



EC Certificate

Full Quality Assurance System

Certificate No.:
249047-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-528306-2015-MSL-IND

Valid Until:
11 May 2021

This is to certify that the quality system of:

S.H. Pitkar Orthotools Pvt. Ltd.
EL-32, J Block, MIDC, Bhosari, Pune - 411 026, India

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

Orthopedic Implant and Appliances

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, 7 November 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

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	Supersedes DNVGL (NB 0434) Certificate no: 5678-2014-CE-IND-NA rev 1 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-07

Products covered by this Certificate:

Product Description	Product Name	Class
Trauma Fixation System – Bone screws	Cortical screw, Cancellous screw, malleolar screw, Cannulated Cancellous screws, Locking head screws, DHS screws	IIb
Trauma Fixation System – Bone plates	Self Compression Plates, Low Contact Self Compression Plates, DHS Plates, Locking plates, Reconstruction plates, Tubular plates, L plates, T plates, Buttress plates, Spoon plate, Clover leaf plates, DCS plates	IIb
Intramedullary Nail System	Ultralock Nails, Humeral Nails, Supracodylar Nails, SOL T Tibia Nails, SOL T Femur Nails, SOL T PFD Nails, Trochantric Femoral Nails, Universal Locking nails, Elastic nails, Yt Nails, PFNA II Nails	IIb
Intramedullary Nail System- Screws	Cervical screws, Hip pin, Hip Bolt, Lag screws, Interlocking screws, Antirotational Screws, PFNA II Blades	IIb
External fixation system- Implants	Tapered pin with HA coating, Half Pin, Tapered pin, Wires, Pins, Olive wire	IIb
External fixation system- Appliances	Components such as rails, C.D. Unit, rods, clamps, T end clamps, Self adjusting clamp, Elbow clamp, Guide rods, Spacer disc, rods, bolts, Tubes, Fixing elements	IIb

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External fixation system- Ring fixation system	Half rings, Composite half rings, Curved rings, 5/8 rings, Foot rings, Arches, Arc, rods, Hinges, Connection plates, Twisted plates, Curved plates, Sockets, Bolts, Nut, Washers, Bock for half pin, Sleeves, Post male & female, Clamps, Oblique support, Universal joint, Rotational and translation devices, Bushing, Washers	IIb
External fixation system- Ortho SUV Frame	Struts, Threaded rods, Ring connection plates- straight and Z shape	IIb
Spinal system-Unilock	Pedicle screw, Polyaxial screw, Reduction screw, pre-cut rod, Bridge plates, Grub screws, Lamina hook, anterior washer, D connector, D connector rod	IIb
Spinal system-Mesh	PLIF cages, PEEK PLIF cages, TLIF cages, Expandable cages, Spinal Hybrid adjustable cages, mesh, Titax Cranial mesh	IIb
Spinal system-Cervical System	Cervical locking plates, self-tapping locking head screw, cervical disc spacer	IIb
Spinal system-O-C-T System	Poly pedicle screw for small anatomy system, Pedicle screw for small anatomy system, Spinal precut rod for small anatomy system, Occipital Y plate, Occipital T plate, Bias screw, Polypedicle screw for Lateral mass, Locking head screw, D connector rod for lateral mass, occipital rod, D connectors	IIb
Spinal system-Trigen Spinal System	Trigen polyaxial pedicle screw, Trigen pedicle screw, Trigen polyaxial reduction screw, Trigen precut rod	IIb
Spinal system- VS System	VS plate and VS screw	IIb
Spinal system- MIS System	MIS Polyaxial screw, MIS spinal precut rod, MIS straight rod	IIb
Maxillofacial System	Screws and plates	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

S.H.Pitkar Orthotool Pvt. Ltd. EL-32, J Block, MIDC, Bhosari, Pune - 411 026

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EU Representative

Obelis S. A., Bd. General 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 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