Number: 2224396CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

JJGC Indústria e Comércio de Materiais Dentários SA

Avenida Juscelino Kubitschek de Oliveira, 3291
81270200 Curitiba – Paraná
Brazil
SRN ID.: BR-MF-000014512

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2197651CN

Authorized Representative: Etkon GmbH, Lochhamer Schlag, 6, 82166 Gräfelfing, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: **3 December 2021** Date: **25 April 2023** Expiry date**: 1 December 2026**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active dental implants and dental materials (MDN 1103, class Is) **Sterilization method: EtO**
Group of Devices: Abutment impression coping (Sterile)

Non-active non-implantable instruments (MDN 1208, class Is) **Sterilization method: EtO**
Group of Devices: Instruments for Rescue Kit

Non-active non-implantable instruments – (MDN 1208, class Ir)
Reusable Surgical Instruments – Surgical instruments for Dental Implant Systems

Non-active dental implants and dental materials (MDN 1103, class IIa)
Group of Devices: Temporary Solutions
Group of Devices: Permanent Abutment over Abutments
Group of Devices: Connections and Screwdrivers for Contra-angle
Group of Devices: Drilling Instruments
Group of Devices: Implant Impression Coping
Group of Devices: Complete Surgical Kits
Group of Devices: Drill Guides and Sleeves

Dental Implants and Accessories (P010201, Class IIb)	
GM Helix implants Narrow GM Helix Implants HE Helix implants Drive Implants Titamax Implants	*Intended Purpose:* Intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single- or multiple-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading

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Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions
- For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Date of Issue certificate	Certification Notice Reference	Action
3-12-2021	2197651CN11	First issue
18-01-2022	2197651CN12	Revised
18-02-2022	2197651CN13	Revised
15-03-2022	2197651CN14	Revised
25-04-2023	2197651CN15	Revised

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