CERTIFICATE OF ASSESSMENT - EC

DET NORSKE VERITAS

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

Certificate N°.: 2005-OSL-MDD-0422

This is to certify that the Quality System for the product group:

Disposable Medical Devices

- defined by manufacturer as Class IIa devices -

Manufactured by

M/s Sterimed Medical Devices Pvt. Ltd.

38th KM Stone, Delhi Rohtak Highway, Opp. Parle Biscuits Factory, Bahadurgarh, Haryana, India

complies with the applicable requirements of the Directive.

The quality system for these products has been assessed according to the procedure of conformity assessment described in **Article 11.2.b) and Annex V** Identification of the products covered by this certificate is given in the Appendix.

Limitations:

The manufacturer must inform Det Norske Veritas Certification AS of any plan for significant changes to the quality system. Annual Periodical Audits will be held to verify the validity of this Certificate.

Høvik, 30 November 2005

for Det Norske Veritas Certification AS

Line Gangeskar

Head of section, Testing, Product and Personnel Certification

CE 0434

Valid until: 30 November 2010

Cecilie Gudesen Torp

Project engineer

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments t 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

CERTIFICATE OF ASSESSMENT - EC

DET NORSKE VERITAS

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

Certificate N°.: 2005-OSL-MDD-0421

This is to certify that the Quality System for the product group:

Disposable Medical Devices

- defined by manufacturer as Class I sterile devices -

Manufactured by

M/s Sterimed Medical Devices Pvt. Ltd.

38th KM Stone, Delhi Rohtak Highway, Opp. Parle Biscuits Factory, Bahadurgarh, Haryana, India

complies with the applicable requirements of the Directive.

The quality system for these products has been assessed according to the procedure of conformity assessment described in **Article 11.5** and **Annex V** for the aspects of manufacture concerned with securing and maintaining sterile conditions. Identification of the products covered by this certificate is given in the Appendix.

Limitations:

The manufacturer must inform Det Norske Veritas Certification AS of any plan for significant changes to the quality system. Annual Periodical Audits will be held to verify the validity of this Certificate.

Høvik, 30 November 2005
for Det Norske Veritas Certification AS

Line Gangeskar
Head of section, Testing, Product and Personnel Certification

CE
0434

Valid until: 30 November 2010

Cecilie Gudesen Torp
Project engineer

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

DET NORSKE VERITAS

WHO GMP COMPLIANCE VERIFICATION

Report N°.: 2008-NDE-WHOGMP-0005

This is to certify that WHO GMP requirements were verified at the request of M/s. Sterimed Medical Devices Pvt. Ltd. for the product group:

MANUFACTURE AND SUPPLY OF FOLEY BALLOON CATHETERS, DISPOSABLE MEDICAL DEVICES FOR ANAESTHESIA, GENERAL SURGERY, UROLOGY, GASTROENTEROLOGY, GYNAECOLOGICAL PROCEDURES AND REHABILITATION AIDS

Manufactured by:

Sterimed Medical Devices Pvt. Ltd.

at

38 KM Stone, Delhi Rohtak Road, Opposite Parle Biscuit Factory, Bahadurgarh, Haryana, India

complies with the requirements applicable to it as per WHO GMP Guidelines

Details attached in the report. Reference No. DNV/Sterimed Medical/WHOGMP/RA/001 Dt. 2008-05-26

New Delhi, 2007-11-26

Det Norske Veritas AS

Dr. Atul Anand
Auditor

Valid upto 2009-11-25

P J Singh
District Manager

DET NORSKE VERITAS

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 2005-OSL-AQ-7738 / 2005-OSL-AQ-0332

This is to certify that
THE QUALITY MANAGEMENT SYSTEM
of

M/s Sterimed Medical Devices Pvt. Ltd.

at
8th KM Stone, Delhi Rohtak Highway, Opp. Parle Biscuits Factory, Bahadurgarh, Haryana, India

has been found to conform to the Quality Management System Standard
ISO 9001 : 2000 / ISO 13485 : 2003

This Certificate is valid for the following product or service ranges:

Manufacture and Supply of Folley Balloon Catheters and Supply of Medical Disposables for Anaesthesia, General Surgery, Urology, Gastro Enterology, Gynaecological Procedures and Rehabilitation Aids.

Original certificate valid from:
2005-10-10

This Certificate with Appendix is valid until:
2008-10-10

D.V. Rabi Kumar
Lead Auditor

NORWEGIAN ACCREDITATION
QUAL 002

Place and date:
Høvik, 2005-10-24

For the accredited unit:
Det Norske Veritas Certification AS

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Appendix may render this Certificate invalid.