



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



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

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

RTMED[®] Shandong Haidike Medical Products Co.,Ltd.	Version number	A/5
	File No.	HDK-CE-001-13
	Effective date	2018.12.28

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

Brand name: RTMED

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, straight
Needle Shape	Round body, cutting, reverse 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

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Article 8 of the MDD93/42/EEC IX Classification Guidelines.

Rule 8: Implanted tissue for more than 30 days

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	EN ISO10993-6-2009
93/42/EEC	EN ISO10993-7-2008 (AC:2009)
MEDDEV 2.12/1 rev.8	EN ISO10993-9-2009
EN ISO 14971:2012	EN ISO10993-10-2013
MEDDEV 2.7.1:2016	EN ISO10993-11-2009
ISO15223-1:2012	YY 1116-2010
EN 1041:2008	ASTM F1980-07 (2011)
ISO15223-2:2012	YY/T 0043-2016
EN ISO10993-1:2018	EP 9.0
EN ISO 11607-1:2009+A1:2014	EN ISO11737-1:2018
EN ISO 11607-2:2006+A1:2014	ISO11737-2:2019
EN ISO10993-3-2014	EN 556-1:2001 (AC:2006)
EN ISO10993-4-2009	EN ISO 11135-1:2014
EN ISO10993-5-2009	

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:

程克超

Position/Title: Managing Director

Issued Date: Dec. 28th, 2018

Shandong Haidike Medical Products Co.,Ltd.





C E R T I F I C A T E

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.

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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01 with the number M.2019.106.11727-1 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.	

