

CERTIFICATE

Number: 2224396

The management system of the organization(s) and locations mentioned on the addendum belonging to:

JJGC Indústria e Comércio de Materiais Dentários SA

Avenida Juscelino Kubitschek de Oliveira, 3291
81270-200 Curitiba - Paraná, PR
Brazil

Manufacturer Facility Identifier F000581

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, development, manufacture and distribution of dental implant systems, including endosseous implants, prosthetic components, surgical drills and other dedicated instruments for surgery and restoration.

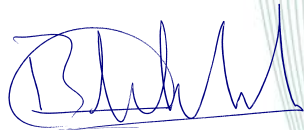
Manufacture and distribution of patient specific orthodontic appliances and associated instruments.

Design, development, manufacture and distribution of additive manufacturing resins for dental applications.

Certificate expiry date: 2024-11-01
Certificate effective date: 2023-03-08
Certified since: 2018-11-01

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



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ADDENDUM

To certificate: 2224396

The management system of the organization(s) and/or location(s) of:

JJGC Indústria e Comércio de Materiais Dentários SA

Avenida Juscelino Kubitschek de Oliveira, 3291
81270-200 Curitiba - Paraná, PR
Brazil

Certified organization(s) and/or locations:

Different scope

JJGC Indústria e Comércio de Materiais
Dentários SA
Rua Benjamin Lins,742, Batel
80420-100 Curitiba, PR
Brazil
Facility Identifier F005296

Distribution of dental implant systems, including endosseous implants, prosthetic components, surgical drills and other dedicated instruments for surgery and restoration.

JJGC Indústria e Comércio de Materiais
Dentários SA
Site 4401
Avenida Juscelino Kubitschek de
Oliveira 3715,
81270-200 Curitiba, PR
Brazil
Facility Identifier F000581

Machining of dental implants, prosthetic components, and surgical instruments. Manufacture and distribution of patient specific orthodontic appliances.
Manufacture of dental implant systems, including endosseous implants, prosthetic components, surgical drills and other dedicated instruments for surgery and restoration.
Manufacture and distribution of patient specific orthodontic appliances and associated instruments.
Manufacture and distribution of additive manufacturing resins for dental applications.

Addendum expiry date: 2024-11-01
Addendum effective date: 2023-03-08