

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.: C/2014/EU

Manufacturer:

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

Product: Product name:
Model:

DENTAL SUCTION UNIT

DO 2.1, DO 2.1T, DO 2.1Z, DO 2.1TZ, DO 2.1-10,
DO 2.1-10T, DO 2.1-10Z, DO 2.1-10TZ.

Risk Classification:

I , non sterile/without measure

Purpose of use:

Source of underpressure air for driving dental- medical devices

Registration code:

P68340

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

Directive:

MDD 93/42/EEC
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


Ing. Vladimír Batora
Director

