MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C582222

Initial certification date:
06 February 2023

Valid:
06 February 2023 – 21 May 2025

This is to certify that the management system of

ORTOSINTESE INDÚSTRIA E COMÉRCIO LTDA.

Rua Professor Affonso José Fioravanti, 63, 02998-010, São Paulo, SP, Brazil

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURE, SALES AND DISTRIBUTION OF SURGICAL TABLES, REUSABLE SURGICAL INSTRUMENTS, STERILE AND NON-STERILE ARTICULATED AND SYNTHESIS ORTHOPEDICS IMPLANTS TO TRAUMA AND JOINTS , SURGICAL FOCUS, THERMAL DISINFECTOR AND STEAM STERILIZER FOR HOSPITAL USE, AND SERVICING OF SURGICAL TABLES, SURGICAL INSTRUMENTS, SURGICAL FOCUS, THERMAL DISINFECTOR AND STEAM STERILIZERS.

Place and date:
Høvik, 06 February 2023

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Certificate no.: C582222
Place and date: Høvik, 06 February 2023

Appendix to Certificate

ORTOSINTESE INDÚSTRIA E COMÉRCIO LTDA.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
ORTOSINTESE INDÚSTRIA E COMÉRCIO LTDA.	Rua Nelson Palma Travassos, 651, Jaraguá, 02998-010, São Paulo, SP, Brazil	DESIGN, DEVELOPMENT, MANUFACTURE, SALES AND DISTRIBUTION OF REUSABLE SURGICAL INSTRUMENTS, STERILE AND NON-STERILE ARTICULATED AND SYNTHESIS ORTHOPEDICS IMPLANTS TO TRAUMA AND JOINTS AND SERVICING OF SURGICAL INSTRUMENTS.
ORTOSINTESE INDÚSTRIA E COMÉRCIO LTDA.	Rua Professor Affonso José Fioravanti, 63, 02998-010, São Paulo, SP, Brazil	DESIGN, DEVELOPMENT, MANUFACTURE, SALES AND DISTRIBUTION OF SURGICAL TABLES, SURGICAL FOCUS, THERMAL DISINFECTOR AND STEAM STERILIZER FOR HOSPITAL USE, AND SERVICING OF SURGICAL TABLES, SURGICAL FOCUS, THERMAL DISINFECTOR AND STEAM STERILIZERS.

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