Circular Informativa

N.º 120/CD/550.20.001

Data: 10/10/2022

Assunto: **Certificado CE de conformidade falso – Fabricante Divine Medicure Technology (Índia)**

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 Lituânia foi detetado um **certificado CE de conformidade falso** (em anexo) relativo a vários dispositivos médicos, como tubos de ventilação e produtos utilizados em otorrinolaringologia, pertencentes às classes IIa e IIb do fabricante Divine Medicure Technology (Índia).

O certificado falso apresenta o número 245067-2019-CE-IND-NA-PS Rev. 0.0, data de emissão 15-04-2019, data de expiração 10-12-2023, e faz referência ao Organismo Notificado DNV Product Assurance AS (ON 2460) que informou não ter realizado a avaliação da conformidade dos dispositivos em apreço.

Em Portugal não foram identificados registos ativos da comercialização de dispositivos médicos deste fabricante, mas, atendendo a que existe livre circulação de produtos no espaço económico europeu, o Infarmed, I.P recomenda que os produtos identificados no certificado não sejam adquiridos nem utilizados, uma vez que apresentam aposta marcação CE 2460 falsa.

Qualquer questão sobre o assunto pode ser dirigida à Direção de Produtos de Saúde do Infarmed, I.P. através dos contactos: tel.: +351 21 798 72 35; e-mail: daps@infarmed.pt.

A Vogal do Conselho Diretivo

Erica Rodrigues Viegas

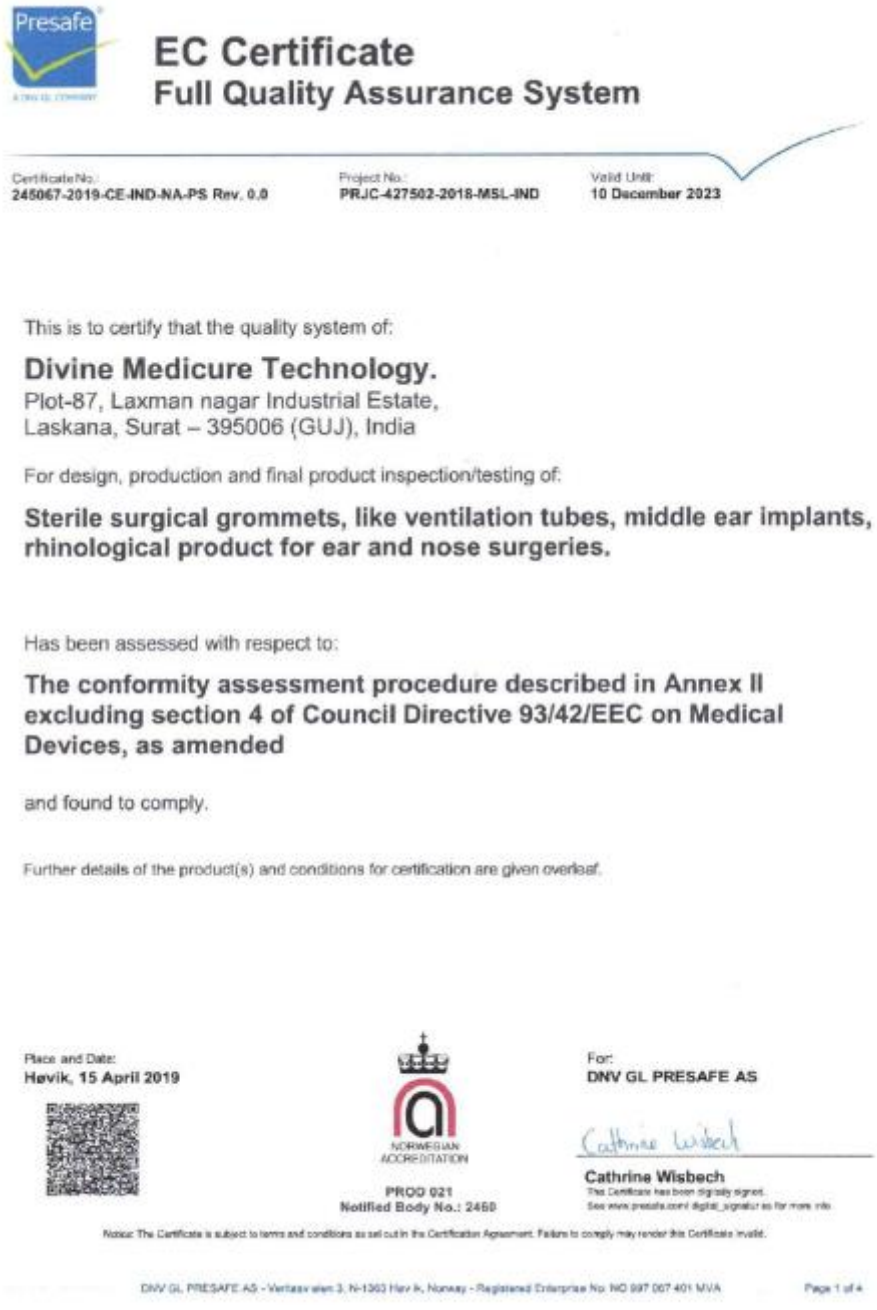
Assinado de forma digital por Erica Rodrigues Viegas
DN: c=PT, title=Vogal do Conselho Diretivo, ou=Conselho Diretivo, o=INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde I.P., sn=Viegas, givenName=Erica Rodrigues, cn=Erica Rodrigues Viegas
Dados: 2022.10.10 18:59:00 +01'00'

