



C E R T I F I C A T E

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 certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device 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 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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C E R T I F I C A T E

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

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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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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2018.106.11953 and with the registration date of 14.05.2019 issued for "Huaian Pingan Medical InstrumentCo., Ltd." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Polyglactin 910 (PGLA) - GMDN NO:17471
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are single or loop, with single, double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7
Suture Lengths : Variety of lengths, from 13 cm to 250 cm
Needle Lengths : Variety of lengths, from 4.5 mm to 90 mm
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J shape
Needle Properties: Round bodied needle, cutting needle, reverse cutting needle, tapercut needle, blunt needle, micro-point spatula needle
Polyglycolic Acid (PGA) - GMDN NO:13908
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are single or loop, with single, double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7
Suture Lengths : Variety of lengths, from 13 cm to 250 cm
Needle Lengths : Variety of lengths, from 4.5 mm to 90 mm
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J shape
Needle Properties: Round bodied needle, cutting needle, reverse cutting needle, tapercut needle, blunt needle, micro-point spatula needle
Polydioxanone (PDO) - GMDN NO: 16584
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are single or loop, with single, double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7
Suture Lengths : Variety of lengths, from 13 cm to 250 cm
Needle Lengths : Variety of lengths, from 4.5 mm to 90 mm
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J shape
Needle Properties: Round bodied needle, cutting needle, reverse cutting needle, tapercut needle, blunt needle, micro-point spatula needle
Poliglecaprone (PGCL) - GMDN NO:17246
Synthetic, Sterile, Absorbable, Monofilament, Undyed or Violet colored Surgical Sutures are single or loop, with single, double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7
Suture Lengths : Variety of lengths, from 13 cm to 250 cm
Needle Lengths : Variety of lengths, from 4.5 mm to 90 mm
Needle Shapes : 1/2, 3/8, 1/4, 5/8, Straight, J shape
Needle Properties: Round bodied needle, cutting needle, reverse cutting needle, tapercut needle, blunt needle, micro-point spatula needle