CERTIFICATE

Full Quality Assurance System

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

M.2019.106.11727-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Shanxian HAIDIKE Biotechnology Co., Ltd.
Company Address	: Plant No.1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China.
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile Braided Coated Violet or Undyed Absorbable Polyglycolic Acid (PGA) Suture with or without Needle - Class III - Sterile Braided Coated Violet or Undyed Absorbable Polyglactin (PGLA) Suture with or without Needle - Class III - Sterile Single Use Non-Absorbable Silk Suture with or without needle - Class IIb - Sterile Single Use Non-Absorbable Nylon Suture with or without needle - Class IIb - Sterile Single Use Non-Absorbable Polyester Suture with or without needle - Class IIb - Sterile Single Use Non-Absorbable Polypropylene Suture with or without needle - Class IIb
GMDN	: 13908, 17471, 13910, 13905, 13906, 13909 Product Types are attached.
Certificate Number	: M.2019.106.11727
Report Number	: MD.3626.IB
Initial Assessment Date	: 10.02.2018
Registration Date	: 10.04.2019
Revision Date /No	: -
Expiry Date	: 09.04.2024

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 applied 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 II 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 validity 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.

CE 2292

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

PCA

PARTNERS CERTIFICATE ASSURANCE

Certificate

ISO 13485 : 2016

Shanxian HAIDIKE Biotechnology Co., Ltd.

Plant No.1, Science and Technology Incubation Park, Southern Jiantai Road. Economic Development Zone, Shanxian, Heze City, Shangdong Provice, China

This certificate shows that the medical devices - quality management system(TS 13485:2012 and EN 13485:2016)of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

SCOPE

Disposable sutpre needles with non-absorbable threads,sterile syringe for single use, sterile infusion sets for single use, disposable lancets for blood specimen collection,absorbable surgical sutures with or without needle

Certificate No	: TC-75059
Registration Date	: 27.04.2018
Reissue Date	:
Expiry Date	: 26.04.2021
Certificate Period	: 3 Years (From the date of registration)

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com

FR.86 Rev.2