

Sede legale: 46025 Poggio Rusco (MN) Via Galilei n. 18 Cap. sociale € 52.000 i.v. iscritta al Reg. Imprese di Mantova C.F. e n. iscrizione 01796710810 ed al n. 245014 R.E.A. di Mantova- P. I.V.A. n. 02556750368 Tel.: + 39 0386 830582 - Fax.: +39 0386 51898 e-mail: <u>info@redax.it</u> - sito internet: www.redax.it

## **Declaration of Conformity**

Redax Srl with headquarters based in Poggio Rusco (MN) Via Galileo Galilei nr. 18, declare, on their own responsibility that the medical devices listed as per the attached documentation have been accepted at all stages of production through incoming, moulding, processing, packaging and have passed all visual, physical and functional quality testing according to the following standards:

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for

regulatory purposes;

- ISO 9001:2008 Quality management system - Requirements.

and comply with the requirements of the following directive:

- Directive 93/42/EEC Council Directive 93/42/EEC concerning medical devices.

- Directive 2007/47/EC Council Directive 2007/47/EC updating directive 90/385/EEC, directive

93/42/EEC, directive 98/8/EC.

The Vice President