with or without needle - Class III - Sterile, Absorbable Poliglecaprone (PGCL) suture with or without needle - Class III
GMDN	: 17471, 13908, 16584, 17246
	Product Types are attached.
Certificate Number	: M.2019.106.11953
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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Digitally signed by Iarovoi Petru
Date: 2021.12.16 14:03:04 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2019.106.11953 the validity of the certificate M.2019.106.11953-1 will also end.

Company Name	: Huaian Pingan Medical Instrument Co., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: - Sterile, Absorbable Polyglactin 910 (PGLA) suture with or without needle - Class III - Sterile, Absorbable Polyglycolic Acid (PGA) suture with or without needle - Class III - Sterile, Absorbable Polydioxanone (PDO) suture with or without needle - Class III - Sterile, Absorbable Poliglecaprone (PGCL) suture with or without needle - Class III
GMDN	: 17471, 13908, 16584, 17246

Product Types are attached.

Certificate Number	: M.2019.106.11953-1
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc., Co.

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Huaian Pingan Medical InstrumentCo., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile, Non-Absorbable Silk Braided Suture with or without needle - Class IIb - Sterile, Non-Absorbable Polyester Braided Suture with or without needle - Class IIb - Sterile, Non-Absorbable Polypropylene monofilament Suture with or without needle - Class IIb - Sterile, Non-Absorbable Nylon / Polyamide monofilament Suture with or without needle - Class IIb
GMDN	: 13910, 13906, 13909, 13905

Product Types are attached.

Certificate Number	: M.2019.106.11952
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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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 :	PASORB, 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)

(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)

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	2010	Absorbable Surgical Suture
35	YY0166	2002	Surgical Suture Needles with threads
36	YY043	2005	Medical Suture Needle
37	YY0033	2000	Management Criterion for the Sterile Medical Devices Production,
38	YY1116	2010	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;

	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;

	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;