

DECLARATION OF CONFORMITY CE

Declaration of conformity issued by:

Company	Medical Ibérica S.A. (MEDISA)
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Manufacturer licence No.	5606 P.S.

Design and manufacture of medical devices

Clasification of medical device	Class I
Product	Electric bed
Model	MAJESTIC II
Serial number	See label
Date of manufacture	See label
Origin	Spain
Description	Electric Hospital Bed for standard, critical and long stay patients
Complements	Adaptation of different accessories

HEREBY DECLARES THAT IS COMPLIANT WITH THE FOLLOWING DIRECTIVES:

Directive 2007/47/CEE, concerning medical devices, Annex I, Annex VII

Directive 98/37/CE, concerning on the approximation of the laws of the Member States relating to machinery

NORMATIVES OF REFERENCE:

IEC 60601-1	Electromedicine Equipments. General safety requirements
IEC 60601-1-2	Electromedicine Equipments, general safety requirements. Electromagnetic compatibility
IEC 60601-2-52	Medical equipment – Part 2-52: particular requirements for basic safety and essential performance of medical beds
UNE-EN ISO 12100:2012	Safety of machinery - General principles for design - Risk assessment and risk reduction

Signed: D. Carlos Lara Martínez
General Manager



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