



# 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.2019.106.11727-1 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 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](http://www.udem.com.tr).

  
UDEM International Certification  
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This document containing 2 (two) pages is the Annex of the Certificate with the number M.2018.106.11727 and with the registration date of 10.04.2019 issued for “Shanxian HAIDIKE Biotechnology Co., 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

<b>[Polyglycolic acid] (PGA)</b>	<b>GMDN NO:13908</b>
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
<b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6	
<b>EP:</b> 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7, 8	
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm	
<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm	
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI	
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
<b>Poly[glycolide(90%)-co-lactide(10%)] (PGLA)</b>	<b>GMDN NO:17471</b>
Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or Violet colored Surgical Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
<b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2	
<b>EP:</b> 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5	
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm	
<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm	
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI	
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
<b>[Polyamide 6] (Nylon)</b>	<b>GMDN NO:13905</b>
Synthetic, Sterile, Non-Absorbable, monofilament, Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
<b>USP:</b> 11/0, 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4,	
<b>EP:</b> 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6	
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm	
<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm	
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI	
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.	
<b>[Fibroin] (Silk)</b>	<b>GMDN NO:13910</b>
Synthetic, Sterile, Non-Absorbable, Multifilament, Braided, Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:	
<b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5	
<b>EP:</b> 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7	
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm	



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<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.
<b>[Polyester] (Polyester)</b> <b>GMDN NO:13906</b>
Synthetic, Sterile, Non-Absorbable, Multifilament, Braided, Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
<b>USP:</b> 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4,
<b>EP:</b> 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6,
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm
<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.
<b>[Polypropylene] (Polypropylene)</b> <b>GMDN NO:13909</b>
Synthetic, Sterile, Non-Absorbable, monofilament, Sutures are loop, single or with double needle or without needle, and in the following USP, EP, Suture Length, Needle Length, Needle Shape and Needle properties:
<b>USP:</b> 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3
<b>EP:</b> 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6
<b>Suture Lengths:</b> Variety of lengths, from 10 cm to 500 cm
<b>Needle Lengths:</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes:</b> 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
<b>Needle Properties:</b> Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.