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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	: Shandong Haidike Medical Products 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	: 22.07.2019/ 01
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

This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01 with the number M.2019.106.11727 and with the registration date of 10.04.2019 with the revision date of 22.07.2019 issued for "Shandong Haidike Medical Products 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

[Polyglycolic acid] (PGA) **GMDN NO:13908**
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:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7, 8
Suture Lengths: Variety of lengths, from 10 cm to 500 cm
Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
Needle Properties: 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.
Poly[glycolide(90%)-co-lactide(10%)] (PGLA) **GMDN NO:17471**
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:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5
Suture Lengths: Variety of lengths, from 10 cm to 500 cm
Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
Needle Properties: 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.
[Polyamide 6] (Nylon) **GMDN NO:13905**
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:
USP: 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,
EP: 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6
Suture Lengths: Variety of lengths, from 10 cm to 500 cm
Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
Needle Properties: 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.
[Fibroin] (Silk) **GMDN NO:13910**
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:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7
Suture Lengths: Variety of lengths, from 10 cm to 500 cm

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Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
Needle Properties: 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.
[Polyester] (Polyester) **GMDN NO:13906**
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:
USP: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4,
EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6,
Suture Lengths: Variety of lengths, from 10 cm to 500 cm
Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8,4/9, Straight, J, SKI
Needle Properties: 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.
[Polypropylene] (Polypropylene) **GMDN NO:13909**
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:
USP:7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3
EP: 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6
Suture Lengths: Variety of lengths, from 10 cm to 500 cm
Needle Lengths: Variety of lengths, from 3 mm to 150 mm
Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI
Needle Properties: 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.

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 2292 APPROVED

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Shandong Haidike Medical Products Co., Ltd.
Manufacturer address and contact details	Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China +86 530-4660062
Single Registration Number (SRN) (if available)	CN-MF-000026113

Authorized Representative name (if applicable)	CMC Medical Devices & Drugs s.L.
Authorized Representative address and contact details	C/ Horacio Lengo Nº 18, CP 29006, Malaga, Spain +34 951 214 054
Single Registration Number (SRN) (if available)	ES-AR-000000293

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive	

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☑A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☐A QMS in accordance with Article 10(9) MDR is in place.
☐A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

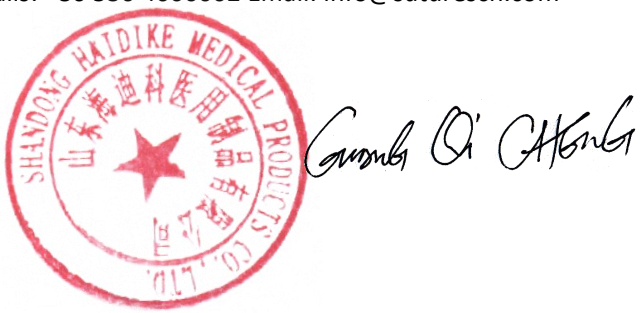
Signed for and on behalf of the manufacturer:

Full Company Name: Shandong Haidike Medical Products Co., Ltd.

Location & Date: Heze City, Shandong on April 8th, 2024

Signature, Print Name, Title: Mr. Guangqi Cheng Managing Director

Contact Details: +86 530 4660062 Email: info@suturescn.com



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile Braided Coated Violet or Undyed Absorbable Polyglycolic Acid (PGA) Suture with or without Needle-ClassⅢ	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2027	
Sterile Braided Coated Violet or Undyed Absorbable Polyglactin (PGLA) Suture with or without Needle-Class Ⅲ	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2027	
Sterile Single Use Non-Absorbable Nylon Suture with or without needle-Class Ⅱb	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Silk Suture with or without needle -Class Ⅱb	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Polyester Suture with or without needle-Class Ⅱb	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Polypropylene Suture with or without needle-Class Ⅱb	M.2019.106.11727	**09.04.2024**	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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eurofins | Product Testing

To M. Luyv/Jiang
Shandong Haidike Medical Products Co., Ltd.
Tianfu Road, Dongcheng District, Shan County,
274300 Heze City, Shandong Province, China
VAT/ID n: 91371722059049941D
Ph. 0530-4660062 / 15506406108
Email registration@suturescn.com

