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°.: 2000-OSL-MDD-0348

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

Surgical Blades and Disposable Scalpels

- defined by manufacturer as Class IIa devices -

Manufactured by

Jai Surgical Limited

Plot No. SP – 146, (L) RIICO Industrial Area, Bhiwadi, Distt. (Alwar) Rajasthan – 301 019, 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 Region Norge AS of any plan for substantial changes to the quality system in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.

Høvik, 19 October 2000
for Det Norske Veritas Region Norge

Lars Lundgreen
Head of section, Accredited Certification

CE
0434

Valid until: 19 October 2005
Original Certificate valid from: 1997-09-19

Eugenie Winger Husebye
Service responsible Medical Devices

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