



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 40104-2008-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

Absorbable Sutures

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 Nytn
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.: 40104-2008-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
Synthetic Absorbable Sutures	Sterile Synthetic Absorbable Sutures (PGA) with or without Needles	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. 40104-2008-CE-NOR

Manufacturer name: GST Corporation	
Manufacturer address: B-13, Okhla Industrial Area, Phase-II New Delhi – 110 020 India	
Type of medical device and identification no.: Sterile Synthetic Absorbable Sutures (PGA) with or without Needles	Class of Medical Device: III
Short description of the medical device: Synthetic Absorbable Suture With & Without Suture Needle Surgical suture needle with thread (synthetic absorbable suture) is a kind of suture needle, which is made of high-quality stainless steel used for medical application and after firmly combining with synthetic absorbable suture, applied to suture, soft tissues on human body. The product is of two kinds, one with needles and another without needles. After sterilized by ethylene oxide gas, the product may be directly applied at the clinic. The needle body of surgical suture needle with thread (synthetic absorbable suture) is made of 3Cr13 stainless steel. Whereas, the suture thread, employed on surgical suture needle with thread of medical application, is made of Polyglycolic Acid which molecular formula is (C ₂ H ₂ O ₂) by weaving and processing finely. The surgical suture needle with thread (synthetic absorbable suture) is applied to suture soft tissues of the human body at the clinic. It can be applied for surgical suture and ligation of soft tissues in department like surgical, gynecology, obstetrics, urology, orthopedics, orthopaedic, ophthalmic and stomatology. However, it cannot be employed to suture the organs, like heart, central nerve, etc., with high risk, on human body.	
This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.	
Limitations: 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 validity of this Certificate.	

This certificate is valid until: 18 November 2013

for DET NORSKE VERITAS CERTIFICATION AS  Marianne Spæren Certification Manager	Høvik, 18 November 2008  Jenny Helen Nyttun Technical Reviewer
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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.