

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.
Priemyselná 5031/18
SK - 921 01 Piešťany

Product: Product name:
Model:

DENTAL COMPRESSOR WITH SUCTION UNIT
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:
Purpose of use:

I , non sterile/without measure
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

