

"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: STRETCHER EMERGENCY
Model: TARSIS
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.

STANDARDS OF REFERENCE:

- Standard **UNE-EN ISO 12100** "Safety of machinery. General principles for design risk assessment and risk reduction"
- Standard **UNE EN 60601-1**, "Medical electrical equipment. Part 1. General requirements for safety and essential performance"
- Standard **UNE EN 60601-2-38**, "Medical electrical Equipment. Part 2: Particular requirements for the safety of electrically operated hospital beds"



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SIGNATURE:

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Zaragoza, 04th November 2015

