

中华人民共和国  
PEOPLE'S REPUBLIC OF CHINA  
医疗器械产品出口销售证明

CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鲁药监械出 20250061 号  
Certificate NO.:

产品名称：可吸收性外科缝线  
Product(s): Absorbable Polyglycolic Acid Surgical Suture

规格型号：见附件  
Model: See Attachment

产品注册或备案凭证号：国械注准 20233021204  
Registration certificate(s):

生产企业：山东海迪科医用制品有限公司  
Manufacturer: Shandong Haidike Medical Products Co., Ltd.

生产企业住所：山东省菏泽市单县东城办事处天福路南端路西 88 米  
Address of manufacturer: Tianfu Road, Dongcheng District, Shan County,  
274300 Heze City, Shandong Province, China

生产许可或备案凭证号：鲁药监械生产许 20200018 号  
Exportation Registration certificate(s):

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be  
manufactured and sold in China.

证明有效日期至：2027 年 1 月 16 日  
This certification valid until:

备注：无  
Remark:



证书编号：鲁药监械出 20250061 号

Certificate NO:

附件

Attachment

规格型号：

缝线品名		可吸收性外科缝线
缝合线	规格（线号）	6-0#、5-0#、4-0#、3-0#、2-0#、0#、1#、2#
	线长（cm）	10~550cm
缝合针	针的弧形	1/2 弧、3/8 弧、5/8 弧、直形
	针形	圆针、正三角、反三角、铲形
	针径	0.2~1.2mm
	弦长（mm）	4~31mm

Model:

Suture product name		Absorbable Polyglycolic Acid Surgical Suture
Surgical Suture	Specification	6-0#、5-0#、4-0#、3-0#、2-0#、0#、1#、2#
	Suture length (cm)	10~550cm
Surgical Needle	Needle arc type	1/2arc, 3/8arc, 5/8arc, Straight shape
	Needle type	Round needle, Cutting needle, Reverse cutting needle, Spatula needle
	Needle diameter	0.2~1.2mm
	Chord length (mm)	4~31mm

中华人民共和国

PEOPLE' S REPUBLIC OF CHINA

医疗器械产品出口销售证明

CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鲁药监械出 20250063 号

Certificate NO.:

产品名称：非吸收性外科缝线

Product(s):Non-absorbable Surgical Suture

规格型号：见附件

Model:See Attachment

产品注册或备案凭证号：鲁械注准 20182020362

Registration certificate(s):

生产企业：山东海迪科医用制品有限公司

Manufacturer: Shandong Haidike Medical Products Co.,Ltd.

生产企业住所：山东省菏泽市单县东城办事处天福路南端路西 88 米

Address of manufacturer:Tianfu Road,Dongcheng District,Shan County,  
274300 Heze City, Shandong Province, China

生产许可或备案凭证号：鲁药监械生产许 20200018 号

Exportation Registration certificate(s):

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be  
manufactured and sold in China.

证明有效日期至：2027 年 1 月 19 日

This certification valid until:

备注：无

Remark:



证书编号：鲁药监械出 20250063 号

Certificate NO:

附件

Attachment

规格型号：



非吸收性外科缝线带针型号规格

缝线品名	尼龙线	真丝编织线	聚丙烯线	聚酯编织线
缝线材质	聚酰胺 6	蚕丝	聚丙烯	聚酯
线长	45cm~5.5m	45cm~5.5m	45cm~5.5m	45cm~5.5m
线规格	11-0、10-0、9-0、8-0、7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#	8-0、7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#、4#	7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#	6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#、4#、5#
针的弧形	1/2 弧、3/8 弧	1/2 弧、3/8 弧	直形、1/2 弧、3/8 弧、5/8 弧	直形、1/2 弧、3/8 弧、5/8 弧
针形	圆针、角针、铲形针	圆针、角针、铲形针	圆针、角针、铲形针	圆针、角针、铲形针
针径×弦长 (0.1mm×mm)	(0.7~13)×(4~30)	(0.7~13)×(4~30)	(0.8~13)×(4~25)	(0.8~13)×(4~25)

