



# 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<sup>o</sup>.: 2005-OSL-MDD-0170

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

### Dental Treatment Sets with Accessories

- defined by manufacturer as Class IIa devices -

*Manufactured by*

**Chirana-Dental, s.r.o.**

Vrbovská cesta 17, 921 01 Piešťany, Slovak Republic

**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, 11 May 2010*

for Det Norske Veritas Certification AS

Line Gangeskar

Head of section, Testing, Product and Personnel  
Certification



*Valid until: 11 May 2020*

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*