March 29, 2024

Project 24Q03053 Rev.01

Subject: EC Certification activity in accordance with Reg. (EU) 2017/745 – Annex IX for the following Medical Devices (MD):

1) **Absorbable Polyglycolic acid Surgical Suture**
2) **Absorbable Polyglactin Surgical Suture**
3) **Non Absorbable Surgical Nylon Suture**
4) **Non Absorbable Silk Surgical Suture**
5) **Non Absorbable Surgical Polyester Suture**
6) **Non Absorbable Surgical Polypropylene Suture**

In response to your kind request and based on previous agreements, we are pleased to confirm our availability to provide the above specified activities as herewith specified.

To accept our proposal, please return this form stamped and signed via fax at +39.011.22.22.226 or by email Epti@cpt.eurofinseu.com

For any clarification, don't hesitate to contact our Customer Service (Tel. +39.011.22.22.225).
Best regards

Eurofins Product Testing Italy Srl
Customer Service Manager
Stefano Compalati

I. MEDICAL DEVICES UNDER CERTIFICATION and SITES INVOLVED

- Medical Devices under certification:

Medical Device (MD)	MDA MDN	MDS	MDT	Cert. Req.	Class MDR	Legacy Device	Ref. MD
Absorbable Polyglycolic acid Surgical Suture - is a synthetic absorbable, braided, coated suture composed of a Polyglycolic acid (PGA) and is available dyed with or without needle.	1104	1005 1008	2001, 2002 2008, 2011	First cert	III	YES (*)	1)
Absorbable Polyglactin Surgical Suture - is a synthetic absorbable, multifilament, braided surgical suture which is supplied sterile, surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Surgical Suture are coated with copolymer of poly(glycolide-co-Llactide)(30/70) and calcium stearate. Absorbable Polyglactin Surgical Suture is available dyed with or without needle.	1104	1005 1008	2001, 2002 2008, 2011	First cert	III	YES (*)	2)
Non Absorbable Surgical Nylon Suture - The proposed device is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed device will be offered in diameters ranging from USP size 11-0 through 4 and available with or without needles attached. The proposed device is dyed blue.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	3)
Non Absorbable Silk Surgical Suture - Non absorbable Surgical silk Suture is a non absorbable, braided surgical suture which is supplied sterile,surgical suture composed of an organic protein called fibroin.this protein is derived from the domesticated species Bombyx mori of the family Bombycidae.Silk for braided material is processed to remove the natural waxes and gums.Silk suture is dyed black(Logwood extract) and coated with silicone.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	4)
Non Absorbable Surgical Polyester Suture - The proposed device is a coated,braided,non absorbable synthetic surgical suture composed of polyethylene terephthalate which is supplied sterile.The suture is coated with bees wax and dyed green. The color additive is D&C Green 6.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	5)
Non Absorbable Surgical Polypropylene Suture - Non Absorbable Surgical Polypropylene Suture is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed device is dyed blue. The color additive is [phtalocyaninato(2-)] copper(Color Index Number 74160), and the weight percentage for the color additive is less than 0.1%.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	6)
(*) MD for which the tripartite agreement (including the MDD NB) is required in case of MDD Surveillance takeover before 26/09/2024.							
Note: during the Application Review phase and/or during the certification process we will carry out the check of the codes and classifications actually applicable to the devices. In the event the codes and classifications above would result as not corrected, we will terminate the present quotation/contract and, where possible (codes and classifications falling into our scope), we will issue a new quotation							

- Sites / Plants involved and to be audited by the Inspectors:

COMPANY	FUNCTION / PROCESS MANAGED	FTE N°	Ref. MD	AREA (*)	Ref. Site
Shandong Haidike Medical Products Co., Ltd. - Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China	Manufacturer: legal site, production, packaging, warehouse, sterilization	60	All	MDR/MDD	A)
(*) Sites marked only with Area MDR will be subject to Audit on the basis of the evolution of the phases of the MDR certification process. Sites marked only with Area MDD will be subject to Audits only to maintain the validity of MDD certified products pursuant to Regulation (EU) 2023/607. Sites marked Area MDR/MDD will be audited both to maintain the validity of the MDD certificates and during the activities envisaged for the MDR certification.					
Note: in the event that during the Application Review phase and/or during the certification process our Experts and Inspectors should find that other sites additional to the ones above have to be audited (Eg. because there some critical processes are managed in full or partially, same sites will have to be audited in order to move forward with the process and related invoicing will occur by basing on tariffs shown in Par. III.V and actual commitments (audit time, travel time, travel expenses)					