线束型号规格

缝线品名	尼龙线	真丝编织线	聚丙烯线	聚酯编织线
缝线材质	聚酰胺 6	蚕丝	聚丙烯	聚酯
线长	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm
线规格	11-0、10-0、9-0、8-0、7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#	8-0、7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#、4#	7-0、6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#	6-0、5-0、4-0、3-0、2-0/T、2-0、0#、1#、2#、3#、4#、5#

线团型号规格

缝线品名	尼龙线	真丝编织线	聚丙烯线	聚酯编织线
缝线材质	聚酰胺 6	蚕丝	聚丙烯	聚酯
线长	45cm、50cm、60cm、 75cm、90cm、1m、 1.5m、2m、2.5m、 3m、3.5m、4m、4.5m、 5m、5.5m	45cm、50cm、60cm、 75cm、90cm、1m、 1.5m、2m、2.5m、 3m、3.5m、4m、4.5m、 5m、5.5m	45cm、50cm、60cm、 75cm、90cm、1m、 1.5m、2m、2.5m、 3m、3.5m、4m、4.5m、 5m、5.5m	45cm、50cm、60cm、 75cm、90cm、1m、 1.5m、2m、2.5m、 3m、3.5m、4m、4.5m、 5m、5.5m
线规格	11-0、10-0、9-0、8-0、 7-0、6-0、5-0、4-0、 3-0、2-0/T、2-0、0#、 1#、2#、3#	8-0、7-0、6-0、5-0、 4-0、3-0、2-0/T、2-0、 0#、1#、2#、3#、4#	7-0、6-0、5-0、4-0、 3-0、2-0/T、2-0、0#、 1#、2#	6-0、5-0、4-0、3-0、 2-0/T、2-0、0#、1#、 2#、3#、4#、5#

Model:

Non-Absorbable Surgical Suture With Needle Specifications And Models

Suture product name	Nylon suture	Silk braided suture	Polypropylene suture	Polyester braided suture
Suture Material	Polyamide 6	Silk	Polypropylene	Polyester
Suture length	45cm~5.5m	45cm~5.5m	45cm~5.5m	45cm~5.5m
Suture specification	11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#	7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#	6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#, 5#
Needle arc type	1/2arc, 3/8arc	1/2arc, 3/8arc	Straight shape, 1/2arc, 3/8arc, 5/8arc	Straight shape, 1/2arc, 3/8arc, 5/8arc
Needle type	Round needle, Cutting needle, Spatula needle	Round needle, Cutting needle, Spatula needle	Round needle, Cutting needle, Spatula needle	Round needle, Cutting needle, Spatula needle
Needle diameter×chord length(0.1mm×mm)	(0.7~13)×(4~30)	(0.7~13)×(4~30)	(0.8~13)×(4~25)	(0.8~13)×(4~25)

**Suture Beam Specifications And Models**

Suture product name	Nylon suture	Silk braided suture	Polypropylene suture	Polyester braided suture
<b>Suture Material</b>	Polyamide 6	Silk	Polypropylene	Polyester
<b>Suture length</b>	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm	45cm、50cm、60cm、75cm、90cm、100cm、150cm、200cm、300cm、350cm、400cm、450cm、500cm、550cm
<b>Suture specification</b>	11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#	7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#	6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#, 5#

