EC CONFORMITY DECLARATION

The undersigned CASALUCI GIULIANO SRL, with seat in Castrignano de'Greci prov. of LE in Via prov.le Corigliano Km.1 – Italy, manufacturer of the following medical device (system)

HYDRA CENTRAL TOTEM

Declares under its own responsibility that this device complies with all the essential requirements stated in the Directive 93/42/EEC, Annex I concerning Medical Devices and also with its implementation into the Italian law. The above mentioned device is a CLASS I, not sterile, not a measurement instrument, not foreseen for diagnosis nor clinical investigation.

The device also complies with :

- IEC EN 60601-1 Medical Electrical Equipment – General Requirements for Safety
- UNI EN ISO 11197 Medical Supply Unit
- UNI EN ISO 14971 Risk Analysis for Medical Devices

This device will be sold with the CE marking as per art. 16 of the Dlgs n. 46/97.
CASALUCI GIULIANO Srl has established complete procedures to ensure appropriate checks and necessary tests, after release of the product on the market.

Castrignano de' Greci, 25 September 2009

Casaluci Giuliano
Healthy Design

Casaluci Giuliano S.r.l.
Via Prov.le per Corigliano KM.1
73020 Castrignano de' Greci (LE) – ITALY
Tel +39 0836/583339 – Fax +39 0836/589136
www.casalucigiuliano.it – info@casalucigiuliano.it

CASALUCI GIULIANO SRL
The Legal Rapresentative
Casaluci Flavio
CASALUCI GIULIANO SRL
P.Iva 03470080759