



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

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

Brand name: RTMED

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, 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): PGLA 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: 2009/AC:2010	EP 9.0
EN ISO 11607-1:2009+A1:2014	EN ISO11737-1: 2006 (AC:2009)
EN ISO 11607-2:2006+A1:2014	ISO11737:2009
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: 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.



CERTIFICATE



Environmental Management System Certificate

Certificate Number:00222E34558R0S

CQM hereby certifies that

Shandong Haidike Medical Products Co.,Ltd.

Unified Social Credit Identifier: 91371722059049941D

Domicile:West 88m of Tianfu Road South End, Dongcheng Office, Shan County, Heze City,
Shandong, P.R.China

Certification Add.:West 88m of Tianfu Road South End, Dongcheng Office, Shan County, Heze City,
Shandong, P.R.China

the management system conform to

GB/T 24001-2016/ISO 14001:2015

This certificate is valid to the following scope:

Design, development, production and sales of non-absorbable surgical sutures (with or without needle), medical suture needle (without suture), disposable medical face mask, disposable surgical face mask, medical protective mask, medical disposable protective clothing, sales of absorbable surgical sutures (with or without needle)

(The information of this certificate can be inquired on www.cnca.gov.cn or website of CQM. The continual validity of the certificate can be checked by Certificate Confirmation of surveillance.)

Issued on: 2022-12-15

Expires on: 2025-12-14



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C002-M



方圆标志认证集团

CHINA QUALITY MARK CERTIFICATION GROUP

地址:北京市海淀区增光路33号(100048) Address:No.33,Zengguang Road,Haidian District,Beijing,P.R. China(100048)