**Suture Ball Specifications And Models**

Suture product name	Nylon suture	Silk braided suture	Polypropylene suture	Polyester braided suture
<b>Suture Material</b>	Polyamide 6	Silk	Polypropylene	Polyester
<b>Suture length</b>	45cm、50cm、60cm、75cm、90cm、1m、1.5m、2m、2.5m、3m、3.5m、4m、4.5m、5m、5.5m	45cm、50cm、60cm、75cm、90cm、1m、1.5m、2m、2.5m、3m、3.5m、4m、4.5m、5m、5.5m	45cm、50cm、60cm、75cm、90cm、1m、1.5m、2m、2.5m、3m、3.5m、4m、4.5m、5m、5.5m	45cm、50cm、60cm、75cm、90cm、1m、1.5m、2m、2.5m、3m、3.5m、4m、4.5m、5m、5.5m
<b>Suture specification</b>	11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#	7-0, 6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#	6-0, 5-0, 4-0, 3-0, 2-0/T, 2-0, 0#, 1#, 2#, 3#, 4#, 5#



中华人民共和国  
PEOPLE' S REPUBLIC OF CHINA  
医疗器械产品出口销售证明  
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鲁菏药监械出 20230081 号  
Certificate NO.:

产品名称：可吸收性外科缝线  
Product(s): Absorbable surgical suture

规格型号：见附件  
Model: see Attachment

产品注册或备案凭证号：国械注准 20233020195  
Registration certificate(s):

生产企业：山东海迪科医用制品有限公司  
Manufacturer: Shandong Haidike Medical Products Co., Ltd

生产企业住所：山东省菏泽市单县东城办事处天福路南端路西 88 米  
Address of manufacturer: Tianfu Road, Dongcheng District, Shan County,  
274300 Heze City, Shandong Province, China

生产许可或备案凭证号：鲁食药监械生产许 20200018 号  
Exportation Registration certificate(s):

兹证明上述产品已准许在中国生产和销售。  
This is to certify that the above products have been registered to be  
manufactured and sold in China.

证明有效日期至：2025-02-14  
This certification valid until:

备注：该产品分为带针和不带针两种，带针缝线由医用缝合针和可吸收性外科  
缝线（PGLA）连接组成，缝线主要成分为 90% 乙交酯和 10% 丙交酯多股紧密编织  
Remark: The product is divided into two types: with and without needles,  
the suture with needle is composed of medical needle and absorbable  
surgical suture (Polyglatin), surgical suture is composed of a copolymer  
made from 90% glycolide and 10% L-lactide.



证书编号：鲁药监械出 20230081 号

附件

Certificate NO: 鲁药监械出 20230081 号

Attachment

序号	产品名称 Product name	规格型号 Model	产品注册或备案凭证号 Registration certificate(s)
中文	可吸收性外科缝线	缝线品名：可吸收性外科缝线 线长：2cm~550cm 线规格：7-0#、6-0#、5-0#、4-0#、3-0#、2-0#、0#、1#、2# 针的弧形：1/2弧、3/8弧、5/8弧、直形 针形：圆针、正三角、反三角、铲形 针径×弦长(mm×mm)：(0.2~1.2)×(4~31)	国械注准 20233020195
英文	Absorbable surgical suture	Suture product name: Absorbable surgical suture Thread length: 2cm~550cm Thread specification: 7-0#, 6-0#, 5-0#, 4-0#, 3-0#, 2-0#, 0#, 1#, 2# Needle arc type: 1/2arc, 3/8 arc, 5/8 arc, Straight Needle type: Round needle, Cutting needle, Reverse cutting needle, Spatula needle Needle diameter × chord length (mm × mm): (0.2 ~ 1.2) × (4 ~ 31)	国械注准 20233020195

以下空白

# 管理体系认证证书

证书号码:  
C564964

首次签发日期:  
2023年4月20日

有效期限:  
2026年4月20日 - 2029年4月19日

兹证明

## 山东海迪科医用制品有限公司

山东省菏泽市单县东城办事处天福路南端路西88米  
(统一社会信用代码: 91371722059049941D)

质量管理体系符合:  
ISO 13485:2016

此证书对下列范围有效:

一次性使用无菌可吸收性外科缝线(带针或不带针)、一次性使用  
无菌非吸收性外科缝线(带针或不带针)的设计,制造和销售

证书制作地点及日期:  
Høvik, 2026年3月02日



证书认可签发机构:  
DNV Product Assurance AS  
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp  
管理代表

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C564964

Initial certification date:  
20 April 2023

Valid:  
20 April 2026 – 19 April 2029

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, Disposable Sterile Non Absorbable  
Surgical Sutures with or without Needle.**

Place and date:  
Høvik, 02 March 2026



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

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative

## 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*<sup>1</sup>
- 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)	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive	

<sup>1</sup> 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.

