



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-0457

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

Ophthalmic Surgical Blades

- defined by manufacturer as Class IIa devices -

Manufactured by

Bio-Tech Vision Care Pvt. Ltd.

Plot No. 555- 556- 557, Opp. Subham Tex-O-Pack, Khatraj-Vadsar Road, P.O.- Khatraj. Taluka -Kalol, Dist.- Gandhinagar, Gujarat, 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.

Høvik, 20 December 2005

for Det Norske Veritas Certification AS

Valid until: 20 December 2010

Line Gangeskar

Line Gangeskar

Head of section, Testing, Product and Personnel Certification

CE

0434



Cecilie Gudesen Torp

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

Signature