



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

EC Design-Examination Certificate

No. 10 0220 CN/NB/a

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class III,

**Synthetic Absorbable Sutures with/without Needles,
Polyglycolic Acid (PGA), Polydioxanone Monofilament (PDO),
Poly(glycolide-co-L-lactide) (PGLA)**

manufactured by company

Shandong Sinorgmed Co.,Ltd.

Middle Jinan Road, Heze Development Zone, Shandong, China

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.

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. 803600784/2010 and 343603060/2015, which are enclosed to this Certificate.

This Certificate is issued under the following conditions:

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 15th March 2017 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



Paul Vaj
RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023

Issued in Zlín, on 16th March 2015