Circular Informativa

N.º 044/CD/550.20.001

Data: 03/05/2017

Assunto: **Fios de sutura para *face lifting* do fabricante Shandong Sinorgmed Co., Ltd**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373; Fax: 21 111 7552; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

A autoridade competente alemã detetou que estão colocados no mercado europeu **fios de sutura para *face lifting*** (anexo I) do fabricante **Shandong Sinorgmed Co., Ltd** não conformes.

O fabricante apresentou, relativamente a estes dispositivos, os certificados CE de conformidade número 10 0220 CN/NB/a e número 10 0221 QS/NB/a (anexo II) com referência ao organismo notificado ITC (código 1023). No entanto, este organismo notificado não emitiu estes certificados.

Em Portugal não foram identificados registos da comercialização de dispositivos médicos deste fabricante, mas atendendo a que existe livre circulação de produtos no espaço económico europeu, o Infarmed recomenda que os produtos em apreço, associados aos certificados supramencionados, não sejam adquiridos nem utilizados.

A existência destes dispositivos em Portugal deve ser reportada à Direção de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 21 798 72 35; fax: +351 21 798 72 81; *e-mail*: daps@infarmed.pt.

O Conselho Diretivo

Helder Dias Mota Filipe

Assinado de forma digital por Helder Dias Mota Filipe
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Anexo I

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
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Anexo II

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

Issued in Zlín, on 16th March 2015

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque de Saúde de Lisboa - Av. do Brasil, 53
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Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Notified Body No. 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, 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

INSTITUTE FOR TESTING AND CERTIFICATION * NOTIFIED BODY * 1023

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

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