Certificate prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input checked="" type="checkbox"/> 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*<sup>2</sup>
- 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

<sup>2</sup> 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

Add: Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China  
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.



SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD.

山东海迪科医用制品有限公司

Add: Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China

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**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



*Guangqi Cheng*

**Schedule of Devices**

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

Identification of the device(s) <sup>3</sup> (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-Class III	M.2019.106.11727	<b><u>09.04.2024</u></b>	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	<b><u>09.04.2024</u></b>	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2027	
Sterile Single Use Non-Absorbable Nylon Suture with or without needle-Class II b	M.2019.106.11727	<b><u>09.04.2024</u></b>	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Silk Suture with or without needle -Class II b	M.2019.106.11727	<b><u>09.04.2024</u></b>	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Polyester Suture with or without needle-Class II b	M.2019.106.11727	<b><u>09.04.2024</u></b>	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	
Sterile Single Use Non-Absorbable Polypropylene Suture with or without needle-Class II b	M.2019.106.11727	<b><u>09.04.2024</u></b>	UDEM 2292	Eurofins Product Testing Italy Srl NB 0477	December 31, 2028	

<sup>3</sup> 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)



SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD.

山东海迪科医用制品有限公司

Add: Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China

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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:*

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

<p>I dispositivi coperti dalla domanda formale e dall'accordo scritto di cui sopra sono elencati nella Tabella 1 di seguito.</p>	<p><i>The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.</i></p>
<p>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.</p>	<p><i>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></p>
<p>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):</p> <ul style="list-style-type: none"> <li>• 26 Maggio 2026 per i dispositivi impiantabili su misura di Classe III.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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).</li> </ul>	<p><i>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):</i></p> <ul style="list-style-type: none"> <li>• <i>26 May 2026 for Class III custom-made implantable devices.</i></li> <li>• <i>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.</i></li> <li>• <i>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.</i></li> <li>• <i>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).</i></li> </ul>

**Tabella 1: Dispositivi inclusi nella presente comunicazione**  
*Table 1: Devices covered by this letter*

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

suture with or without needle	Denetim Egitim Merkezi San. ve Tic. A.S.
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<p>Con riferimento al Vostro ordine per il progetto di certificazione secondo il Regolamento UE 2017/745 di cui ai riferimenti sopra citati:</p> <ul style="list-style-type: none"> <li>• si conferma la nostra accettazione dello stesso;</li> </ul>	<p><i>With reference to your order for the certification project in accordance with the information listed above:</i></p> <ul style="list-style-type: none"> <li>• <i>we confirm our acceptance of the contract;</i></li> </ul>
<ul style="list-style-type: none"> <li>• 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";</li> </ul>	<ul style="list-style-type: none"> <li>• <i>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;</i></li> </ul>
<ul style="list-style-type: none"> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• <i>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.</i></li> </ul>
<p>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.</p>	<p><i>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.</i></p>

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 number EC Design-Examination Certificate for devices of category III

**Eurofins Product Testing Italy Srl**  
 Firma / Signature   
 Paolo Trisoglio  
 Data / Date 12/07/2024

<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-003-13
	Effective date:	2024.09.26

## Declaration of Conformity

**Manufacturer:**

Shandong Haidike Medical Products Co., Ltd.  
 Add: Tianfu Road, Dongcheng District, Shan  
 County, 274300 Heze City, Shandong Province,  
 China  
 TEL: +86 530-4660062

