EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

M.2017.106.8823-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Kollsut International Inc.
Company Address	: 1763 NE 162nd Street, North Miami Beach, FL 33162 USA
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile Monofilament Non-coated Violet or undyed Absorbable Polydioxanone Sutures with or without Needle - Class III - Sterile Braided Coated Violet or undyed Absorbable Polyglycolic Acid Fast Sutures with or without Needle - Class III - Sterile Braided Coated Violet or undyed Absorbable Polyglactin 910 Fast Sutures with or without Needle - Class III - Sterile Braided Coated Violet or undyed Absorbable Polyglycolic Acid Sutures with or without Needle - Class III - Sterile Monofilament Non-coated Violet or undyed Absorbable Polyglycolic Acid Sutures with or without Needle - Class III - Sterile Braided Coated Violet or undyed Absorbable Polyglactin 910 Suture with or without Needle - Class III - Sterile Monofilament Non-coated Violet or undyed Absorbable Polyglecaprone Suture with or without Needle - Class III - Sterile Monofilament Non-coated Blue or undyed Non-Absorbable Polypropylene Sutures with or without Needle - Class III - Sterile Braided Coated Green or undyed Non-Absorbable Polyester Sutures with or without Needle - Class III - Sterile Monofilament Non-coated Green or undyed Non-Absorbable Polyester Sutures with or without Needle - Class III - Sterile Monofilament Non-coated undyed Non-Absorbable PTFE Sutures with or without Needle - Class III - Sterile Monofilament Non-coated Solvent Blue104, Phthalocyanine blue or undyed Non-Absorbable PVDF Sutures with or without Needle - Class III
GMDN	: 16584, 13908, 17471, 45814, 13909, 13906, 17467, 38873
Certificate Number	: M.2017.106.8823
Report Number	: MD.3428.K.IB
Initial Assessment Date	: 08.06.2017
Registration Date	: 11.09.2017
Revision Date /No	: -
Expiry Date	: 10.09.2022

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 directive 93/42/EEC 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 this Class III devices on the market. 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 currency of the certificate can be checked through www.udem.com.tr.

CE 2292

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EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Kollsut International Inc.
Company Address	: 1763 NE 162nd Street, North Miami Beach, FL 33162 USA
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Braided Coated Blue,black or undyed Non - Absorbable SILK Sutures with or without Needle - Class IIb Sterile Monofilament Non-coated Blue or Logwood black Non - Absorbable Nylon Sutures with or without Needle - Class IIb
GMDN	: 13910, 38000
Certificate Number	: M.2017.106.8822
Report Number	: MD.3428.K.IB
Initial Assessment Date	: 08.06.2017
Registration Date	: 11.09.2017
Revision Date /No	: -
Expiry Date	: 10.09.2022

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 directive 93/42/EEC 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. 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 currency of the certificate can be checked through www.udem.com.tr.

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