Circular Informativa

N.º 034/CD/550.20.001

Data: 22/02/2018

Assunto: **Certificados de conformidade falsos – Fabricante Apex Meditech**

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

Foi detetada, no mercado europeu, a existência de três certificados de conformidade falsos, relativos a dispositivos médicos do fabricante **Apex Meditech** (sediado na Índia).

Os certificados falsos (ver anexo) fazem referência ao organismo notificado Ente Certificazione Macchine (código 1282) e apresentam os números EC.1282.2P150313.AMU023, EC.1282.2P150313.AMU024 e EC.1282.2P150313.AMU025.

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 dispositivos mencionados nos certificados anexos não sejam adquiridos nem utilizados, uma vez que apresentam aposta uma marcação CE 1282 falsa.

A existência desses 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

Maria Sofia Rodrigues Pintado de Oliveira Martins

Assinado de forma digital por Maria Sofia Rodrigues Pintado de Oliveira Martins
DN: c=PT, o=Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde IP, cn=Maria Sofia Rodrigues Pintado de Oliveira Martins
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Anexo

Certificado de conformidade falso EC.1282.2P150313.AMU023

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. EC.1282.2P150313.AMU023

Certificate's Holder: Apex Meditech
"Siddhivinayak", Maheshwari Soc., Sahakar Nagar No.2, Pune - 411 009, India.

Certification Safety Mark: European Community – Type Approved

Product:
Non–Invasive Therapy System
Insufflators
Intra Corporeal Pneumatic Lithotripsy System
Combination Treatment System
Wave Therapy System

Model(s): (see the following annex I)

Verification to:
Standard:
EN ISO 14971:2012, EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN 60601-1-6:2010, EN 980:2008, ISO 15223-1:2012, EN 1041:2008, EN 60601-1-8:2007/AC:2010, IEC 60601-2-10, Ed.2

related to Directive(s):
93/42/EEC as amended by 2007/47/EC (Medical Devices) CLASS IIA, RULE 9 & RULE 11

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Safety Compliance Mark.
This certificate can be checked for validity at www.entecerma.it

Date of issue 13 March 2015
Chief Manager
Tim Mahan

Expiry date 12 March 2020
Deputy Manager
Viola Miller

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Certificate – Сертификат – 證明書 – Certificat – 인증서 – شهادة

Annex I

No. EC.1282.2P150313.AMU023

Model(s):

NON-INVASIVE THERAPY SYSTEM
CellSploder-A, CellSploder-B

INSUFFLATORS
digiCARB-4.3,digiCARB-4.2, digiAIR-4, CellSufflator VX, CellSufflator AX, CellSufflator XT

INTRA CORPOREAL PNEUMATIC LITHOTRIPSY SYSTEM
LITHOSPLIT 4.1 Digital, LITHOSPLIT 4 Classic, DIGI MF 500

COMBINATION TREATMENT SYSTEM (SYNCHROWAVE TREATMENT SYSTEM)
SynchroWave XL, SynchroWave XT, SynchroWave R, SynchroWave T, Time Machine

WAVE THERAPY SYSTEM
CellSonic-A, Sonic-A, CellSonic-B, Sonic-B, CellSonic-C, Sonic-C, CellSonic-D, Sonic-D, C-WAVE+, CellSonic Shape CRT, Shape CRT, CellSonic Shape RT, Shape RT, CellSonic Shape R, Shape R

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Certificado de conformidade falso EC.1282.2P150313.AMU024

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. EC.1282.2P150313.AMU024

Certificate's Holder: Apex Meditech
"Siddhivinayak", Maheshwari Soc., Sahakar Nagar No. 2, Pune - 411 009, India.

Certification Safety Mark: European Conformity – Type Approved

Product: DIGITAL URODYNAMIC & UROFLOWMETRY SYSTEM

Model(s): DYNA ST2, DYNA 10, digiFLOW ST2, digiFLOW S, digiFLOW 4E, digiFLOW 4U, digiFLOW 4W

Verification to: Standard:
EN ISO 14971:2012, EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN 60601-1-6:2010, EN 980:2008, ISO 15223-1:2012, EN 1041:2008

related to Directive(s):
93/42/EEC as amended by 2007/47/EC (Medical Devices) CLASS IIA, RULE 10

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.
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Certificado de conformidade falso EC.1282.2P150313.AMU025

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. EC.1282.2P150313.AMU025

Certificate's Holder: Apex Meditech
"Siddhivinayak", Maheshwari Soc., Sahakar Nagar No.2, Pune - 411 009, India.

Certification Safety Mark: European Community – Type Approved

Product: TURP ELECTRODES
Model(s): (see the following annex I)

Verification to: Standard:
EN ISO 14971:2012; EN 60601-1:2006/AC:2010; EN 60601-1-2:2007/AC:2010; EN 60601-1-6:2010; EN 980:2008; ISO 15223-1:2012; EN 1041:2008

related to Directive(s):
93/42/EEC as amended by 2007/47/EC (Medical Devices) CLASS IIB, RULE 9

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
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Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Annex I

No. EC.1282.2P150313.AMU023

ELECTRODES FOR TRANS URETHRAL RESECTION OF PROSTATE (TURP ELECTRODES)

Type Of Electrode	Stem [1]	Channel Fr.	Pole [2]	Compatibility [3]
Cutting Loop	SS / DS	24 Fr. / 27 Fr.	M / B	S
Cutting Loop	SS	24 Fr. / 27 Fr.	M / B	W / O
Collin's Knife	SS / DS	24 Fr. / 27 Fr.	M / B	S
Collin's Knife	SS	24 Fr. / 27 Fr.	M / B	W / O
Roller Electrode 3mm	SS / DS	24 Fr. / 27 Fr.	M / B	S
Roller Electrode 3mm	SS	24 Fr. / 27 Fr.	M / B	W / O
Roller Electrode 5mm	SS / DS	24 Fr. / 27 Fr.	M / B	S
Roller Electrode 5mm	SS	24 Fr. / 27 Fr.	M / B	W/O
Ball Electrode 3mm	SS / DS	24 Fr. / 27 Fr.	M / B	S
Ball Electrode 3mm	SS	24 Fr. / 27 Fr.	M / B	W/O
Ball Electrode 5mm	SS / DS	24 Fr. / 27 Fr.	M / B	S
Ball Electrode 5mm	SS	24 Fr. / 27 Fr.	M / B	W/O
Cold Knife Straight	SS / DS	24 Fr. / 27 Fr.	M / B	S
Cold Knife Straight	SS	24 Fr. / 27 Fr.	M / B	W/O
Cold Knife Half Moon	SS / DS	24 Fr. / 27 Fr.	M / B	S
Cold Knife Half Moon	SS	24 Fr. / 27 Fr.	M / B	W/O
Necklace	SS / DS	24 Fr. / 27 Fr.	M / B	S
Necklace	SS	24 Fr. / 27 Fr.	M / B	W/O
Spike Roller	SS / DS	24 Fr. / 27 Fr.	M / B	S
Spike Roller	SS	24 Fr. / 27 Fr.	M / B	W/O
Bugbee Electrode, 65mm	–	3 Fr. / 4 Fr. / 5 Fr.	–	–
Bugbee Electrode, 35mm	–	5 Fr.	–	–

[1] SS=Single Stem, DS=Double Stem
[2] M=Monopolar, B=Bipolar
[3] S=Storz, W=Wolf, O=Olympus

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