IIa. METHODOLOGY – MDR CERTIFICATION

The activity provides the following steps:

- Acceptance of the quote:
  - in order to accept the present quotation you are required to send it stamped and signed by your legal representative in both dedicated sections for signature at the bottom together with the information sheet table filled;

- you are also required to send your formal Request for Certification filled, stamped and signed by your legal representative on your company letterhead (form attached), in accordance with Par. 4.3 of MDR – Annex VI, and jointly with the documents listed here below.

Note: the start of the activities and, in particular, the opening of the process and the execution of the Application Review does not imply definitive acceptance of your application, nor the stipulation of the Certification Contract, which will be evaluated and possibly definitively confirmed only following a positive outcome of the Application Review.

- Documentation required - Preliminary phase: in order to be able to carry out the preliminary activities for the definitive stipulation of the Certification Contract you will have to send us the necessary documentation (in Italian or English) for the execution of the Application Review as required by Reg. (EU) 2017/ 745 - Annex IX - Chapter I - point 2.1 and Chapter II - point 4.1. In summary, a copy of your QMS, some documents of the technical file, the description and classification of the MD and, for class IIb Implantable and III MDs, the complete technical file.

- Application review: having received the above documentation, we will proceed with the analysis of the same with reference to point 4.3, third paragraph of Annex VII of the MDR.

- Order Confirmation: following the successful Application Review, we will proceed to send the Order Confirmation which will constitute the formal stipulation of the certification contract also pursuant to point 4.3, second paragraph of Annex VII of the MDR.

- Documentation required - Activation of the certification procedure: to start the certification activities, the submission of the complete Technical File of each device (in Italian or English) is required, having already acquired the documentation of the Quality Management System.

- Examination of the technical documentation: We will then proceed with the verification of the conformity of the Technical File according to Annex IX, chapter II and chapter III and the drafting of the relative Documentary Examination Report for each product evaluated, with an indication of any deficiencies found and any need to carry out examinations, tests and checks. We will also proceed with the verification of the assessment of clinical efficacy and the relative release of the Report.

- Additional activities that may be required where applicable: with reference to:
  - Medical devices incorporating medicinal substances;
  - Medical devices manufactured utilising tissues or cells of animal origin, or their derivatives (falling into Reg. EU No. 722/2012;
  - Medical devices composed of substances or a combination of substances to be introduced into the human body via a body orifice or the dermal route and that are absorbed by or locally dispersed in the human body, according to applicable provision of the Directive 2001/83/EC – Annex I;
  - Medical devices, or their metabolism products, which are systematically absorbed by the body in order to achieve their intended use;
  - Class III implantable medical devices and class IIb active devices intended to administer and / or remove a medicinal product from the body;

  where applicable, the Verification of the clinical data, the Verification by specialized and qualified professionals in the sector, the opinion and / or approval by competent European Agencies and Commissions, the Preliminary Verification of the Reports to be submitted to the same Agencies and Commissions, are necessary as specified below in the economic conditions.

- Initial certification Audit: it will be conducted at the Manufacturer site, at the production site and at all the sites involved in the critical processes of the production and marketing of the devices (including critical suppliers). During the Audit an examination of the QMS will be conducted with the consequent release of a Report.

- Certificate release: in case of positive outcome of all the activities above, we will issue the Certificate according to Reg. (EU) 2017/745 – Annex IX with a validity as specified in Chp. IV of the present quote.

