# DET NORSKE VERITAS

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 2000-OSL-AQ-6952 / 2006-OSL-AQ-0685

This is to certify that
THE QUALITY MANAGEMENT SYSTEM
of

## EKOM spol. s r.o.
## Division Compressor

at
**Priemyselná 5031/18, 921 01 Piešťany, Slovak Republic**

has been found to conform to the Quality Management System Standard
**ISO 9001 : 2000 / ISO 13485 : 2003**

This Certificate is valid for the following product or service ranges:

**Design, manufacture and sale of suction systems, oil-less compressors, drying and filtration systems for industry and medical use.**

*Original certificate valid from:*
2000-08-15

*This Certificate with Appendix is valid until:*
2009-07-19

E. Tavandzis
*Lead Auditor*

NORWEGIAN ACCREDITATION
QUAL 002

*Place and date:*
Høvik, 2006-12-30

*For the accredited unit:*
Det Norske Veritas Certification AS

Eugenie Winger Husebye
*Management Representative*

Lack of fulfilment of conditions as set out in the Appendix may render this Certificate invalid.

DET NORSKE VERITAS CERTIFICATION AS, Veritasveien 1, N-1322 Høvik, Tel.: +47 67 57 99 00, Fax: +47 67 57 99 11
AQN-23wk 25.10.2001

# EC DECLARATION OF CONFORMITY

**for CE – marking according to Annex VII of Medical Devices Directive 93/42 EEC**

**Document No.:** D/2007/EU

**Manufacturer:**

**Ekom spol. s r.o.**
Priemyselná 5031/18
SK - 921 01 Piešťany

**Product:** Product name: **DENTAL COMPRESSOR**

Model: DK50 2V, DK50 2V/K, DK50 2V/M, DK50 2VS, DK50 2VS/K, DK50 2VS/M, DK50 2V/110, DK50 2V/110/K, DK50 2V/110/M, DK50 2V/110S, DK50 2V/110S/K, DK50 2V/110S/M, DK50 2x2V/110, DK50 2x2V/110/K, DK50 2x2V/110/M, DK50 2x2V/110S, DK50 2x2V/110S/K, DK50 2x2V/110S/M, DK50 4x2V/M, DK50 4x2V, DK50 6x2V/M, DK50 6x2V, DK50 4x2VT/M, DK50 6x2VT/M, DK50 9x2VT/M, DK50 12x2VT/M, DK50 15x2VT/M, DK50 4x2VT, DK50 6x2VT, DK50 9x2VT, DK50 12x2VT, DK50 15x2VT, DUO 2, DUO 2/M

Risk Classification: I , non sterile/without measure

Purpose of use: Source of pressure air for driving dental- medical devices

Registration code: P68338

**Noted product is in conformity with technical requirements and applicable regulations:**

Directive: MDD 93/42EEC, Annex VII
EMC-Directive 89/336 EEC

Quality Assurance Standards: EN ISO 13485:2003

Procedural Standards: EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996, EN 60601-1-2:2001, EN ISO 14971:2000

Product is compliance with requirements of Annex I the MDD 93/42 EEC and is safety for declares use in standard conditions.

Any modification to the product, not authorized by us, will invalidate this declaration.

ekom - 26 - spol. s r.o. Priemyselná 5031/18 921 01 Piešťany IČO: 31416513 IČ DPH: SK2020205646

Piešťany 4.5.2007

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Ing. Vladimír Bátora
Director

EKOM spol. s r.o.
Priemyselná 5031/18
SK - 921 01 PIEŠŤANY

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