"EC" DECLARATION OF CONFORMITY

INDUSTRIAS PARDO, S.L.
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Authorized company by the Spanish Agency of Medicines and Medical Devices (AEMPS) of the Spanish Ministry of Health **nº 261 P.S.**

HEREBY DECLARES THE DESIGN AND MANUFACTURING OF THE FOLLOWING PRODUCTS:

Type:	**MEDICAL BED**
Model:	**HITECH**
Serial number:	See labels
Manufacturing year:	See labels

This product is classified as a **class I** device, according to annex 93/42/CE.

ARE IN CONFORMITY WITH THE FOLLOWING PROVISIONS:

- Directive **93/42/CE** European Parliament and Council, 14th June 1993, concerning medical devices.
- Directive **2006/42/CE** European Parliament and Council, 17th may 2006, concerning the machinery by amending Directive 95/16/CE.
- Directive **2006/95/CE** European Parliament and Council, 12th December 2006, relative to the approximation of the legislations of the Member States on the electrical material destined to be used with certain limits of tension.
- Directive **2004/108/CE** European parliament and Council, 15th December 2004, relative to the approximation of the legislations of the Member States as for electromagnetic compatibility.

STANDARDS OF REFFERENCE:

- Standard **UNE-EN ISO 12100** "Safety of machinery. General principles for design risk assessment and risk reduction"
- Standard **UNE EN 20324**, "Degrees of protection provided by enclosure, IP code". Same as IEC 60529"
- Standard **UNE EN 60204 -1**, "Safety of the machinery. Electrical equipment of machines. Part 1: General requirements"
- Standard **UNE EN 60601-1**, "Medical electrical equipment. Part 1. General requirements for safety and essential performance"
- Standard **UNE EN 60601-1-2**, "Medical electrical equipment. Part 2: General requirements for safety. Collateral standard: electromagnetic compatibility. Requirements and test"
- Standard **EN 60601-2-52**, "Medical electrical equipment. Part 2-52: Particular requirements for basic safety and essential performance of medical beds"

SIGNATURE:

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Adolfo Gaudes Martí
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Zaragoza, 29th March 2016