Circular Informativa

N.º 152/CD/550.20.001

Data: 28/12/2022

Assunto: **Certificado de Conformidade Falso – Fabricante Foshan Nanhai Hager Medical Machinery 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

Foi identificada a falsificação do certificado CE de conformidade n.º G2 058482 0010 Rev. 00 relativo ao dispositivo *Integral Dental Unit* do fabricante **Foshan Nanhai Hager Medical Machinery 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 o dispositivo *Integral Dental Unit* do fabricante **Foshan Anle Medical Apparatus Co., Ltd.** (anexo II).

Em Portugal, não foram identificados registos de dispositivos do fabricante Foshan Nanhai Hager Medical Machinery Co., Ltd., mas, atendendo a que existe livre circulação de produtos no Espaço Económico Europeu, o Infarmed recomenda que o dispositivo supramencionado não seja adquirido nem utilizado.

A deteção, em Portugal, deste dispositivo 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

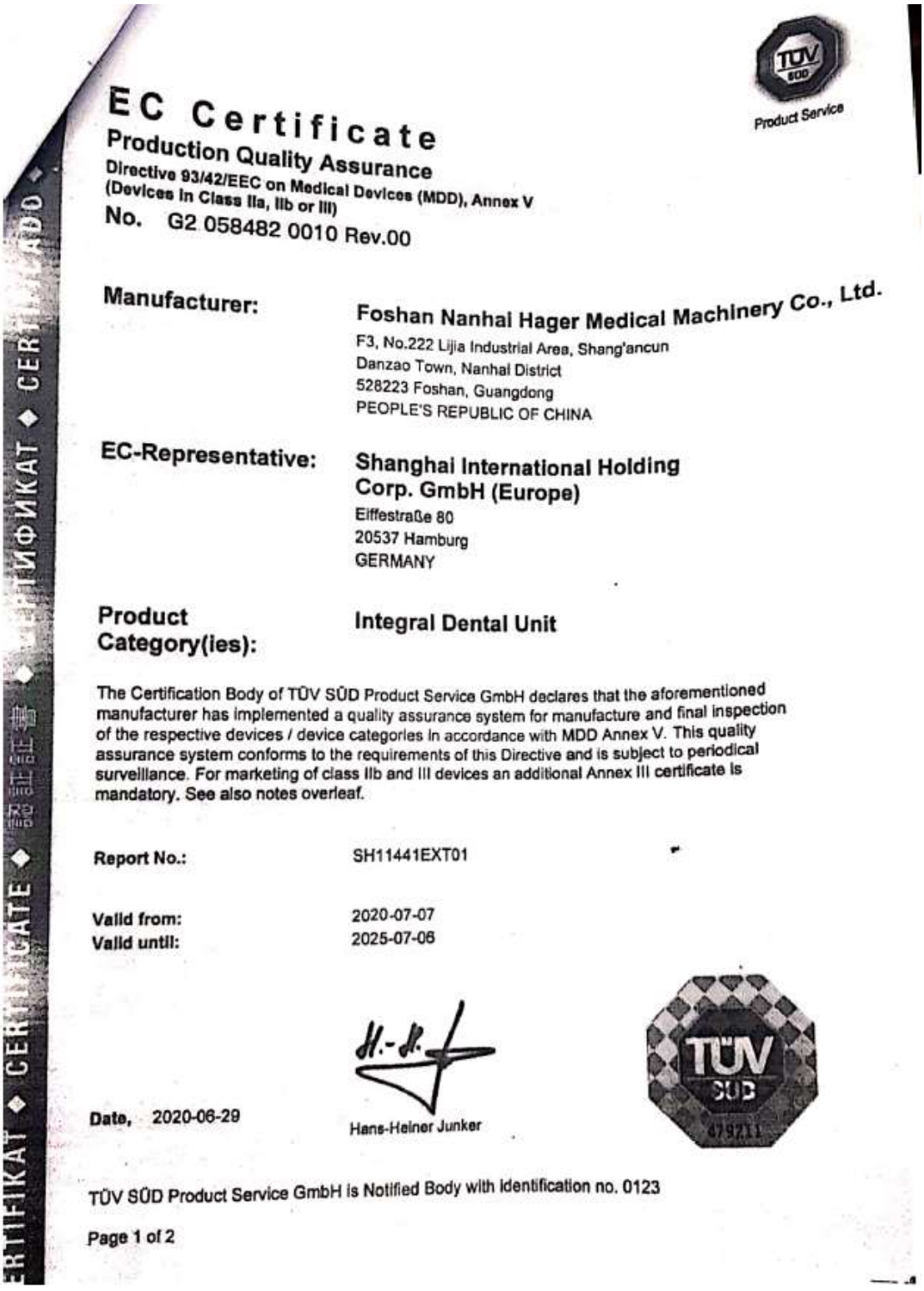
Erica Rodrigues Viegas

Assinado de forma digital por Erica Rodrigues Viegas
Dados: 2022.12.28 19:40:57 Z

(Erica Viegas)

M-ATEND-008/8

Anexo I – Certificado falsificado



EC Certificate

Product Service

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 058482 0010 Rev.00

Manufacturer: **Foshan Nanhai Hager Medical Machinery Co., Ltd.**
F3, No.222 Lijia Industrial Area, Shang'ancun
Danzao Town, Nanhai District
528223 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Integral Dental Unit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH11441EXT01

Valid from: 2020-07-07
Valid until: 2025-07-06

Date, 2020-06-29

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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

RTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CE

TÜV SÜD Product Service

EC Certificate
Production Quality Assurance
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)
No. G2 058482 0010 Rev.00

Facility(ies):

F3, No.222 Lijia Industrial Area, Shang'ancun, Danzao Town
Nanhai District 528223 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

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Anexo II – Certificado Original

ZLG-BS-244.10.08

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 058482 0010 Rev. 00

Manufacturer: **Foshan Anle Medical Apparatus Co., Ltd.**
2 Flat, No 7, C District, Technology
& Industry Garden, Sanshui Centre
528137 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Integral Dental Unit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19441EXT01

Valid from: 2019-07-02
Valid until: 2024-05-26

Date, 2019-07-02

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZLG-BS-244.10.08

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 058482 0010 Rev. 00

Facility(ies): Foshan Anle Medical Apparatus Co., Ltd.
2 Flat, No.7, C District, Technology, & Industry Garden, Sanshui Centre, 528137 Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

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