

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)

LYBRA BED

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
- IEC EN 60601-1-2 Medical Electrical Equipment – General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and Tests
- IEC EN 60601-1-4 Medical Electrical Equipment – General Requirements for Safety – 4. Collateral Standard : Programmable electrical medical systems
- IEC EN 60601-2-38 Specific Requirements for the Safety of Electrically Operated Hospital Beds
- IEC EN 60601-2-38/A1 Specific Requirements for the Safety of Electrically Operated Hospital Beds
- IEC EN 60529 Degrees of Protection Provided by enclosures (IP Code)
- UNI EN ISO 14971 Medical Devices – Risk Analysis for Medical Devices
- UNI EN 980 Symbols for the labelling of Medical Devices
- UNI EN 1041 Information supplied by the Manufacturer together with the 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

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