



DECLARATION of CONFORMITY
NYLON MONOFILAMENT SUTURE
WITH / WITHOUT NEEDLES
Ref. MDD 93/42/EEC

Document No : TF-02.06
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 :	Nylon / Polyamide monofilament suture
Classification :	Class IIb by Rule 8 of Annex IX, Council Directive 93/42/EEC
GMDN Code :	Nylon / Polyamide suture (13905)

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 in 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 11137-1:2015	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: PAAMIDE, Nylon monofilament (NL)	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;
	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;



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