

DECLARATION OF CONFORMITY

European Medical Devices Directive 93/42/EEC, Annex 1, + 2007/47/EC

This is a declaration made in accordance with the requirements of Annex VII of the European Medical Devices Directive 93/94/EEC Annex 1, Amended to 2007/47/EC, in relation to the stated devices.

Manufacturers Name: Bionic Products Pty. Ltd.
Business Address: Unit 11, 15 John Duncan Court,
Varsity Lakes, Qld. 4227, Australia.
Medical Devices: Elanra Air Pendant Ioniser
P.N. C1000109/110 (Black, package/unit)
P.N. C1000117/118 (White, package/unit)
Classification: Class I (Rule 12 of Annex IX)

Each medical device complies with the applicable provisions of the essential requirements under Annex I, the classification under Annex IX and the requirements under Annex VII before being supplied.

Standards Applied: EN60601-1:2006+A11:2011 - Medical Electrical Equipment - General requirements for basic safety and essential performance.
EN60601-1-2:2007 - Medical Electrical Equipment, Electromagnetic compatibility - Requirements and tests
EN60529 + *A2:2013 - Degrees of protection provided by enclosures (IP22 Rated)

Authorised Signatory:



(name and title)
DIRECTOR



Date 5 / 4 / 16