



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

EC CERTIFICATE

No. 10 0221 QS/NB/a

issued in compliance with the 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

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer 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 quality system maintained in the manufacture of the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 15th March 2017 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of 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

Issued in Zlín, on 16th March 2015



Paul Koj

RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023