WINNCARE
Spain

CE

File CE102104xxx

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, S.L.*** *with* ***CIF B·96221718***

address ***Carretera Masía del Juez, 37B - 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:

102104004	*Arnés rejilla dorso-lumbar mediano sencillo 175Kg*
102104004XL	*Arnés rejilla dorso-lumbar mediano sencillo 175Kg – tirantes largos*
102104013	*Arnés rejilla dorso-lumbar grande 250Kg*
102104014	*Arnés rejilla asiento-respaldo mediano 250Kg*
102104014XL	*Arnés rejilla asiento-respaldo mediano 250Kg – tirantes largos*
102104015	*Arnés rejilla asiento-respaldo grande 250Kg*
102104016	*Arnés rejilla apoyo-cabeza mediano 250Kg*
102104016XL	*Arnés rejilla apoyo-cabeza mediano 250Kg – tirantes largos*
102104017	*Arnés rejilla apoyo-cabeza grande 250Kg*

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,

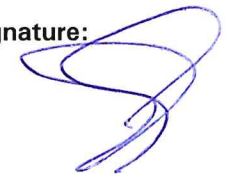
COMPROMISES TO notify the competent authorities of the following incidents immediately on learning of them:

a) 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.

b) 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: 07/05/2018

Signature:



WINNCARE
Spain

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File: CE102105XXX

EC DECLARATION OF CONFORMITY

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

Mss. ***Sonia Ferrandis Tello***

as ***Technical Director***

in name and representation of the enterprise ***Winncare Spain, S.L. - CIF B·96221718***

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

Product marketing name:

10 2105012	*Arnés acolchado dorso-lumbar mediano 250kg*
10 2105013	*Arnés acolchado dorso-lumbar grande 250kg*
10 2105014	*Arnés acolchado asiento-respaldo mediano 250kg*
10 2105015	*Arnés acolchado asiento-respaldo grande 250kg*
10 2105016	*Arnés acolchado apoyo-cabeza mediano 250kg*
10 2105017	*Arnés acolchado apoyo-cabeza grande 250kg*

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b) 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: 12/09/2018

Signature:

WINNCARE
Spain

CE

Expediente: CE1021070XX

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, S.L. - CIF B·96221718***

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

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

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

Product marketing name:

10 2107012	***Arnés Fletty M s/reposacabezas***
10 2107013	***Arnés Fletty L s/reposacabezas***
10 2107016	***Arnés Fletty M c/reposacabezas***
10 2107017	***Arnés Fletty L c/reposacabezas***

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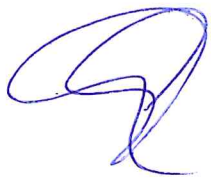
b) Any technical or medical reason connected with the characteristics on the performance of the medical device for the reasons referred to in subparagraph a) leading to systematic recall of devices of the same type by the manufacturer.



Date: 13/09/2018

Signature:

WINNCARE
Spain

CE

Expediente: CE1021090XX

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, S.L. - CIF B·96221718***

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

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

Product marketing name:

102109012	***Arnés malla comfort dorso-lumb***	***Piernas Acolchadas Talla M***
102109012B	***Arnés malla comfort dorso-lumb***	***Piernas Acolchadas M -PISCINA***
102109013	***Arnés malla comfort dorso-lumb***	***Piernas Acolchadas Talla L***
102109014	***Arnés malla comf. asiento-resp***	***Acolchado muslos Talla M***
102109014B	***Arnés malla comf. asiento-resp***	***Acolchado muslos M -PISCINA***
102109015	***Arnés malla comf. asiento-resp***	***Acolchado muslos Talla L***
102109016	***Arnés malla comf. apoyo cabeza***	***Piernas acolchadas Talla M***
102109016B	***Arnés malla comf. apoyo cabeza***	***Piernas acolchadas M -PISCINA***
102109017	***Arnés malla comf. apoyo cabeza***	***Piernas acolchadas Talla L***

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a) 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.

b) 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: 05/09/2019

Signature: