m e d i c a l a i r

EC DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42 EEC in the wording of later regulations

Document No.: xxxx/2014/EU

Manufacturer:

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

Product:

Product name:	**MEDICAL COMPRESSOR**
Model:	DK50 DE
Serial number:	xxxxx
Risk Classification:	IIb
Purpose of use:	FOR DELIVERY OF COMPRESSED AIR TO SUPPORT VENTILATORS AND RESPIRATORS
Registration code:	P58533

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

Directive:	MDD 93/42EEC MDD 2007/47/EC 2011/65/EU
Quality Assurance Standards:	ISO 13485:2003
Procedural Standards:	EN 60601-1:2011 EN 60601-1-2:2007 EN ISO 14971:2012 EN 50581:2012

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

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

Notified Body: Det Norske Veritas Region Norge AS
Veritasveien 1, N-1322 Hovik

Piešťany 18.7.2014

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Ing. Vladimír Bátora
Director

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