EU Quality Management System Certificate

Certificate no.:
C751660

Initial certification date:
05 December 2025

Valid Until:
04 December 2030

This is to certify that the quality system of

S.I.N. Implant System LTDA

Front Gate - Rua Soldado Ocimar Guimarães da Silva 421, São Paulo, SP, Postal Code 03348-060, Brazil.

Back Gate - Avenida Vereador Abel Ferreira 2140, São Paulo, SP, Postal Code 03340-000, Brazil.

SRN: BR-MF-000019848

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

Sterile dental implants, Sterile and Non-sterile prosthetic components and Non-Sterile surgical instruments.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 30 January 2026

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Khanpara B.C.

Bhautik khanpara
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2877327	05 December 2025
1.0	**Extension to Non-sterile surgical instruments**	**2877330**	**30 January 2026**

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
The purpose is to replace missing, condemned teeth or conventional prostheses, with the aim of restoring aesthetics and masticatory function, stopping bone resorption and reducing overload on remaining teeth. They are based on the mechanical principles of load transmission system assembly.	DENTAL IMPLANTS WITHOUT HIDROXOPATITE IMPLANT TRYON – External Hexagon & Cone Morse Connection IMPLANT STRONG SW – External Hexagon, Internal Hexagon & Cone Morse Connection IMPLANT EPIKUT - External Hexagon & Cone Morse Connection	IIb
The purpose is to replace missing, condemned teeth or conventional prostheses, with the aim of restoring aesthetics and masticatory function, stopping bone resorption and reducing overload on remaining teeth. They are based on the mechanical principles of load transmission system assembly.	DENTAL IMPLANTS WITH HIDROXOPATITE IMPLANT STRONG SW PLUS- External Hexagon, Internal Hexagon & Cone Morse Connection IMPLANT UNITITE-Cone Morse Connection IMPLANT EPIKUT PLUS–External Hexagon & Cone Morse Connection	IIb
The purpose is to replace missing teeth, condemned teeth or conventional prostheses, with the aim of recovering aesthetics and chewing function, curbing bone resorption and reducing the overload on remaining teeth. They are based on the mechanical principles of load transmission system assembly.	ZYGOMATIC DENTAL IMPLANTS WITHOUT HYDROXYAPATITE IMPLANT ZYGOMATIC - External Hexagon Connection	IIb
The purpose is to replace missing, condemned teeth or conventional prostheses, with the aim of restoring aesthetics and masticatory function, stopping bone resorption and reducing	ZYGOMATIC DENTAL IMPLANTS WITH HYDROXYAPATITE IMPLANT ZYGOMATIC PLUS - Cone Morse Connection	IIb

overload on remaining teeth.		
Its purpose is to form the emergence profile for correct seating of the prosthesis, besides protecting the interior of the implant from intra-oral contamination. They are based on the principle of stabilization and epithelialization of the gum tissue.	STERILE COMPONENTS HEALING CAP - External Hexagon, Internal Hexagon & Cone Morse Connection	IIa
Its purpose is to form the emergence profile for correct seating of the prosthesis, besides protecting the interior of the implant from intra-oral contamination. They are based on the principle of stabilization and epithelialization of the gum tissue.	STERILE COMPONENTS PROTECTOR - External Hexagon, Internal Hexagon & Cone Morse Connection	IIa
It has the finality of forming the emergency profile for correct seating of the prosthesis, in addition to protecting the interior of the implant from intra-oral contamination.They are based on the principle of stabilization and epithelialization of gingival tissue.	STERILE COMPONENTS HEALING CAP PEEK – External Hexagon , Internal Hexagon & Cone Morse Connection	IIa
It has the finality of, together with the implant, transmitting the strength of mastication to the bone board, in which they are surgically implanted. The Interfaces are based on the mechanical principles of assembling the load transmission system.	STERILE COMPONENTS ABUTMENT - External Hexagon, Internal Hexagon & Cone Morse Connection MINI-ABUTMENT MICRO MINI-ABUTMENT ANGLED MINI-ABUTMENTS CONICAL ABUTMENT MULTIFUNCTIONAL ABUTMENT CEMENTED ABUTMENT ANGLED CEMENTED ABUTMENT ABUTMENT INTERFACE ABUTMENT INTERFACE (Prosthetic Intermediate)	IIb
It has the purpose of fixing the prosthesis to the implant, and thus transmitting the chewing force to the bone plate, in which they are surgically implanted. The principle of operation is the combined effect of rotation and pressure. The torque force exerted on the distal (wider) end, with the help of the driver, is transferred throughout the component body, fixing the assembly on which the screw is inserted.	STERILE COMPONENTS ABUTMENT ACESSORIES SCREW- External Hexagon, Internal Hexagon & Cone Morse Connection	IIb