- Surveillance activity – Audits: Surveillance Audits will be carried out during the duration of the assignment to maintain the validity of the certification of your production, in order to verify the correct functioning of the quality system, the conformity of the product and monitor any changes made to the Technical Files. These audits will take place on an annual basis (as further detailed in Chapter III), will be scheduled well in advance of the deadlines and, at the end of each Surveillance, a specific Inspection Verification Report will be issued. For Medical Devices Class III, tests on materials and essential parts of the device from which the integrity of the same depends on, will be conducted during the Surveillance Audits. For class III MDs, sampling will be carried out in the Surveillance Audit in order to have tests carried out on the essential materials/parts on which the integrity of the MD depends

- Unannounced / Short Notice Audits: they have to be conducted at least one time every 5 years and with the purpose of checking the correct functioning of the QMS and the conformity of the devices. During these Audits, samples of the medical devices under certification might be picked from the production and sent to laboratory for testing. Outcome of the Audits will be a Report including reporting of the laboratory testing where conducted.

- Note - Examination, tests and verifications: the need of these activities may arise from the Technical File assessment and Audits. They will be quoted separately with specific quotations for the purpose.
- Note - Audit planning: the planning of the Audits with reference to information shown on Chapter I of the present quotation may change during the validity period of the certification depending on the following factors: the size of the organization, the scope and complexity of the management system, the products and processes, the level of effectiveness demonstrated by the management system, the results of previous audits, inadequate control over suppliers and crucial suppliers.

IIb. METHODOLOGY – MDD SURVEILLANCE

With reference to **Legacy Devices** (devices already certified pursuant to Directive 93/42/EEC - MDD), for which it will be required and it will be possible to enter into an agreement with Eurofins Product Testing Italy for certification according to Reg. (EU) 2017/745 MDR , we are expected to take charge of the Surveillance of the Certification according to Directive 93/42/EEC MDD (issued by us or another Notified Body) in any case and no later than **26 September 2024**, in accordance with what is indicated in point 1) of the Reg. (EU) 2023/607, which modifies the art. 120 (3) of Reg. (EU) 2017/745.

The activity provides the following steps:

- Documentation required - Preliminary phase: for the purposes of extending the MDD Certificate, pursuant to Regulation (EU) 2023/607 it is necessary that you send us, by and no later than **26 May 2024**, the provisions of the aforementioned Regulation and the explanatory document of the European Commission "Extension of the MDR transitional period and removal of the 'sell off' periods" – Q&A p.to 8. In particular, you must send us:
  - the description and classification of the Medical Device(s) according to the MDR;
  - the Manufacturer's Declaration (fac-simile will be sent);
  - the presentation plan of the technical files;
  - copy of the Quality System updated to what is required by Reg. (EU) 2017/745 and already adopted in the company.

  Furthermore, for devices MDD certified not by our Notified Body:
  - copy of the CE certificates according to MDD issued by the previous Notified Body;
  - copy of the audit reports issued by the previous Notified Body for the entire last certification cycle. Where NCs have been managed in the last audit received from the previous Body, a copy of the resolutions and acceptance by the previous ON (if present) is required;
  - complete copy of the current version of the Technical File approved by the previous Notified Body, in order to access the information necessary for carrying out the surveillance activities. Note: Responsibility for product conformity assessment remains with the former Notified Body;
  - full copy of the assessment reports of the changes made to the technical documentation in accordance with Art120 MDR and MDCG 2020-3 and approved by the previous Notified Body. Subsequent changes to this agreement will be evaluated by Eurofins Product Testing Italy S.r.l. in accordance with the provisions of Art.120 of the Medical Regulations and the MDCG 2020-3 guideline.

  NOTE: In order to be able to take charge of MDD Surveillance, it is necessary to have already stipulated a Contract for the MDR certification of the same Devices

- Check of the documentation: together with the MDR Application Review phase, if not yet carried out, we will proceed with the analysis of the documentation requested above and sent by you with any request for integration of information and documentation that may be missing. Following a positive outcome of the verification, we will proceed with the possible acceptance of your request by sending the Order Confirmation and consequent signing of the final agreement, **which cannot take place beyond 26 September 2024**.
  NOTE: where it is required to take charge of the MDD Surveillance prior to 09/26/2024, it is necessary to stipulate the Agreement between the Manufacturer, Eurofins Product Testing Italy and the outgoing Notified Body as provided for in point 1) of Reg. (EU) 2023/607 which updates art. 120.3 sexies of Reg. (EU) 2017/745.
- Surveillance Audits: we will then proceed with the first Surveillance Audit and, subsequently, with the subsequent ones which must be carried out approximately every 12 months (without prejudice to our possibility of bringing them forward if deemed necessary and appropriate). At the end of each Surveillance Audit, a specific Inspection Verification Report will be issued.
- Un-expected Audits: one must be carried out at least every three years aimed at verifying the correct functioning of the quality system and the conformity of the product. During these visits, samples of the certified products may be taken in order to carry out laboratory tests. At the end of the Audit, a Verification Report will be issued and, if tests have been carried out, a test report.
- Examinations, tests and verifications: where necessary, any examinations, tests and verifications will be carried out, and will be quoted to you separately. This need can arise from un-expected audits or any other check.