**European Authorized Representative:**

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@cmcmmedicaldevices.com

**Product:** Non-absorbable Sutures

**Medical device:** Silk, Nylon, Polyester, Polypropylene

**Sizes:**

Non-absorbable surgical sutures	Nylon	Silk	Polyester	Polypropylene
Sizes	USP11/0-4	USP8/0-5	USP8/0-4	USP7/0-3

**Specifications:**

Non-Absorbable surgical suture	Nylon	Silk	Polyester	Polypropylene
Raw Material	Polyamide 6	Fibroin	Polyester	Polypropylene
Structure	Monofilament	Braided	Braided	Monofilament
Coated	None	Coated	Coated	None
Needle Radian	1/2 circle, 3/8 circle, 1/4 circle, 5/8circle, 4/9 circle, Straight, J, SKI	1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, 4/9 circle, Straight, J, SKI	1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, 4/9 circle, Straight, J, SKI	1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, 4/9 circle, Straight, J, SKI
Needle Shape	Round body, Cutting, Spatula, Reverse cutting	Round body, Cutting, Spatula, Reverse cutting	Round body, Cutting, Spatula, Reverse cutting	Round body, Cutting, Spatula, Reverse cutting
Needle diameter × chord length (0.1mm×mm)	1.5-15mm × 4.5-55mm	1.5-15mm × 4.5-55mm	1.5-15mm × 4.5-55mm	1.5-15mm × 4.5-55mm

<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-003-13
	Effective date:	2024.09.26

Manufacturer's Name: Shandong Haidike Medical Products Co., Ltd.

Manufacturer's Address: Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China

EU Representative: CMC Medical Devices & Drugs S.L.

Classification: Class IIb (Annex VIII, Rule 8)

Conformity Routes: (EU) 2017/745 Annex IX (I) and Annex X (II)

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

EN ISO 13485:2016	EN ISO11737-1:2006 (AC:2009)	EN ISO10993-6-2009
93/42/EEC	ISO11737:2009	EN ISO10993-7-2008 (AC:2009)
MEDDEV 2.12/1 rev.8	EN 556-1:2001(AC:2006)	EN ISO10993-9-2009
EN ISO 14971:2012	EN ISO 11135-1:2014	EN ISO10993-10-2013
MEDDEV 2.7.1:2016	EN ISO 11607-1:2009+A1:2014	EN ISO10993-11-2009
ISO15223-1:2012	EN ISO11607-2:2006+A1:2014	YY 0167-2020
EN 1041:2008	EN ISO10993-3-2014	ASTM F1980-07(2011)
ISO15223-2:2012	EN ISO10993-4-2009	YY/T 0043-2016
EN ISO10993-1:2009/AC:2010	EN ISO10993-5-2009	Regulation (EU) 2023/607

The products are covered by CE Certificate Number: M.2019.106.11727

Identification of Notified Body: CE 0477

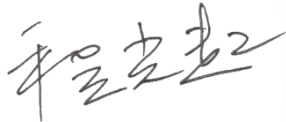
GMDN: 13910, 38000, 13906, 13909

Registration date: 10.04.2019

Expiry date of the Certificate: 31.12.2028

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: September 26<sup>th</sup>, 2024

Shandong Haidike Medical Products Co., Ltd.



<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-002-02-01
	Effective date:	2024.09.26

# Declaration of Conformity

## Manufacturer:

Shandong Haidike Medical Products Co., Ltd.  
Add: Tianfu Road, Dongcheng District, Shan  
County, 274300 Heze City, Shandong Province, China  
TEL: +86 530-4660062

