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

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: Tianfu Road, Dongcheng District, Shan County, 274300 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

Digitally signed by Morozov Maria
Date: 2024.07.01 17:21:20 EEST
Reason: MoldSign Signature
Location: Moldova

Shandong Haidike Medical Products Co., Ltd.	Version No.:	A/6
Declaration of Conformity	File No.:	HDK-CE-001-13
	Effective date:	2024.04.02

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 1116-2020
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: 31.12.2027

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: April 2nd, 2024
Shandong Haidike Medical Products Co., Ltd.