DECLARAÇÃO DE CONFORMIDADE UE
EU Declaration of Conformity

CE 1434

Notified Body: 1434
Certificate No: 1434-MDD-277/2021

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:

MTA ANGELUS
MTA ANGELUS

Referência(s):
Reference:

820; 821; 822; 824; 1822; 8249.

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. 23, OF APRIL 04, 2012 - Rules to mandatory implementation and reporting of field actions by registration holders of health products in Brazil.
- ✓ ANVISA Resolution - RDC N. 16 OF MARCH 28, 2013 - 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.
- ✓ BS EN 62366-1:2015+A1:2020 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.
- ✓ ISO 6876:2012 Dentistry - Root canal sealing materials.

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, 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 IIb e regra 5 de acordo com o anexo IX da diretiva 93/42/ EEC.
Being classified as class IIb devices and rule 5 in accordance with Annex IX of the Directive 93/42/EEC.

GMDN Code: 36095 Dental material, root canal sealing

Representante Europeu:
European Representative:

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EU Notified Body:

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

Londrina, 20 de maio de 2021.
Londrina, May 20, 2021.

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