



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



Place and date:
Høvik, 2006-12-30

For the accredited unit:
Det Norske Veritas Certification AS

Eugenie Winger Husebye
Eugenie Winger Husebye
Management Representative

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

EC DECLARATION OF CONFORMITY

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

Document No.: A/2007/EU

Manufacturer:

Ekom spol. s r.o.
Priemysel'na 5031/18
SK - 921 01 Piešťany

Product: Product name:
Model:

DENTAL COMPRESSOR

DK50 B, DK50 BS, DK50 I, DK50 H, DK50C, DK50 K,
DK50 P, DK50 M, DK50 Z, DK50 Z/K, DK50 S, DK50 S/K,
DK50-10 I, DK50-10 Z, DK50-10 Z/K, DK50-10 S, DK50-10
S/K, DK50-10 Z/M, DK50-10 S/M, DK50 PLUS, DK50
PLUS/K, DK50 PLUS/M, DK50 PLUS S, DK50 PLUS S/K,
DK50 PLUS S/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, 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.

Piešťany 11.4.2007



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spol. s r.o.

Priemysel'na 5031/18

921 01 Piešťany

IČO: 31416517 IČ DPH: SK2020010306

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Ing. Vladimír Batora
Director

