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 MkIII Portable Ioniser, P.N. C1000082/83

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: **AS14971:2007** - Application of Risk Management to Medical Devices
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

Authorised Signatory:

Common
BIONIC PRODUCTS
PTY. LTD.
A.C.N. 002 850 035
Seal

(name and title) Managing Director

Date 14 / 3 / 16