



# DET NORSKE VERITAS

## FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 40102-2008-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 11.1.a and Annex II (Module H1)  
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.: 40102-2008-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
Hip Prosthesis	Austin Moore, Thompson, Bipolar	III

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

# EC design-examination certificate Medical Devices



**Design Approval no. 40102-2008-CE-NOR**

<b>Manufacturer name:</b> G.S.T. Corporation	
<b>Manufacturer address:</b> B-13, Okhla Industrial Area, Phase-II New Delhi – 110 020 India	
<b>Type of medical device and identification no.:</b> Orthopaedic Implants • Hip Prosthesis	<b>Class of Medical Device:</b> III
<p><b>Short description of the medical device:</b> Orthopaedic Implants - Hip Prosthesis are medical devices, made of high quality implant grade steel 316 LVM and used to replace part of a hip joint with a prosthesis device. The Hip prosthesis being manufactured at GST Corporation are of 3 different types,</p> <ul style="list-style-type: none"> <li>• Austin Moore Hip Prosthesis – The medical device is used for fractures of the femoral head, osteoarthritis, and other hip disorders in patients</li> <li>• Thomson Hip Prosthesis – The Medical device is used in patient with a short femoral neck or in cases in which an existing femoral neck may have been absorbed.</li> <li>• Bipolar Hip Prosthesis – The medical device is used when primary prosthetic replacement of the femoral neck is required.</li> </ul> <p>Intended for medical use and to be used by orthopaedic surgeons only, the medical devices are to be sterilized before use by the process of steam autoclaving with temperatures between 121°C and 135°C, 15 17 PSI (11.2 Bar) pressure for at least 30 Minutes.</p>	
<p><b>This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.</b></p> <p><b>Limitations:</b> Any changes in the Design shall immediately be reported to Det Norske Veritas Certification AS in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the</p>	

**This certificate is valid until: 18 November 2013**

<p>for DET NORSKE VERITAS CERTIFICATION AS</p> <p style="text-align: center;"><i>Marianne Spæren</i> Marianne Spæren Certification Manager</p>	<p>Høvik, 18 November 2008</p> <p style="text-align: center;"><i>Jenny Helen Nytnun</i> Jenny Helen Nytnun Technical Reviewer</p>
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*This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.*