



# 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 for mentioned 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 III devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining stable conditions, if the device is stable; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. The 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 know 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](http://www.udem.com.tr).

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# 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  
Province, 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 suture 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)



**ACCREDITED**

Management  
Systems  
Certification Body  
MSCB-103

PCA Certification Approval

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