## European Authorized Representative:

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

**SRN:** CN-MF-000026113

**Product:** Absorbable Polyglactin Surgical Suture

## Specifications:

<b>Absorbable surgical suture</b>	PGLA
<b>Sizes</b>	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
<b>Raw material of the suture</b>	90% glycolide and 10% L-lactide
<b>Structure</b>	Multifilament
<b>Coated</b>	Poly (glycolide-co-L-lactide) + Calcium Stearate
<b>Needle radian</b>	1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, 4/9 circle, Straight, J, SKI
<b>Needle Shape</b>	Round body, Cutting, Spatula, Reverse cutting
<b>Needle Lengths</b>	3mm-150mm

**Basic UDI-DI:** 697164280PGLAH010101029F9

**GMDN:** 17471

**Medical Device REGULATION:** (EU) 2017/745.

**Intended Purpose:** Used for general soft tissue approximation and/or ligation, including use in ophthalmic procedures. But not for use in cardiovascular and neurological tissues.

**Classification (MDR, Annex VIII):** Class III (Annex VIII, Rule 8)

**Conformity Routes:** (EU) 2017/745 Annex IX ( I ) and Annex XI ( II ).

## References to any CS used and in relation to which conformity is declared:

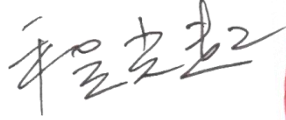
EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417-2021, EN ISO 11135-2014, EN ISO 10993-1:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, ISO 11737-2:2019, EN ISO 14155:2020, EN ISO 14644-1:2015, EP 10.0, YY 1116-2020, YY/T 0043-2016.

**The name and identification number of the notified body:** Eurofins Product Testing Italy Srl, CE 0477.

**Certificate No.:**

<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-002-02-01
	Effective date:	2024.09.26

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

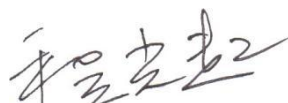


Name, Surname:

Position/Title: Managing Director

Issued Date: September 26<sup>th</sup>, 2024

**Shandong Haidike Medical Products Co., Ltd.**



<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-001-02-01
	Effective date:	2024.09.26

## Declaration of Conformity

### Manufacturer:

Shandong Haidike Medical Products Co., Ltd.  
Add: Tianfu Road, Dongcheng District, Shan  
County, 274300 Heze City, Shandong Province, China  
TEL: +86 530-4660062

### European Authorized Representative:

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@cmcmmedicaldevices.com

**SRN:** CN-MF-000026113

**Product:** Absorbable Polyglycolic acid Surgical Suture

### Specifications:

<b>Absorbable surgical suture</b>	PGA
<b>Sizes</b>	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5, 6
<b>Raw material of the suture</b>	Polyglycolic acid
<b>Structure</b>	Multifilament
<b>Coated</b>	Polycaprolactone + Calcium Stearate
<b>Needle radian</b>	1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, 4/9 circle, Straight, J, SKI
<b>Needle Shape</b>	Round body, Cutting, Spatula, Reverse cutting
<b>Needle Lengths</b>	3mm-150mm

**Basic UDI-DI:** 697164280PGAH0101010201LD

**GMDN:** 17471

**Medical Device REGULATION:** (EU) 2017/745.

**Intended Purpose:** Used for general soft tissue approximation and/or ligation, including use in ophthalmic procedures. But not for use in cardiovascular and neurological tissues.

**Classification (MDR, Annex VIII):** Class III (Annex VIII, Rule 8)

**Conformity Routes:** (EU) 2017/745 Annex IX ( I ) and Annex XI ( II ).

**References to any CS used and in relation to which conformity is declared:**

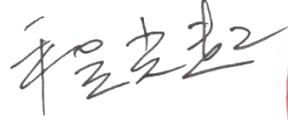
EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417-2021, EN ISO 11135-2014, EN ISO 10993-1:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, ISO 11737-2:2019, EN ISO 14155:2020, EN ISO 14644-1:2015, EP 10.0, YY 1116-2020, YY/T 0043-2016.

