

EC DECLARATION OF CONFORMITY

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

Document No.: B/2014/EU

Manufacturer:

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

Product:

Product name: **DENTAL COMPRESSOR WITH SUCTION UNIT**
Model: DUO, DUO 2V, DUO/M, DUO 2V/M, DUO T, DUO T/M,
DUO 2VT, DUO 2VT/M, DUO 2, DUO 2/M, DUO 2T, DUO
2T/M
Risk Classification: I, non sterile/without measure
Purpose of use: Source of pressure and underpressure air for driving dental-
medical devices
Registration code: P68339

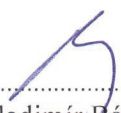
Noted product is in conformity with technical requirements and applicable regulations:

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.

Piešťany 18.7.2014


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Ing. Vladimír Batora
Director