It has the finality of, together with the implant, transmitting the strength of mastication to the bone board, in which they are surgically implanted. The Interfaces are based on the mechanical principles of assembling the load transmission system.	NON-STERILE COMPONENTS TEMPORARY ABUTMENT – External Hexagon, Internal Hexagon & Cone Morse Connection TEMPORARY CYLINDER TEMPORARY CYLINDER (Prosthetic Intermediate)	IIb
Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board.They are based on the mechanical principles of assembling the load transmission system.The pre milled abutment is used for making dental protheses unitary, cemented oy screwed by the CAD-CAM system.	NON-STERILE COMPONENTS ABUTMENT PRE MILLED TITANIUM – External Hexagon, Internal Hexagon & Cone Morse Connection	IIb
Its purpose is, together with the implant, to transmit the force of mastication to the bone plate. They are based on the mechanical principles of load transmission system assembly.	NON-STERILE COMPONENTS METALLIC ABUTMENT – External Hexagon, Internal Hexagon & Cone Morse Connection ABUTMENT CHROME COBALT INTERFACE CHROME COBALT ABUTMENT CHROME COBALT (Prosthetic Intermediate) INTERFACE CHROME COBALT (Prosthetic Intermediate)	IIb
Drills without DLC and Drills with DLC	**NON-STERILE SURGICAL INSTRUMENTS:** **DRILLS WITHOUT DLC:** **EXTRACTING, COUNTERSINK, HELICAL, CONICAL, LANCE, PILOT, TREPHINE, BONE PROFILE, SPHERICAL** **DRILLS WITH DLC:** **CONTERSINK, HELICAL, CONICAL, LANCE, PILOT, SPHERICAL**	**IIa**
Driver without DLC and Driver with DLC	**NON-STERILE SURGICAL INSTRUMENTS:** **DRIVER WITHOUT DLC: HANDPIECE** **DRIVER WITH DLC: HANDPIECE**	**IIa**

Screw Tap	**NON-STERILE SURGICAL INSTRUMENTS:** **SCREW TAP**	**IIa**
KIT Surgical Instruments	**NON-STERILE SURGICAL INSTRUMENTS:** **KIT SURGICAL TRYON** **KIT SURGICAL STRONG SW** **KIT SURGICAL UNITITE** **KIT SURGICAL EPIKUT** **KIT SURGICAL EPIKUT LONG** **KIT SURGICAL ZYGOMATIC** **KIT SURGICAL GUIDED STRONG SW** **KIT SURGICAL GUIDED UNITITE** **KIT SURGICAL GUIDED EPIKUT** **KIT SHORT DRILL STRONG SW** **KIT SHORT DRILL UNITITE** **KIT REPLACEMENT DRILL TRYON** **KIT REPLACEMENT DRILL TRYON CONICAL** **KIT REPLACEMENT DRILL UNITITE** **KIT REPLACEMENT DRILL STRONG SW** **KIT ROTARY EXPANDER**	**IIa**

The complete list of devices is filed with the Notified Body:

Sites covered by this certificate

Site Name	Address
S.I.N. Implant System LTDA	Front Gate - Rua Soldado Ocimar Guimarães da Silva 421, São Paulo, SP, Postal Code 03348-060, Brazil. Back Gate - Avenida Vereador Abel Ferreira 2140, São Paulo, SP, Postal Code 03340-000, Brazil.

EU Representative
OBELIS S.A Registered Address: Bd. Général Wahis, 53 1030 Brussels, Belgium

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.