

"EC" DECLARATION OF CONFORMITY

INDUSTRIAS PARDO, S.L.

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CIF: B50057322

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: TECHNOPLUS (BASIC / ADVANCE)
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.
- Directive **2009/23/CE** European parliament and council, 23th April 2009, relative to the non-automatic weights.

STANDARDS OF REFERENCE:

- 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"
- Standard **EN 45501-95**, "Metrological aspects of non automatic weighing instruments"



SIGNATURE:

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