

"EC" DECLARATION OF CONFORMITY

INDUSTRIAS PARDO, S.L.

C/ Los Ángeles 5, (Polígono Centrovía)

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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: MATTRESS
Model: STRATUS (3.1 / 5.1 / 7.1 / 9.1 / TURN)
Serial number: See labels
Manufacturing year: See labels

The medical products have been assigned to class I, according to rule 12 of the Directive 93/42/EEC

ARE IN CONFORMITY WITH THE FOLLOWING PROVISIONS:

Directive **93/42/CE** European Parliament and Council, 14th June 1993, concerning medical devices.

STANDARDS OF REFERENCE:

- **UNE EN 60601-1**, "Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance"
- **UNE EN 60601-1-11**, "Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment"

SIGNATURE:

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Zaragoza, 04th November 2016

