

# 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

Av Juscelino Kubitschek de Oliveira 3291 Cidade Industrial  
81270-200 Curitiba, 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. 665/2022, 551/2021 and 67/2009  
Canada: Medical Devices Regulations - Part 1- SOR 98/282  
Japan: MHLW Ministerial Ordinance 169 and Article 4 to Article 68  
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

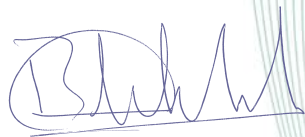
### Scope:

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: 2027-11-01  
Certificate effective date: 2024-11-01  
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. 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-checkme.com/org>

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





# ADDENDUM

To certificate: 2224396

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

## JJGC Indústria e Comércio de Materiais Dentários SA

Av Juscelino Kubitschek de Oliveira 3291 Cidade Industrial  
81270-200 Curitiba, PR  
Brazil

Certified organization(s) and/or locations:

Different scope

JJGC Indústria e Comércio de Materiais  
Dentários SA  
Av Juscelino Kubitschek de Oliveira  
3715, Cidade Industrial  
81270-200 Curitiba, PR  
Brazil

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.

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.

Addendum expiry date: 2027-11-01  
Addendum effective date: 2024-11-01