# "EC" DECLARATION OF CONFORMITY

**INDUSTRIAS HIDRÁULICAS PARDO, S.L.**
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50198 La Muela, Zaragoza (Spain)
CIF: B50057322

Authorized company by the Spanish Agency of Medicines and Medical Devices (AEMPS) of the Spanish Ministry of Health with **num. 261 P.S.**

## STATES THAT THE PRODUCTS DESIGN AND MANUFACTURING ARE:

| | | | |
|---|---|---|---|
| **Type:** | Anti-decubitus devices & pumps, air flotation mattress | | |
| **Family:** | | **Basic UDI-DI:** | |
| **Models:** | Dual GT P.U, Dual GT M-Set, Dual Plus P.U, Dual Plus M-Set, Revo Plus P.U, RevoPlus M-Set, Centrius P.U, Entrix P.U, Entrix Lux M-Set, Entrix MR M-Set, Entrix M M-Set | | |
| **Serial number:** | See labels | **Manufacturing date:** | See labels |

These products are **class I**, according to Annex IX rule XII of MDDD 93/42/ECC as amended by 2007/47/EC.

## IN ACCORDANCE WITH THE FOLLOWING DISPOSITIONS:

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

## REFERENCE STANDARDS:

- Standard **UNE EN ISO 13485,** "Medical devices - Quality management systems - Requirements for regulatory purposes".
- Standard **UNE EN ISO 14971,** "Medical devices - Application of risk management to medical devices".
- Standard **UNE EN ISO 15223-1,** "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements".
- Standard **UNE EN 1041,** "Information supplied by the manufacturer of medical devices"
- Standard **UNE EN 60601-1,** " Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- Standard **UNE EN 60601-1-2**, " Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests".
- Standard **UNE EN 62366**, "Medical devices - Part 1: Application of usability engineering to medical devices".
- Standard **UNE EN 62304**, "Software de dispositivos médicos. Procesos del ciclo de vida del software".

**SIGNATURE:**

Industrias Hidráulicas Pardo, S.L.
NIF: B-50057322

Adolfo Gaudes Martí
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Zaragoza, 02nd December 2021

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