Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC Design-Examination Certificate

No. 12 0019 CN/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws) certifies that the products – medical devices of Class III, types

Synthetic Absorbable Sutures with/without Needles

Model names: **Polyglycolic acid (PGA)**
Polydioxanone (PDO)
Polyglactin (PGLA)
Poliglecaprone (PGCL) (for detailed specification refer to the Annex, pages 1-2)

manufactured by company

SHANXIAN RUNTE MEDICAL INSTRUMENTS CO., LTD

fulfil the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use, as they are stated in the harmonized standards applied in conformity assessment procedures.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to the Annex II, paragraph 4, of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the Final Report No. 803601366/2012 and 343602853/2015, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the design of the above referenced models of the medical devices.*
2. *It does not imply that the Notified Body has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
4. *The Certificate remains valid until the approved design is changed but until the **10th January 2020** at the latest.*
5. *After receiving of the complementary EC Certificate, confirming the manufacturer's quality system approval by the Notified Body No. 1023, and fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Issued in Zlín, on 30th January, 2017
(Replaces the withdrawn EC Certificate No. 12 0019 CN/NB issued on 11th January 2012)

Annex to EC Design-Examination Certificate
No. 12 0019 CN/NB/a

Issued for the company:

SHANXIAN RUNTE MEDICAL INSTRUMENTS CO., LTD
Nanduan Wenhua Road, Shanxian, 274300, Hezecity, Shandong Province, China

List of the medical devices covered by the Certificate:

Synthetic Absorbable Sutures and Needles List

SUTURE TYPE (corresponding code)	**SUTURE** LENGTH in cm (code)	**SUTURE** DIAMETER in mm (USP) (code)
POLYGLYCOLIC ACID (PGA)	45 (1)	0.040-0.049 (8-0) (80)
POLYDIOXANONE (PDO)	70 (2)	0.050-0.069 (7-0) (70)
POLYGLACTIN (PGLA)	75 (3)	0.070-0.099 (6-0) (60)
POLIGLECAPRONE (PGCL)	76 (4)	0.10-0.149 (5-0) (50)
	90 (5)	0.15-0.199 (4-0) (40)
	150 (6)	0.20-0.249 (3-0) (30)
	152 (7)	0.30-0.339 (2-0) (20)
		0.35-0.399 (0(1-0)) (10)
		0.40-0.499 (1) (01)
		0.50-0.599 (2) (02)
		0.60-0.699 (3) (03)

INSTITUTE FOR TESTING AND CERTIFICATION ITC 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
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No. 12 0019 CN/NB/a

Issued for the company:

SHANXIAN RUNTE MEDICAL INSTRUMENTS CO., LTD
Nanduan Wenhua Road, Shanxian, 274300, Hezecity, Shandong Province, China

List of the medical devices covered by the Certificate:

NEEDLE LENGTH (code)	**NEEDLE** SHAPE (code)	**NEEDLE** TYPE (code)
4.5 - 90 mm (codes 4.5 – 90)	Straight (A) 1/2 Circle (B) 1/4 Circle (C) 3/8 Circle (D) 5/8 Circle (E)	round bodied (0) blunt taper point (1) curved cutting (2) reverse cutting (3) tapercut (4) micro-point spatula (5)

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1023
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