



**DECLARATION of CONFORMITY**  
**NON-ABSORBABLE POLYPROPYLENE**  
**MONOFILAMENT SUTURE WITH /**  
**WITHOUT NEEDLES**  
Ref. MDD 93/42/EEC

Document No : TF-04.06  
Issue Date : 07.11.2017  
Revision No : 05  
Revision Date : 29.04.2020

## Declaration of Conformity

In accordance with Medical Devices Directive 93/42/EEC

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC as amended by Directive 2007/47/EC.

If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

**Manufacturer :** HUAIAN PINGAN MEDICAL INSTRUMENT CO., LTD

**Address** No. 128 West Meigao Road, Huaian, Jiangsu, China.

**European Representative :** CMC Medical Devices & Drugs S.L.

**Address** C/ Horacio Lengo No 18, CP 29006, Malaga, Spain

**Product :** Non-absorbable Sutures with/without Needles

**Brand name :** PI

**Model name :** Polypropylene monofilament suture

**Classification :** Class IIb by Rule 8 of Annex IX, Council Directive 93/42/EEC

**GMDN Code :** Polypropylene monofilament suture (13909)

*The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards: (Appendix 1)*

*This Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II (- section 4) under the supervision of Notified body, UDEM (NB No. 2292).*

*Notified body:*

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. LTD. ŞTİ.

**EC Certificate No.: M.2019.106.11952**

**Issue date: 14.05.2019 Valid until: 13.05.2024**

  
President on behalf of  
HUAIAN PINGAN MEDICAL  
INSTRUMENT CO., LTD

**Place:** Huaian Jiangsu, China **Date:** April 29, 2020

(name and signature or equivalent  
making of authorized person)



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**Appendix 1:**

EN ISO 13485:2016	EN ISO 14971:2012	EN ISO 15223-1:2016	EN 1041+A1:2013
EN 10993-1/AC: 2009/AC:2010	EN 10993-3:2014	EN 10993-5:2009	EN 10993-6:2009
EN ISO 10993-7:2015	EN ISO 10993-11:2009	EN ISO 10993-12:2012	EN 14630:2012
EN ISO 11607-1:2006	EN ISO 11607-2:2006	EN ISO 11140-1:2009	EN 556-1: 2001/AC:2006
EN ISO 11737-1:2006/AC:2009	EN ISO 11737-2:2009	EN ISO 11135:2014	EN ISO 10993-10:2013
ISO 11607-1: 2006/Amd 1:2014	MEDDEV 2.7.1	MEDDEV 2.12.1	MEDDEV 2.12.2
MEDDEV 2.4/ 1	USP 35 <861><871><881	ISO 14644-1:2015	ISO 14644-2:2000
ISO 14644-3:2005	ISO 14644-4:2001	ISO 14644-5:2004	YY 0167:2005
YY0166:2002	YY0033:2000	European Pharmacopoeia 9th Edition	YY043:2016

product name	reference	model
Sterile, Non-absorbable Sutures with/without Needles, Brand: PALENE, Polypropylene monofilament (PM)	USP 10/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 9/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 8/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 7/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 6/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 5/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 4/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 3/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 2/0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 0	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;



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	USP 1	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 2	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 3	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;
	USP 4	Suture length: from 13cm to 250cm; Needle length: from 4mm to 90mm;