



# DET NORSKE VERITAS

## FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 38065-2008-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*

**Sterile Disposable Medical Devices**

*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*

Marianne Spæren  
Certification Manager

*Jenny Helen Nytn*

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.: 38065-2008-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
Sterile Disposable Medical Devices	Three Way Stop Cock with/without Extension Tube, I.V. Cannula with/without Wings and with/without Port, Infusion Set with/without Air Vent and Needle, Infusion Set with Flow Regulator, Micro Infusion Set with/without Air Vent, Blood Transfusion Set, Blood Giving Set with/without Air Vent, Scalp Vein Set, Extension Tube, Connection Tube, Ryle’s Tube, Levin’s Tube, Infant Feeding Tube, Suction Catheter with/without Thumb Control, Nasal Oxygen Catheter, Paediatric Drip Set, Flow Regulator, Stylet (Obturator), Mucus Extractor, Close Wound Suction Set, Guedel Airways, Measured Volume Set, Polyvol/Burette Set, Luer Locks, Stomach Tubes, Umbilical Catheters, Abdominal Drainage System, Redon Drainage System, Water Sealed Drainage System, Yankur Suction Set, Thoracic Drainage Catheter with/without Trocar, Oxygen Catheter, Female Catheter, Nelaton Catheter, Fistula Needles, Oxygen Mask Adult & Paediatric, Nebulizer Mask Adult & Paediatric, Blood Collection Set, Spinal Needle, Epidural Needle, Tracheal Tube with/without Cuff, Huber Infusion Set, Foley Balloon Catheter Two Way & Three Way, Femoral Catheter, Haemodialysis Catheter, Peritoneal Dialysis Catheter Kit, Safety Syringe, Disposable Syringe Set, Hypodermic Disposable Needles, Surgical Gloves, Surgical Blades and Scalpels	IIa
Manual Resuscitators and Accessories	Manual Resuscitator Rubber, Manual Resuscitator Silicon, Rebreathing Bag, Face Mask	IIa

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



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## Sites covered by this certificate

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

## 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