



# 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°.: 2004-OSL-MDD-0117

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

### Orthopaedic Implants

*- defined by manufacturer as Class III devices -*

*Manufactured by*

M/s Apothecaries Sundries Manufacturing Co.  
ASCO HOUSE I-30 (a), Kirti Nagar, New Delhi 110015, 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 B (encl. 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 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.

*Havik, 18 March 2004*

for Det Norske Veritas Certification AS

*Line Gangestad*

Line Gangestad

Head of section, Testing, Product and Personnel  
Certification

CE  
0434

*Valid until: 18 March 2009*

*Cecilie Gadesen Torp*

Cecilie Gadesen 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 its representative in accordance with Council Directive 85/374/EEC.*