

## EC DECLARATION OF CONFORMITY

(Council Directive 93/42/CEE concerning medical devices / Annex VII)

*Mss. Silvia Ferrandis Tello*

as *Technical Director*

in name and representation of the enterprise *WinnCare Spain - CIF B-96221718*

address *Carretera Masía del Juez 37B E-46909 Torrente · Valencia · Spain*

number of Spanish license of operation *5191 P.S.*

**DECLARES** that the medical device described below, whose technical documentation corresponding to the above reference number is in my possession, meets the essential requirements set out in Directive Annex I which apply to it, therefore when used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

**Classification:**  Class I  Sterile  With measuring function  
**Origin:**  Spanish  European  No European

**Product marketing name:**

10 2106002 *Arnés banda-tórax polipropileno. Peso max. 150Kg*  
10 2106005 *Arnés banda-tórax poliéster. Peso max. 150Kg*

**COMPROMISES TO** institute and keep up to date systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risk in relation to the product. Likewise, **COMPROMISES TO** notify the competent authorities of the following incidents immediately on learning of them:

- Any malfunction or deterioration in the characteristics and/or the performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
- Any technical or medical reason connected with the characteristics on the performance of the medical device for the reasons referred to in subparagraph a) leading to systematic recall of devices of the same type by the manufacturer.



Date: 17/09/2018

Signature: