



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-0278

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

Oxygen Concentrator

- defined by manufacturer as Class IIa devices -

Manufactured by

Invacare Medical Equipment (Suzhou) Co., Ltd.

Unit 2B, Export Processing Zone, No. 200 Suhong Road, SIP Suzhou, Jiangsu 215021, 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 11.2.b) and Annex V**. 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, 29 July 2005

for Det Norske Veritas Certification AS

Valid until: 29 July 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



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APPENDIX

Appendix to Certificate No.: 2005-OSL-MDD-0278

Manufacturer: Invacare Medical Equipment (Suzhou) Co., Ltd.

Product group: Oxygen Concentrator

The Certificate referred to above covers the following devices:

2006-02-10: the following new device, in bold, has been added to the certificate:

- Invacare[®] Platinum 5 SensO₂
 - Model: IRC 5LX02AW
- **Invacare[®] Platinum S**
 - **Model: IRC 5LX02AWQ**

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10 February 2006

Cecilie Gudesen Torp

Cecilie Gudesen Torp

CE **0434**