(Erica Viegas)

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 CE de conformidade falso



Presafe

EC Certificate
Full Quality Assurance System

Certificate No.: 245067-2019-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-427502-2018-MSL-IND
Valid Until: 10 December 2023

This is to certify that the quality system of:

Divine Medicure Technology.
Plot-87, Laxman nagar Industrial Estate,
Laskana, Surat – 395006 (GUJ), India

For design, production and final product inspection/testing of:

Sterile surgical grommets, like ventilation tubes, middle ear implants, rhinological product for ear and nose surgeries.

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 15 April 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech
This Certificate has been digitally signed.
See www.presafe.com/ digital_signatur as for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

DNV GL PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 007 401 MVA

Page 1 of 4

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

Presafe

EC Certificate
Full Quality Assurance System

Certificate No.: 245067-2019-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-427502-2018-MSL-IND
Valid Until: 10 December 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original certificate	2019-04-15

Products covered by this Certificate:

Product Description	Product Name	Class
EAR VENTILATION TUBES [Tympanostomy tube Rigid & Soft 1.14mm, 1.27 mm, & flexible] [optional accessories includes Stainless steel Wire, 0.1mm or PTFE tail] (Sterile)	Shepard Ventilation tube	IIb
	Donaldson Ventilation tube	IIb
	Armstrong Ventilation tube	IIb
	Modified Armstrong Ventilation tube	IIb
	Shah Ventilation tube	IIb
	Mini shah Ventilation tube	IIb
	Collar button Ventilation tube	IIb
	Reuter bobbin Ventilation tube	IIb
	Bevel bobbin Ventilation tube	IIb
	Baxter bevel bobbin Ventilation tube	IIb
	Straight tube Ventilation tube	IIb
	Paparella type-1 & type-2 Ventilation tube	IIb
	Umbrella Ventilation tube	IIb
	T-tube short & long Ventilation tube	IIb
	Other Ventilation tubes made from Titanium, Silicone & PTFE combinations as per technical file	IIb
EAR IMPLANTS (Sterile)	Partial Ossicles Replacement Prosthesis (PORP VARIAC BELL) Titanium	IIb
	Total Ossicles Replacement Prosthesis (TORP VARIO DRUM), Titanium	IIb
	STAPES PISTON Titanium, PTFE, & Combinations	IIb
	Other Middle Ear Implants products made from Titanium & PTFE combinations as per technical file	IIb

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

Presafe

EC Certificate
Full Quality Assurance System

Certificate No.: 245067-2019-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-427502-2018-MSL-IND
Valid Until: 10 December 2023

RHINOLOGICAL PRODUCTS (Sterile)	K splint Internal nasal Splint	IIa
	Doyle splint / Airway Splint Internal nasal Splint	IIa
	Bi valve splint Internal nasal Splint	IIa
	Dempsey splint Internal nasal Splint	IIa
	Pre-cut splint Internal nasal Splint	IIa
	Nasal septal button Internal nasal Splint	IIa
	Silicone splint Internal nasal Splint	IIa
	Aluminium splint External nasal Splint	IIa
	Thermoplastic splint External nasal Splint	IIa
	Other Items covered under technical file	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Divine Medicure Technology	Plot-87, Laxman nagar Industrial Estate, Laskana, Surat – 395006 (GUJ), India

EU Representative

Medeuropa Certicon Ltd, Säffle 66132,Sweden,
Phone: +46 708 12 81 11
E-Mail: swe@medeuropacerticon.com

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
245067-2019-CE-IND-NA-PS Rev. 0.0	PRJC-427502-2018-MSL-IND	10 December 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

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

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