

<b>RTMED<sup>®</sup> Shandong Haidike Medical Products Co.,Ltd.</b>	Version number	A/3
	File No.	HDK-CE-003-13
	Effective date	2018.12.28

## Declaration of Conformity

# 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@cmcmmedicaldevices.com

**Product:** Non-absorbable Sutures

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

**Brand name:** RTMED

**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, Straight	1/2 circle, 3/8 circle 4/9 circle, Straight	1/2 circle, 3/8 circle 4/9 circle, Straight	1/2 circle, 3/8 circle 4/9 circle, Straight
Needle Shape	Round body, reverse cutting, cutting, spatula	Round body, reverse cutting, cutting, spatula	Round body, reverse cutting, cutting, spatula	Round body, reverse cutting, 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

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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	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 0167-2005
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	

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. 28<sup>th</sup>, 2018

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

