Digitally signed by Iarovoi Petru
Date: 2019.06.17 16:43:47 EEST
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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.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

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 foremention 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, themention 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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