

Circular Informativa

N.º 013/CD/550.20.001

Data: 08/01/2020

Assunto: **Certificado falso – Fabricante GML - German Medical Laser GmbH**

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

O organismo notificado BSI (0086) identificou um certificado falso (em anexo) relativo à produção, instalação, manutenção e distribuição de **laser para acupunctura e terapia** do fabricante **GML - German Medical Laser GmbH**.

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 associados ao certificado supramencionado não sejam adquiridos nem utilizados, uma vez que apresentam aposta marcação CE 0086 falsa.

A deteção, em Portugal, destes dispositivos e deste certificado 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.

O Conselho Diretivo

Anexo – Certificado falso

bsi.


By Royal Charter

EC Certificate - Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V

No. CE 577738
Issued To: GML - German Medical Laser GmbH
Karlsruher Str. 34
75179 Pforzheim
Germany

In respect of:
**Production, installation, servicing and distribution of Acupuncture and Therapy Laser
Devices Produktion, Montage und Vertrieb von Akupunktur- und Therapielasergeräten**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):


Frank Lee, EMEA Compliance & Risk Director

First Issued: 04 June 2018 **Date: 01 February 2019** **Expiry Date: 14 February 2024**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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