Circular Informativa

N.º 124/CD/550.20.001

Data: 17/10/2022

Assunto: **Certificado de Conformidade Falso – Fabricante Jiangsu Sinowise Technology Co. Ltd.**

Para: Divulgação geral

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

Na Roménia foi identificada a falsificação do certificado CE de conformidade n.º G1 104715 0002 Rev. 01 relativo ao sistema completo de garantia de qualidade dos dispositivos *Infusion Pump, Syringe Pump* e *Infusion Warmer, Patient Warming Machine* do fabricante **Jiangsu Sinowise Technology Co. Ltd.** (anexo I).

O organismo notificado TÜV SÜD Product Service GmbH (0123) informou não ter emitido este certificado ao referido fabricante, e que o mesmo se trata de uma falsificação do certificado original com o mesmo número, emitido para os dispositivos *Infusion Pump, Syringe Pump* do fabricante **Dongguan HEPHO Medical Science Technology Co. Ltd.** (anexo II).

Em Portugal, não foram identificados registos de dispositivos do fabricante Jiangsu Sinowise Technology Co. Ltd., mas, atendendo a que existe livre circulação de produtos no Espaço Económico Europeu, o Infarmed recomenda que os dispositivos supramencionados não sejam adquiridos nem utilizados.

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

A Vogal do Conselho Diretivo

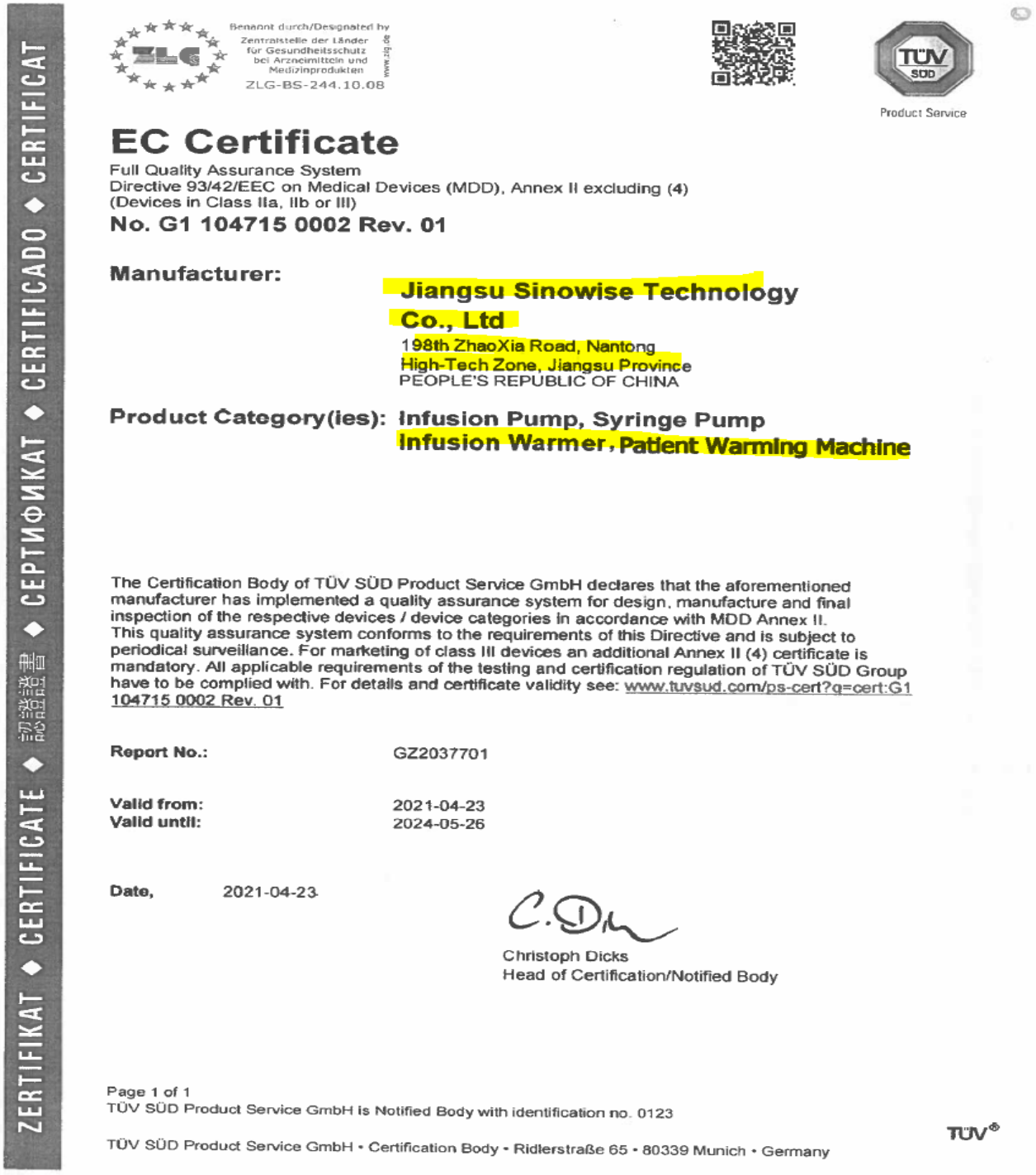
Erica Rodrigues Viegas

Assinado de forma digital por Erica Rodrigues Viegas
Dados: 2022.10.17 18:54:21 +01'00'

M-ATEND-008/8

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque de Saúde de Lisboa - Av. do Brasil, 53
1749-004 Lisboa
Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Anexo I – Certificado falsificado



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104715 0002 Rev. 01

Manufacturer:

Jiangsu Sinowise Technology Co., Ltd
198th ZhaoXia Road, Nantong
High-Tech Zone, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Infusion Pump, Syringe Pump**
Infusion Warmer, Patient Warming Machine

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 104715 0002 Rev. 01

Report No.: GZ2037701

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-04-23

Christoph Dicks
Head of Certification/Notified Body

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1749-004 Lisboa
Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Anexo II – Certificado Original

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104715 0002 Rev. 01

Manufacturer:

Dongguan HEPHO Medical Science Technology Co.,LTD
3F, Building 6
Industrial Center
No.19, Alishanlu, High-tech Development Zone, Songshanhu
523808 Dongguan, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infusion Pump, Syringe Pump

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 104715 0002 Rev. 01

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