



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-0374

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

M/s Jai Surgicals Ltd.

SP-146(L), RIICO Industrial Area, Bhiwadi, Distt: Alwar (Rajasthan), 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 11.3.a) and Annex II (excl. section 4)**. 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.

Hovik, 26 October 2005

for Det Norske Veritas Certification AS

Valid until: 26 October 2010

Line Gangeskar

Line Gangeskar

Head of section, Testing, Product and Personnel Certification

CE

0434

Regd. No. 2122

Aud Løken Eiklid

Aud Løken Eiklid

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

Det Norske Veritas Certification AS, Veritasveien 1, 1322 HØVIK, Norway. Notified body No. 0434 MS-02, 17.01.2002

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My Commission Expires on 8-4-2007

GF-12, 94, Meghdoot Building
Nehru Place, New Delhi-110019

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08 NOV 2005



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APPENDIX

Appendix to Certificate No.: 2005-OSL-MDD-0374

Manufacturer: M/s Jai Surgicals Ltd.

Product group: Surgical Blades and Disposable Scalpels

The Certificate referred to above covers the following devices:



- **Surgical Blades**
 - Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 24D, 25, 25A, 27, 34, 36, 36D, 60
- **Disposable Scalpels**
 - Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 24D, 25, 25A, 27, 34, 36, 36D, 60
- **Dental Disposable Scalpels**
 - Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T
- **Disposable Mini Scalpels**
 - Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T
- **Disposable Thumb Scalpels**
 - Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T
- **Disposable Safety Scalpels**
 - Size: 10, 10A, 10S, 11, 11P, 11K, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T
- **Surgical Blades (Gouge & Curette type)**
 - Size: 1, 2, 3, 4, 5, 6, 8, 10, 12, 15
- **Skin Graft Blades**
 - Size: Standard

- 00 -



Regd. No. 2122

CE 0434



26 October 2005

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Det Norske Veritas Certification AS, Head office: Veritas v. 1, 1322 HØVIK, Norway
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