**The name and identification number of the notified body:** Eurofins Product Testing Italy Srl, CE 0477.

**Certificate No.:**

<b>Shandong Haidike Medical Products Co., Ltd.</b>	Version No.:	A/0
<b>Declaration of Conformity</b>	File No.:	HDK-CE-001-02-01
	Effective date:	2024.09.26

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

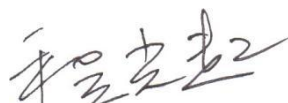


Name, Surname:

Position/Title: Managing Director

Issued Date: September 26<sup>th</sup>, 2024

**Shandong Haidike Medical Products Co., Ltd.**





统一社会信用代码  
91371722059049941D

# 营业执照

0066873



扫描市场主体身  
份码了解更多登  
记、备案、许  
可、监管信息，  
体验更多应用服  
务。

名称 山东海迪科医用制品有限公司  
类型 有限责任公司(自然人投资或控股)  
法定代表人 程光起

注册资本 叁佰贰拾万元整  
成立日期 2012年12月27日  
住所 山东省菏泽市单县东城办事处天福路南端路西  
88米

经营范围 一般项目：第一类医疗器械生产；第一类医疗器械销售；第二类医疗器械销售；宠物食品及用品批发；宠物食品及用品零售；日用化学产品制造；日用品销售；日用化学产品销售；卫生用品和一次性使用医疗用品销售；消毒剂销售（不含危险化学品）；工程和技术研究和试验发展；技术服务、技术开发、技术咨询、技术交流、技术转让、技术推广；新材料技术推广服务；化妆品批发（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）许可项目：第二类医疗器械生产；第三类医疗器械生产；第三类医疗器械经营；饲料生产；化妆品生产；货物进出口；技术进出口；进出口代理；卫生用品和一次性使用医疗用品生产；用于传染病防治的消毒产品生产；消毒剂生产（不含危险化学品）；特殊医学用途配方食品生产；食品经营；保健食品销售；特殊医学用途配方食品销售；互联网信息服务；药品互联网信息服务；医疗器械互联网信息服务（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以审批结果为准）

登记机关



2025 11 年 06 月 日

<https://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家企业信用信息公示系统网址：

国家市场监督管理总局监制

# Enterprise Business License

Unified social credit code: 91371722059049941D



**Company name:** Shandong Haidike Medical Products Co., Ltd.

**Company type:** Limited Liability Company (The natural personal investment or holdings)

**Legal representative:** Cheng Guangqi

**Registered capital:** RMB 3,200,000

**Registered date:** Dec. 27th, 2012

**Address:** Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China

**Business Scope:** General Items: Production of Class I medical devices; Sales of Class I medical devices; Sales of Class II medical devices; Wholesale of pet food and supplies; Retail of pet food and supplies; Manufacturing of daily chemical products; Sales of daily necessities; Sales of daily chemical products; Sales of hygiene products and disposable medical supplies; Sales of disinfectants (excluding hazardous chemicals); Engineering and technical research and experimental development; Technical services, technical development, technical consultation, technical exchange, technology transfer, and technology promotion; New material technology promotion services; Wholesale of cosmetics (except for items that require approval by law, business activities can be carried out independently in accordance with the law based on the business license). Licensed Items: Production of Class II medical devices; Production of Class III medical devices; Sales of Class III medical devices; Feed production; Cosmetic production; Import and export; Import and export agency; Production of hygiene products and disposable medical supplies; Production of disinfectant products for infectious disease prevention and control, disinfectant production (excluding hazardous chemicals); Import and export of goods; Technology operation; Sales of health food; Sales of special medical purpose formula food; Internet information services; Pharmaceutical Internet information services; Medical device Internet information services (items that require approval by law can only be carried out after approval by relevant departments); Production of special medical purpose formula food: Food can be operated, and the specific business items are subject to the approval results.

A handwritten signature in black ink, appearing to read "Cheng Guangqi".

**Registration Authority:** Shan County Administrative examination and Approval Service Bureau

Issued date: Nov. 6th, 2025