

## 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 No.: 4589-2007-CE-NOR

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

## **Dental Unit**

- defined by manufacturer as Class IIa devices 
Manufactured by

Zhuhai Siger Medical Equipment Co., Ltd.

Building 2, No.1 Chuangxin Yi Road, Tangjiawan Town, Zhuhai City Guangdong China

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, 06 May 2008

for Det Norske Veritas Certification AS

0434

Valid until: 06 July 2012

Steinar Kristensen Head of section,

Product Certification

Jenny Helen Nytun
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



## CERTIFICATE OF ASSESSMENT - EC

APPENDIX

Appendix to Certificate No.:

4589-2007-CE-NOR

Manufacturer:

Zhuhai Siger Medical Equipment Co., Ltd.

Product group:

**Dental Unit** 

The Certificate referred to above covers the following devices:

- S30
- S60 .
- S90

2008-05-06: The following models are added to the certificate:

- U500
- **U200**
- U100

- 00 -

06 May 2008