Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-79 din 28.08.2023

Solicitantul ___TRIUMF MOTIV SRL__, cu sediul _or. Chișinău str. Grenoble 193_
(adresa)
_____, tel./fax: _022768462____, e-mail_triumf.motiv@mail.ru,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1 Capron / steril împletit USP 1 -METRIC 4 NL01L
2 Capron / steril împletit USP 2/0-METRIC 3 NL20L
3 Capron / steril împletit USP 2-METRIC 5 NL02L
4 Capron / steril împletit USP 3/0-METRIC 2 NL30L
24 Capron din bobine N 3 NL03M16
25 Capron din bobine N 4 NL05I16
26 Capron din bobine N 5 NL05G16
27 Poliglicolic acid (PGA) PGA00F0164
28 Poliglicolic acid (PGA) PGA01F0164
29 Polipropilen (monofilament) PP30F0122
30 Polipropilen USP 3/0 L -90 cm 2 ace ½rotund 26mm PP30G-226

Se anexează următoarele acte:
__DECLAȚIE DE CONFORMITATE CE_____
__CERTIFICATUL DE CONFORMITATE CE_____
__Scrisoare de autorizare de la producător___

Digitally signed by Jighili Tatiana
Date: 2023.08.28 07:59:22 EEST
Reason: MoldSign Signature
Location: Moldova

Data _28.08.2023__ Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: _____TRIUMF MOTIV SRL_____, cu sediul _____or. Chișinău str. Grenoble 193_____,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1 Capron / steril împletit USP 1 -METRIC - NL01L
2 Capron / steril împletit USP 2/0-METRIC 3 - NL20L
3 Capron / steril împletit USP 2-METRIC 5 - NL02L
4 Capron / steril împletit USP 3/0-METRIC 2 - NL30L
24 Capron din bobine N 3 - NL03M16
25 Capron din bobine N 4 - NL05I16
26 Capron din bobine N 5 - NL05G16
27 Poliglicolic acid (PGA) - PGA00F0164
28 Poliglicolic acid (PGA) - PGA01F0164
29 Polipropilen (monofilament) - PP30F0122
30 Polipropilen USP 3/0 L -90 cm 2 ace ½rotund 26mm - PP30G-226

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Data _28.08.2023___

LETTER OF AUTHORIZATION

Date: April.16th, 2023

To Whom It May Concern:

Hereby, we

Shandong Haidike Medical Products Co., Ltd.
Address: Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, 274300 Heze City, Shandong Province, China, Tel.: +86 17615565226.

Certify that:

Triumf Motiv SRL
Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Tel: (+373 22) 76 84 62, 76 88 41

He is our distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand RTMED in your country.

This letter of authorization remains valid for five years, starting from April 16.2023 and expiring on April 15, 2028.

Name: Cheng Guangqi

Title: CEO & Legal Representative

Signature:

Shandong Haidike Medical Products Co., Ltd.

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

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

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

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: POLYGLYCOLIC ACID

Specifications:

Absorbable surgical suture	PGA
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	Polyglycolic acid
Structure	Multifilament
Coated	Polycaprolactone + 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): PGA 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-001-13
	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 ISO10993-1:2018
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 ISO11737-1:2018
ISO11737-2:2019
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: 13908
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.

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

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, Malaga, Spain
Tel: +34 951 214 054
Contact: Manuel Mateos
Email: info@cmcmedicaldevices.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 4/9 circle	1/2 circle, 3/8 circle 4/9 circle	1/2 circle, 3/8 circle 4/9 circle	1/2 circle, 3/8 circle 4/9 circle
Needle Shape	Round body, Cutting, Spatula	Round body, Cutting, Spatula	Round body, Cutting, Spatula	Round body, Cutting, Spatula
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

Shandong Haidike Medical Products Co.,Ltd.	Version number	A/3
Declaration of Conformity	File No.	HDK-CE-003-13
	Effective date	2018.12.28

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): Non-absorbable surgical sutures are short-term implanted medical devices and belong to Class IIb, according to section 8 of the MDD93/42/EEC IX classification guidelines.
Rule 8: Implanted into skin tissue, contact time greater than 60 minutes, less than 30 days
Conformity Routes: Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 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 ISO11737-1:2006 (AC:2009)
ISO11737:2009
EN 556-1:2001(AC:2006)
EN ISO 11135-1:2014
EN ISO 11607-1:2009+A1:2014
EN ISO11607-2:2006+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 0167-2005
ASTM F1980-07(2011)
YY/T 0043-2016

The products are covered by CE Certificate Number: M.2019.106.11727
Identification of Notified Body: UDEM 2292
GMDN: 13910, 13905, 13906, 13909
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.