WIN CARE	**Instructions for use** **High Resilience foam mattress** **CLINIFLEX**	

Purpose of the device:
Disability compensation in combination with an adult medical bed (standard EN 60601-2-52).

Indications:
Device indicated for the comfort of patients who are bedridden for a few days, can mobilise on their own without any problems, and have no risk of developing a pressure ulcer/injury.

Target group of patients and users:
Adults with a transient or permanent loss of autonomy or with a height greater than or equal to 146 cm.

Contraindications:
- Use on imaging table and stretcher,
- Patient with a maximum weight greater than that tolerated by the mattress.

Indicate any undesirable side effects:
Any serious incident occurring in connection with the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established. Inform the competent authority if you consider or have reason to believe that the device presents a serious risk or is a falsified device.

Composition of the medical device:

References	**312588, 312588K, 312588P**	**312590T**
Description	CLINIFLEX – BED 90	CLINIFLEX – 4 TRUNCATED ANGLES – BED 80
Cover	CARTEX[1]	
Dimensions (cm)	90 x 200 x 14 cm	80 x 200 x 14 cm
Patient weight (kg)	Minimum and maximum: 30 à 130 kg	
Mousse specification	High Resilience foam (HR) 37 kg/m^3	
Fire standards	NF EN 597-1 & NF EN 597-2	

[1]: 65% polyurethane, 35% polyester (grammage 140 g/cm²).

Clinical benefit, performance, mechanism of action:
Characteristics in terms of device performance: this mattress adapts to the different positions of the medical bed base required for care, medical procedures and/or bed rest comfort and basic daily activities (personal hygiene, transfers, etc.).
Expected clinical benefits: Contribute to life-support activities.
Information for healthcare professionals: Observe the condition of the patient's skin in contact with the mattress several times a day. Use pressure relief devices or positioning systems on patients with pressure ulcers/injuries.

Requirements before use and instructions for use:
Training and qualification of the user of the device: The training of users must be carried out by persons trained and validated by the economic operators concerned, particularly in terms of safety and the reporting of non-conformities.
Installation of the device: The mattress is delivered with its cover. The product is ready to install. The cover must be dry. The principle of perfect symmetry allows the mattress to be positioned in 4 different positions.
Preventive maintenance: Carry out regular visual checks on the condition of the foam: the presence of visible sagging of the material and an uneven and very slow return of the foam are ageing criteria that compromise the properties of the support. Check the condition of the cover, the foam, and the surface appearance of the cover annually. Annually check the outer surface of the cover by exposing the inside to a light source to check for holes and/or tears.

Warnings, precautions for use, measures required:
Precautions for use
Non-stabilised bone injuries and/or muscular injuries in contact with the support. The first few days after pressure ulcer/injury surgery (skin graft or flap). Patients cared for at home with no possibility of medical auxiliary intervention. Also check the condition of exposed skin at each treatment and change of position. COPD-type bronchopulmonary disorders with a severe reduction in respiratory muscle tone. Joint stiffening and tendon retractions. Fractures of the pelvis or spine.
Warnings
(Re)assess the risks of patient entrapment in the non-movable parts of the medical bed associated with "therapeutic mattresses and accessories and articulated bed base positions" in accordance with standard EN 60601-2-52 in adults. The use of segmented or full-length side rails must be prescribed.
External cardiac massage is not compatible without a board between the thorax and the upper surface of the mattress.
The use of dry hot water bottles heated in the microwave in direct contact with the surface of the mattress is prohibited.
Required measures
- A mattress must be installed on a good quality flat base.
- Ensure that the dimensions of the mattress are compatible with the bed. The device must be used with its original protection.

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- If necessary, check that the height of the bed rails is compatible with the thickness of the mattress (a minimum distance of 22 cm between the top of the bed rail and the top of the mattress in the presence of the patient is recommended).

If there is a risk of pressure ulcers/injuries, combine relief devices or positioning systems or replace the mattress with a therapeutic mattress to help prevent pressure sores. It is advisable to:

- Change position at least every 2 to 3 hours.
- Maintain skin hygiene and avoid maceration. Do not tuck bed linen in too tightly; use elastic sheets to maintain the effectiveness of the mattress.
- In the event of incontinence, change incontinence protectors regularly.
- Observe the condition of the skin on a daily basis or have someone do so for you.
- Ensure that you are eating enough and appropriate food, and drink regularly and in sufficient quantities.
- If any of these measures cannot be followed, it is essential to inform your doctor or nurse as soon as possible.
- For the support to be effective, it is important to keep excess thickness between the body and the support to a minimum, with the exception of the sheet for a bed support, the body garment and any full nappy. Cotton outerwear should be loosely fitting and, if possible, without seams in the support area. Do not interpose folded towels or sheets, extra cushions, etc.
- Make sure there are no foreign objects such as tubing, crumbs, grease, etc.

Circumstances in which the user should consult a healthcare professional

Report as soon as possible to your doctor or nurse any abnormal event such as fever, pain, redness or whitening of support points (head, shoulder, back, hip, shoulder blade, pelvis, heel, etc.).

Information concerning the maximum number of reuses permitted

The medical device may be reused as many times as possible, provided that its performance is still guaranteed to be optimal.

Accessories

The accessories intended to be used in combination with CLINIFLEX mattresses are Cartex covers. The use of accessories other than those supplied and specified by WINNCARE France may result in malfunction of the medical device.

Cleaning and disinfection:

Cover					
	Moderate wash up to 90°C	Maximum allowable chlorine concentration of 5000 ppm	Trumble dry on low heat	Do not iron	Do not dry clean
Mattress	Clean with a neutral detergent / disinfect with suitable sprays or aerosols.				

Storage, handling, disposal:

Conditions of use and storage

	Use	**Stockage**
Temperature range	+15°C à +45°C / +59°F à + 113°F	-25°C à +70°C / +13°F à +158°F
Humidity range	30% - 70%	30% - 95%
Atmospheric pressure	50 kPA – 106 kPA	

Mattresses should preferably be stored flat, away from direct light and excessive humidity.

Disposal: Do not burn or dispose of used products in the open air. Dispose of used products at a waste collection centre.

Lifespan: The estimated lifespan of the product is 6 years.

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