

Notified Body: 1434
Certificate No: 1434-MDD-278/2021

Nome do fornecedor:
Name of Manufacturer

Angelus Indústria de Produtos Odontológicos S/A
Rua Waldir Landgraf, 101
Londrina, Paraná 86031-218, Brazil

Declara sob sua responsabilidade, que o (s) produto(s):
Declare under our sole responsibility that the product:

INTERLIG
INTERLIG

Referência(s):
Reference:

483; 4839.

A que se refere esta declaração, estão em conformidade com a(s) seguinte(s) norma(s) ou documento(s) normativo(s):
to which this declaration relates is in conformity with the following standard(s) or other normative document(s):

- ✓ ANVISA Resolution - RDC N. 67, OF DECEMBER 21, 2009 - Provisions regarding post-market surveillance applicable to registration holders of health products in Brazil.
- ✓ ANVISA Resolution - RDC N. 551, OF AUGUST 30, 2021 - Rules to mandatory implementation and reporting of field actions by registration holders of health products in Brazil.
- ✓ ANVISA Resolution - RDC N. 665 OF MARCH 30, 2022 - Approves the Technical Regulation for Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices and gives other provisions - Brazil.
- ✓ 21 CFR Parts 820, 803, 806, 807 (Subparts A to D) and 821 (where applicable) - United States.
- ✓ Medical Devices Regulations - Part 1- SOR 98/282 - Canada.
- ✓ MHLW Ministerial Ordinance 169, Article 4 to Article 68 - Japan.
- ✓ Council Directive 93/42/EEC (CE Marking) - Medical Devices - European Economic Community.
- ✓ Regulation (EU) 2017/745 on medical devices (MDR).
- ✓ EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
- ✓ EN ISO 13485:2016 MDSAP Certificated – Brazil, Canada, Japan and United States.
- ✓ EN ISO 14971:2019 Medical devices - Application of risk management to medical devices.
- ✓ EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- ✓ BS EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.
- ✓ IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices.
- ✓ EN ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ✓ MEDDEV 2.7/1 revision 4, June 2016: Clinical Evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC.

e cumpre(m) o disposto nas seguintes Diretivas CE:
and is in accordance with the provisions of the following EC Directives:

MDD 93/42/ EEC, ANEXO [2007/47/EC](#)

Seguindo a rota de conformidade de acordo com o Anexo II (-4),
Following the route of conformity according to Annex II (-4),

Estando classificado como dispositivos classe IIa e regra 8 de acordo com o anexo IX da diretiva 93/42/EEC.
Being classified as Class IIa devices and Rule 8 in accordance with Annex IX of the directive 93/42/EEC.

GMDN Code: 44786 Dental material, reinforcing fibre

Representante Europeu:
European Representative:

EMERGO EUROPE
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
E-Mail: EmergoEurope@ul.com

Organismo Notificado da UE:
EU Notified Body:



Polskie Centrum Badań i Certyfikacji S.A.
ul. Puławska 469
02-844 Warszawa - Poland
+48 (22) 46 45 200
+48 (22) 46 45 251
pcbc@pcbc.gov.pl

Local e data de emissão:
Place and Date of issue:

Londrina, 22 de novembro de 2022.
Londrina, Nov 22, 2022.



Paulo Sergio Calixto de Oliveira
Diretor Financeiro e
Representante Legal /
Financial Director and Legal
Representative
CPF: 608516789-04