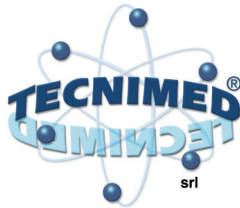


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## CE CONFORMITY DECLARATION

The writing firm TECNIMED S.r.l., with office in Piazzale Cocchi, 12 – 21040 VEDANO OLONA (VA) – Tel. 0332/402347, Fax 0332/402350, declares to be the manufacturer of the medical devices commercialised in Italy with the brands Thermofocus mod 0700, Thermofocus *professional*, Thermofocus *plus*, Thermofocus series 01500 (composed by several models with little custom differences), all them infrared thermometers without contact.

With this declaration it moreover guarantees, under its responsibility, that its medical devices satisfy all the regulations relevant at the 93/42/CEE Directive about the medical devices.

To this end it guarantees and states what follows:

- The devices satisfy the essential requisites (Encl. I of the Directive);
- The devices belongs to the class I (Art. 1, point 2° of the Directive);
- The devices have been submitted to the assessment of the risks according to the directive UNI EN 1441;
- The devices are marketed in a non sterile packaging;
- The devices are manufactured with a suitable production proceeding;

In the light of what we exposed (stated), the writing firm thinks it can put on

**“Thermofocus series 0700”**

**“Thermofocus professional mod 0800”**

**“Thermofocus plus mod 0900”**

and

**“Thermofocus series 01500”**

the “conforming marking CE” according to the graphic symbol fixed by the directive (Encl. XII).

The writing firm, moreover, commits itself to keep the enclosed dossier of product (Art. 17, paragraph 5 legislative decree of 24.2.1997, nr 46) at the supervision organisations’ disposal for a period of 5 years from the date of end-production of the devices.

Francesco Bellifemine  
President of Tecnimed srl

A handwritten signature in blue ink, appearing to read 'Francesco Bellifemine', is written over a faint, larger version of the signature.