EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
261130-2018-CE-BRA-NA-PS Rev. 0.0	**PRJC-21622-2007-MSC-BRA**	**02 July 2023**

This is to certify that the quality system of:

ORTOSINTESE INDÚSTRIA E COMÉRCIO LTDA.

Rua Nelson Palma Travassos 651, CEP 02998-000. São Paulo, SP, Brazil.

For design, production and final product inspection/testing of:

ORTHOPEDIC IMPLANTS

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 02 July 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate.	02-July-2018

Products covered by this Certificate:

Product Description	Product Name	Class
Intramedular nail	– -Intramedular fin – -mini stem fin	IIb
Pin	– -Schanz – -ender pin	IIb
Tibial system	Ortolock tibial system: – Tibial ortolock, – Cannulated tibial ortolock, – Plug screw, – Locking bolt (astm f138) smart tibial system: – Sts ortolock, – Reduction srew, – Plug screw standard, plug screw, – Locking screw – (astm f136)	IIb
Pin signus system	-Pin signus system – Intramedular nail (two versions: astm f136 and f138) – Intramedular nail f, sliding screw, and locking bolt. – Intramedulary cannulated nail	IIb
Wire	Astm f1350: – Luque wire – Double luque wire	IIb

	Inox astm f138: – Threaded double kirschner wire – Threaded kirschner wire – Smooth wire with sphere Astm f138: – Smooth wire – Double kirschner wire – Threaded double trocater wire – Double steinmann wire – Threaded double trocater wire – Threaded double steinmann wire – Suture wire – Trocater smooth wire – Trocater threaded wire Astm f136: – Kirschner wire – Steinmann wire	
Staples	– Staple blount – Coventrystaples	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate
Rua Nelson Palma Travassos 651, CEP: 02998-010, São Paulo, SP, Brazil.
Rua Professor Affonso Jose Fioravanti 63, CEP: 02998-010, São Paulo, SP, Brazil.

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate