puranox
MEDICAL BV

6.3.1 CE declaration

DECLARATION OF CONFORMITY OF PURANOX
PURANOX TRADING B.V.

We hereby declare that the distributed CE marked products

PURANOX ANTI-SNORING SPRAY bag on valve system 75 ml product code 100
PURANOX ANTI-SNORING SPRAY pump system 40 ml product code 200
PURANOX ANTI-SNORING SPRAY bag on valve system 45 ml product code 300
SLEEPZZ ANTI-SNORING SPRAY bag on valve system 45 ml product code 600

will be covered by the "CE Marking of Conformity Certificate" and delivered by Dekra Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC, concerning medical devices.

We ensure and declare that the distributed CE marked products ANTI-SNORING SPRAY, 75 ml, 40 ml and 45 ml, falling within Class IIa, meets the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System which will be approved for the manufacture and final inspection of the product concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in Annex V, will be described in the said CE Marking of Conformity Certificate, to be issued and delivered by Dekra Certification B.V.

In addition we ensure and declare that ANTI-SNORING SPRAY 75 ml and 45 ml meets the requirements set out in the Aerosol Directive 94/1.

Certification number : 2134338

Oosterhout,
Date : 27-8-2015   Name : Ruizendaal   Function : Director

100 PuraNox 75 ml Batch NL-CBDFB 2145 and beyond
200 PuraNox 40 ml Batch CH-ABDBB-0152 and beyond
300 PuraNox 45 ml Batch 2015002632   and beyond
600 Sleepzz 45 ml Batch 2015001311   and beyond

Approval Signature: Date: 27/8/2015