Circular Informativa

N.º 063/CD/550.20.001

Data: 01/06/2017

Assunto: **Termómetros por infravermelhos sem contacto com marcação CE falsa**

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

Os **termómetros por infravermelhos sem contacto** do fabricante **Shenzhen Pacom Medical Instruments Co., Ltd.** foram impedidos de entrar no mercado europeu por se ter verificado que o certificado CE, com referência ao organismo notificado com o número 1023 – Institut for Testing and Certification - era falso (cf. anexo).

Este organismo notificado confirmou não ter emitido qualquer certificado para o fabricante mencionado.

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 este produto não seja adquirido nem utilizado, uma vez que apresenta aposta marcação CE 1023 falsa.

A existência deste dispositivo 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
DN: c=PT, o=Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde IP, ou=Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde IP, cn=Helder Dias Mota Filipe
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INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
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Anexo

ITC

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

EC CERTIFICATE

No. 16 0711 QS/NB

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 IIa

Digital Thermometer

Models: PC120, PC130, PC150, PC180, PC190, PC120T

Infrared Thermometer

Models: PC800, PC801, PC808, PC828, PC868

manufactured by company

Shenzhen Pacom Medical Instruments Co., Ltd.

On the 8th floor of B District, B Building, No.5 Industry Five Road, Jiangbian Community, Songgang, BaoAn District, Shenzhen, 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. 80360124312015, which is 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 above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 18th August 2021 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After 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 Zlin, on 19th August 2016

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

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