Declaration of Conformity

Manufacturer:

Name: Shandong Haidike Medical Products Co.,Ltd.
Add: Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China
TEL: +86 530-4660062
FAX: +86 530-4660055

European Authorized Representative:

Name: CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34 951 214 054
Contact: Manuel Mateos
Email: info@cmcmedicaldevices.com

Product: Absorbable surgical suture

Medical device: POLYGLACTIN

Specifications:

Absorbable surgical suture	PGLA
Sizes	8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6
Raw material of the suture	90% glycolide and 10% L-lactide
Structure	Multifilament
Coated	Poly (glycolide-co-L-lactide) + Calcium Stearate
Needle radian	1/2 circle, 3/8 circle, 4/9 circle
Needle Shape	Round body, Cutting, Spatula
Needle diameter × chord length (0.1mm×mm)	(1.5-15)×(4.5-55)

Manufacturer's Name: Shandong Haidike Medical Products Co.,Ltd.
Manufacture's Address: Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China
EU Representative: CMC Medical Devices & Drugs S.L.

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Classification (MDD, Annex IX): PGLA is a long-term implanted device belonging to Class III, according to Article 8 of the MDD93/42/EEC IX Classification Guidelines.
Rule 8: Implanted tissue for more than 30 days

Shandong Haidike Medical Products Co.,Ltd.	Version number	A/5
Declaration of Conformity	File No.	HDK-CE-002-13
	Effective date	2018.12.28

Conformity Routes: Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (4).

For the evaluation of the conformity with this Directive, the following standards have been applied:

EN ISO 13485:2016
93/42/EEC
MEDDEV 2.12/1 rev.8
EN ISO 14971:2012
MEDDEV 2.7.1:2016
ISO15223-1:2012
EN 1041:2008
ISO15223-2:2012
EN ISO10993-1: 2009/AC:2010
EN ISO 11607-1:2009+A1:2014
EN ISO 11607-2:2006+A1:2014
EN ISO10993-3-2014
EN ISO10993-4-2009
EN ISO10993-5-2009
EN ISO10993-6-2009
EN ISO10993-7-2008 (AC:2009)
EN ISO10993-9-2009
EN ISO10993-10-2013
EN ISO10993-11-2009
YY 1116-2010
ASTM F1980-07 (2011)
YY/T 0043-2016
EP 9.0
EN ISO11737-1: 2006 (AC:2009)
ISO11737:2009
EN 556-1:2001 (AC:2006)
EN ISO 11135-1:2014

The products are covered by CE Certificate Number: M.2019.106.11727
Identification of Notified Body: UDEM 2292
GMDN: 17471
Registration date: 10.04.2019
Expiry date of the Certificate: 09.04.2024

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards.

Name, Surname:
Position/Title: Managing Director
Issued Date: Dec. 28th, 2018
Shandong Haidike Medical Products Co.,Ltd.

SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD.
山东海迪科医用制品有限公司

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C564964

Initial certification date:
20 April 2023

Valid:
20 April 2023 – 19 April 2026

This is to certify that the management system of

Shandong Haidike Medical Products Co., Ltd

Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China
(Unicode: 91371722059049941D)

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, Development, Manufacture, Sales and Distribution of Disposable Sterile Absorbable Surgical Sutures with or without Needle, Sterile Non Absorbable Surgical Sutures with or without Needle, Disposable Sterile or non-sterile Medical face mask and Disposable Sterile or non-sterile Medical protective clothing.

Place and date:
Høvik, 20 April 2023

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative