



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 40099-2008-CE-NOR
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

GST Corporation

India

for production and final product inspection/testing of

Orthopaedic Implants

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, 18 November 2008

This Certificate is valid until:

18 November 2013

For DET NORSKE VERITAS CERTIFICATION AS
Norway



Notified Body No.:
0434


Marianne Spæren
Certification Manager


Jenny Helen Nytnun
Technical Reviewer

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.: 40099-2008-CE-NOR
 Rev. No.:
 Project No.: PRJC-53558-2008-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
	Original Certificate – Recertification	2008-11-18

Products covered by this Certificate

Product Description	Product Name	Class
Plates	Dynamic Compression Bone Plate Narrow & Broad, T Plates, T Plates Oblique, L Plates, L Plates Oblique, Sherman Bone Plates, Semi Tubular Plates, One Third Tubular Plates, Angle Blade Plates, DHS Plates without Screws, Condylar DCP Plates, Cobra Plates, Quarter Tubular Plates, Straight Recon Plates, Y Recon Plates, Curved Recon Plates, Calcaneal Plates, Hook Shaped Plates, LC DCP Plates, Colverleaf Plates, Narrow & Board Plates with Round Holes, Thin Narrow Plates, Lengthening Plates, Condylar Butteres Plates, Lateral Tibial Head Plates, T & L Butteres Plates, Angular Plates, DCS Plates, Locking Plates	I Ib
Screws	Lag & Compression Screws, Cortical Screws, Self Tapping Screws, Cancellous Screws, Cannulated Screws, Cannulated & Cancellous Screws, Shaft Screws, Malleolar Screws, Cortical Cannulated Screws, Locking Screws	I Ib
Wires & Pins	K Wires, Steinman Pins, Guide Pins, Knowel Pins, Gigue Wires, Modified Hagi Pins, Suture Wires, Cerclage Wires, Staples	I Ib
Nails	Kunstscher Nails, Rush Nails, Universal Tibial/Femoral/Humerous Nails, Supra Condylar Nails, Proxmal Femoral Nails, Unreamed Humorous Nails, Square Nails, Ender Intramedulory Nails, Smith Peterson Nails	I Ib

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

Sites covered by this certificate

B-13, Okhla Industrial Area, Phase-II, New Delhi – 110 020, India



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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