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

CERTIFICATE

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2019.106.11727 the validity of the certificate M.2019.106.11727-1 will also end.

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 (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
GMDN	: 13908, 17471

Product Types are attached.

Certificate Number	: M.2019.106.11727-1
Report Number	: MD.3626.IB-1
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.

The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, 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 aforementioned directive. 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

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name	: Shandong Haidike Medical Products Co., Ltd.
Company Address	: Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China
Related Directive	: 93/42/EEC Medical Devices Directive
Definition of Change	: Company address has been changed.
Number of Related Certificate	: M.2019.106.11727, M.2019.106.11727-1
Report Number	: MD.3626
Issue Date	: 19.09.2023
Revision Date	: -
Revision Number	: 00

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120 (3) and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

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@udem.com.tr www.udem.com.tr

eurofins | Product Testing

CP MDR.MOD.005a.04 - 08.01.2024

To: Luyv Jiang
Shandong Haidike Medical Products Co., Ltd.
Tianfu Road, Doncheng District, Shan County,
274300 Heze City, Shandong Province, China
Email: registration@suturescn.com

Conferma ordine / *Order confirmation* - Confirmation letter

Letter Reference: 24Q03053 Rev.01 COVer.1

Confermiamo con la presente dello stato di una domanda formale e di un accordo scritto nell'ambito del Regolamento UE 2017/745 modificato dal Regolamento (UE) 2023/607 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici La presente lettera conferma che, Eurofins Product Testing Italy Srl, Organismo Notificato (NB) designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero NB0477, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma, dell'allegato VII dell'MDR e ha firmato un accordo scritto in conformità alla sezione 4.3, secondo comma, dell'allegato VII dell'MDR con il seguente fabbricante:	***Confirmation of the status of a formal application and written agreement in the framework of Regulation EU 2017/745 amending by Regulation (EU) 2023/607 as regards the transitional provisions for certain medical devices*** *This letter confirms that, Eurofins Product Testing Italy Srl designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB0477, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:*

Azienda / *Company*	**Shandong Haidike Medical Products Co., Ltd.**	
Sede Legale / *Registered Office*	Tianfu Road, Doncheng District, Shan County, 274300 Heze City, Shandong Province, China	
Contratto n° / *Contract No.*	24-11-000109	
SRN	CN-MF-000026113	
Quotazione / *Quotation*	**Progetto N°** / *Project No.*	**24Q03053 Rev.01**
	Emessa in data / *Issue date*	29/03/2024
	Firmata e timbrata per accettazione in data / *Stamped and signed for acceptance on date*	21/04/2024
Riferimento normativo / *Regulatory reference*	Regolamento (UE) 2017/745 (MDR) ☒ Allegato IX(I) / *Annex IX(I)* ☒ Allegato IX(II) / *Annex IX(II)* ☐ Allegato X / *Annex X* ☐ Allegato XI(A) / *Annex XI(A)* ☐ Allegato XI(B) / *Annex XI(B)*	
in relazione alla richiesta di certificazione: *for the following certification request*	☒ **iniziale** / ***initial*** ☐ **sorveglianza** / ***surveillance*** ☐ **rinnovo** / ***renewal*** ☐ **subentro** / ***transfer*** ☐ **revisione** / ***revision*** ☐ **estensione** / ***extension***	
Dispositivi Medici / *Medical Devices*	Vedi tabella di seguito riportata con i dispositivi oggetto di incarico / *See table below with the medical device list included in the order.*	

I dispositivi coperti dalla domanda formale e dall'accordo scritto di cui sopra sono elencati nella Tabella 1 di seguito.	*The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.*
Il fabbricante ha rilasciato specifica dichiarazione in data 08/04/2024 con richiesta di utilizzo della proroga di cui al Regolamento UE 2023/607 nella quale precisa che sono soddisfatte le condizioni di accesso alla proroga stessa.	*The manufacturer has issued a specific declaration on 08/04/2024 requesting the use of the extension provided for in EU Regulation 2023/607 in which it specifies that the conditions for access to the extension are met.*
I tempi di transizione che si applicano ai dispositivi oggetto della presente lettera (vedi Tabella 1) e che sono di seguito riportati, permangono a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120.3c della MDR (come modificato dal Regolamento UE 2023/607): • 26 Maggio 2026 per i dispositivi impiantabili su misura di Classe III. • 31 Dicembre 2027 per i dispositivi di Classe III e per i dispositivi impiantabili di Classe IIb, escluse le suture, graffette, otturazioni dentali, apparecchi ortodontici, corone dentali, viti, cunei, placche, fili, perni, clip e connettori. • 31 Dicembre 2028 per dispositivi di Classe IIb che non ricadono nel punto precedente, per i dispositivi di Classe IIa e Classe I immessi sul mercato in condizioni di sterilità o con funzione di misurazione. • 31 Dicembre 2028 per i dispositivi che non richiedono l'intervento di un organismo notificato ai sensi della MDD ma che lo richiedono ai sensi della MDR (ad esempio, i dispositivi di classe I che si qualificano come strumenti chirurgici riutilizzabili).	*The transition timelines that apply to the devices covered by this letter (see Table 1) and that are shown below, are valid if the manufacturer continues compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation EU 2023/607):* • *26 May 2026 for Class III custom-made implantable devices.* • *31 December 2027 for Class III devices and Class IIb implantable devices excluding sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.* • *31 December 2028 for devices Class IIb other than those covered by the above point, devices of Class IIa, and devices of Class I placed on the market in sterile condition or have a measuring function.* • *31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments).*

Tabella 1: Dispositivi inclusi nella presente comunicazione

Table 1: Devices covered by this letter

Nome del dispositivo / *Device name* *Basic UDI-DI* (se presente – *if applicable)*	**Classificazione MDR** *MDR Device classification* (come proposta dal fabbricante e verificata al pre application stage / *as proposed by the manufacturer and verified at the pre-application stage*)	**Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del dispositivo MDD corrispondente** *If the MDR device is a substitute device, identification of the corresponding MDD device*	**Riferimento del certificato MDD dei dispositivi oggetto della richiesta MDR e identificazione NB** *MDD Certificate Reference(s) of the devices under MDR application and the NB identification*
Sterile braided coated violet or undyed absorbable polyglycolic acid (PGA) suture with or without needle	III	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S. Certificate M.2019.106.11727-1 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S.
Sterile braided coated violet or undyed absorbable polyglactin (PGLA) suture with or without needle	III	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S. Certificate M.2019.106.11727-1 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S.
Sterile single use non-absorbable nylon suture with or without needle	IIb	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S.
Sterile single use non-absorbable silk suture with or without needle	IIb	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S.
Sterile single use non-absorbable polyester suture with or without needle	IIb	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.S.
Sterile single use non-absorbable polypropylene	IIb	N/A	Certificate M.2019.106.11727 NB2292 UDEM Uluslararasi Belgelendirme

suture with or without needle			Denetim Egitim Merkezi San. ve Tic. A.S.

Con riferimento al Vostro ordine per il progetto di certificazione secondo il Regolamento UE 2017/745 di cui ai riferimenti sopra citati: • si conferma la nostra accettazione dello stesso;	*With reference to your order for the certification project in accordance with the information listed above:* • *we confirm our acceptance of the contract;*
• l'incarico di Certificazione ai sensi del Regolamento UE 2017/745 con la presente è stato perfezionato e ha efficacia agli effetti del punto 4.3 dell'Allegato VII del Regolamento (UE) 2017/745, avendo svolto l'attività di "Application Review";	• *the engagement of Certification in accordance with Regulation (EU) 2017/745 has hereby been perfected and is effective for the purposes of Section 4.3 of Annex VII of Regulation (EU) 2017/745, having carried out the "Application Review" activity;*
• come precisato dal Regolamento UE 2023/607 l'organismo notificato che ha rilasciato il certificato secondo la direttiva 93/42/CEE continua a essere responsabile dell'appropriata sorveglianza dei requisiti applicabili relativi ai dispositivi che ha certificato.	• *as specified by EU Regulation 2023/607 the notified body that issued the certificate according to Directive 93/42/EEC continues to be responsible for the appropriate monitoring of the applicable requirements for the devices it has certified.*
Nel periodo che intercorre dalla data della presente lettera di conferma al 26/09/2024 la sorveglianza dei dispositivi che hanno un certificato rilasciato secondo la direttiva 93/42/CEE e indicati nella tabella 1 di cui sopra rimane in carico all'organismo notificato che li ha rilasciati.	*During the period from the date of this letter of confirmation to 26/09/2024, the surveillance of devices having a certificate issued according to Directive 93/42/EEC and specified in Table 1 above shall remain the responsibility of the Notified Body which issued them.*

Le condizioni e le modalità economiche sono indicate nell'offerta di Eurofins Product Testing Italy Srl **n° 24Q03053 Rev.01** del **29/03/2024** da Voi timbrata e controfirmata per accettazione.
Il programma di tale attività sarà concordato con gli esperti tecnici che Vi contatteranno nei prossimi giorni.
Nel caso in cui riteniate un motivato e documentabile caso di conflitto di interessi, in relazione ad uno o più esperti, è Vostra facoltà sollevare una riserva scritta entro 7 giorni.
L'annullamento o lo spostamento della data di intervento (qualora prevista) che verrà concordata dovrà essere segnalato al Eurofins Product Testing Italy Srl con almeno 5 (cinque) giorni lavorativi di preavviso.

*The general terms and the economic conditions as well as the quotation are indicated in the quotation **n° 24Q03053 Rev.01** of the **29/03/2024** signed.*
The activities dates are scheduled from the office of Eurofins Product Testing Italy S.r.l. of Torino (Italy).
In case you suspect a justified and documentable case of conflict of interest, in relation of the inspectors, you may raise a written reserve within 7 days.
The cancellation or displacement of the intervention date (if any) which will be agreed upon must be communicated to Eurofins Product Testing Italy Srl with at least 5 (five) working days notice.

Indice delle revisioni - *Revision History*

Data / *Date*	**Descrizione** / *Action*
24/05/2024	Prima emissione / Initial issue
12/07/2024	Seconda emissione / Second issue Inserimento numero certificato CE Esame della progettazione del prodotto per dispositivi categoria III / Insert numberEC Design-Examination Certificate for devices of category III

Eurofins Product Testing Italy Srl
Firma / Signature

Paolo Trisoglio
Data / Date 12/07/2024