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# DNV BUSINESS ASSURANCE

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## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

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Certificate No. 5678-2014-CE-IND-NA 0.0

This Certificate consists of 4 pages

*This is to certify that the Quality Management 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*

**Orthopaedic Implants & External Fixators**

*has been assessed with respect to*

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

*Further details are given overleaf*

*Place and date:*

Høvik, 11 May 2016

*This Certificate is valid until:*

**11 May 2021**

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For DNV GL BUSINESS ASSURANCE  
NORWAY AS



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**Tone Kolpus**  
*Certification Manager*

**Notified Body No.:**  
0434

**Aud Løken Eiklid**  
*Technical Reviewer*

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 5678-2014-CE-IND-NA  
 Rev. No.: 0.0  
 Project No.: PRJC-19600-2007-PRC-IND

## Jurisdiction

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

## Certificate history

Revision	Description	Issue Date
0	Original certificate	2016-05-11

## Products covered by this Certificate

Product	Product Type/Model/Variant	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 , Humerous 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
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



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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	I Ib
Spinal system-Trigen Spinal System	Trigen polyaxial pedicle screw, Trigen pedicle screw, Trigen polyaxial reduction screw, Trigen precut rod	I Ib
Spinal system- VS System	VS plate and VS screw	I Ib
Spinal system- MIS System	MIS Polyaxial screw, MIS spinal precut rod, MIS straight rod	I Ib
Maxillofacial System	Screws and plates	I Ib

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

#### Sites covered by this certificate

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

#### EU Representative

Medical Technology Promedt Consulting GmbH, Altenhofstrasse 80, D-66386 St.Ingbert, Germany.



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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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE