

	<p>TECHNICAL DATA SHEET WBS – EMERGENCY BLANKET REF: WBS0003 EMDN: T0299 UDI-DI DI BASE: 08033549310530</p>	<p>DATA: 02.2025</p> <p>ENGLISH VERSION: 06.2025</p>	<p>N° REV: 2</p>
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## WBS EMERGENCY BLANKET

### 1. **DESCRIPTION**

The WBS Emergency Blanket is a single-use, self-heating medical device designed for first aid use in emergency situations where preventing or treating hypothermia and maintaining body temperature control is essential. Its structure and advanced materials make it effective and safe even in extreme conditions.

### 2. **INTENDED USE**

The WBS Emergency Blanket is a ready-to-use heat source designed to support the rapid and effective maintenance of normothermia. It can be used in all situations where it is necessary to prevent or treat hypothermia and control body temperature, such as pre-hospital emergencies, rescue operations in extreme weather conditions, or first aid interventions. The device is intended for use on adult individuals (age > 18 years). It is recommended that the device be used by first responders, even if they do not have specific medical training.

### 3. **PRINCIPLE OF OPERATION**

The WBS Emergency Blanket uses a self-heating system based on an exothermic chemical reaction occurring within the heating patches. When exposed to air, the patches activate a reaction between iron powder and atmospheric oxygen, facilitated by the presence of catalysts. This reaction generates heat quickly and safely, which is then evenly distributed through the integrated pockets within the blanket. The SMS polypropylene fabric design ensures effective thermal insulation, optimizing heat retention and providing continuous thermal support for over 14 hours.

### 4. **PACKAGING**

The WBS Emergency Blanket device is individually vacuum-packed in polyamide and polyethylene pouches, designed to ensure product integrity and protect it from contamination until the time of use. The vacuum packaging provides extended shelf life and enhanced protection against external agents such as moisture and dust.

### 5. **COMPOSITION**

#### **Composition of the Blanket**

The blanket is made of two layers of SMS (Spunbond-Meltblown-Spunbond) non-woven polypropylene fabric, designed to provide strength, lightness, and comfort during use. Integrated within the structure are 12 pockets that contain self-heating patches, ensuring an even distribution of heat.

### 6. **TECHNICAL SPECIFICATIONS**

- Dimensions:
- Opened: 150 x 90 cm.
- Closed: 27 x 31 cm.
- Weight: 648.4 g.
- Heating duration: 14+ ore.
- Temperature range:  $48^{\circ}\text{C} \leq T \leq 52^{\circ}\text{C}$ .



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## 7. **INSTRUCTIONS FOR USE**

To use the WBS Emergency Blanket, follow these steps:





- Carefully remove the device from the vacuum packaging, making sure not to damage the blanket.
- Expose the blanket to air for at least 15 minutes to allow the heating patches to activate.
- Place the blanket over the clothed patient, ensuring that the marked side ("This side up") is facing outward from the patient's body. Avoid covering your face.
- Use the blanket in all emergencies or first aid situations where it is necessary to prevent or treat hypothermia.
- The device is for single use only and must be properly disposed of after use.

## 8. **STORAGE AND STABILITY**

The device should be stored in a cool, dry place, away from heat sources that could compromise the product's integrity. It is essential to ensure that the packaging remains sealed until the time of use to protect the device from contamination and external agents. Proper storage helps maintain the device's efficacy and safety throughout the indicated shelf life. The device retains its properties for 36 months from the production date if kept in its intact packaging. Once opened, the blanket must be used immediately and cannot be stored further.

## 9. **DISPOSAL**

Disposal must be carried out in accordance with local regulations and by consulting the provisions of the relevant municipality.

IFU AND BOX	PAPER	PAP20	
POUCH (VACUUM-PACKED)	PLASTIC	PET1	
BLANKET	GENERAL WASTE	PI	
PATCH	GENERAL WASTE	PI	

## 10. **PRECAUTIONS AND WARNINGS**

### General Warnings

For safe and effective use of the WBS Emergency Blanket, please follow these guidelines:

- The device should only be placed on clothed patients, avoiding direct contact with the skin to ensure safe use.
- Never cover the patient's face with the blanket.
- Do not use in oxygen-rich environments, such as hyperbaric chambers or in the presence of oxygen therapy devices.
- Remove the blanket from the patient before an MRI or X-ray, as the heating materials may interfere with diagnostic equipment.

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- The device is single-use and, after use, no longer functions. It must be properly disposed of according to hospital regulations.
- Avoid damaging the outer packaging of the patches with sharp or pointed objects to prevent compromising the contents.
- To ensure product integrity, open the packaging carefully following the manufacturer's instructions, using only your hands and tearing along the pre-cut corner marked "Open here."

Failure to comply with these warnings may result in serious risks to the patient's health.

### Precautions for Use

The following precautions are essential to ensure the safe use of the WBS Emergency Blanket and to prevent possible thermal injuries:

- The correct side of the blanket is indicated by the inscription "THIS SIDE UP" and must always be positioned accordingly.
- Although the device does not come into direct contact with the skin (it must be placed on clothed patients), it is essential to constantly monitor the skin's response, especially during prolonged use.
- Avoid direct contact with the skin in the presence of open wounds, bruises, edema, early-stage frostbite, or transdermal dressings. The heat generated may increase the absorption of medications from transdermal medical systems (patches).
- Do not fold the blanket onto itself, and do not apply pressure or add weight on the blanket, including medical instruments or other heavy objects.
- Do not use on patients with severe peripheral circulation disorders, including:
  - Severe hypotension or expected prolonged hypotension
  - Severe peripheral vasculopathies
  - Aortic surgery or distal aortic clamping
  - Severe heart failure or cardiogenic shock
- Do not use the device on pregnant or breastfeeding women without prior medical consultation.

In the event of accidental leakage of the material contained in the pouches, remove the blanket from the patient and promptly take the following precautionary measures:

- **Eye contact:** Rinse thoroughly and abundantly with water for at least 15 minutes. Seek medical advice if discomfort or irritation occurs.
- **Skin contact:** Under normal conditions, no damage is expected. First aid is generally not required, but in case of skin reactions, wash with water and soap.
- **Ingestion:** Do not give anything orally to unconscious persons. Contact a physician immediately.
- **Inhalation:** Move the person to fresh air. If breathing difficulties occur, administer oxygen and seek medical advice.

Inform first aid personnel about the nature of the substances contained, referring to this document. For added safety, use appropriate personal protective equipment to avoid contamination.

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### 11. **CONTRAINDICATIONS AND SIDE EFFECTS**

















In case of hypersensitivity, skin irritation, or presence of allergies, it is recommended to immediately discontinue use of the device and consult a physician or pharmacist.

The user must report any contraindications, side effects, or serious incidents related to the use of the device both to the manufacturer ([certificazioni@zetagroupsrl.com](mailto:certificazioni@zetagroupsrl.com)) and to the competent authority of the Member State of residence, in order to contribute to improving product safety.

### 12. **CLASSIFICATION**

- **Category:** Class IIa medical device.
- **Sterility:** Non-sterile.
- **Marking:** CE<sub>1370</sub>, compliant with EU Regulation 2017/745.

### 13. **SYMBOLS IN USE**

Simbolo/Symbol	Significato/Meaning	Simbolo/Symbol	Significato/Meaning
	Fabbricante del dispositivo medico/ Manufacturer of medical device		Marchio dispositivo medico/ Medical Device Mark
	Marchio CE / CE mark		Non usare in caso di danneggiamento della confezione/ Do not use in case of damaged packaging
	Attenzione: leggere le istruzioni per l'uso/ Attention: read the instructions for the use		Mantenere in un luogo asciutto e proteggere dall'umidità e dalla luce diretta del sole/ Keep dry and protected from moisture and direct sunlight
	Dispositivo monouso, non riutilizzare/ Single-use device, do not reuse		Data di scadenza/ Expiration date
	Numero di lotto/ Lot Number		Necessario per la sorveglianza Post Mercato / Required for Post-Market Surveillance
	Codice UDI / UDI Code		Codice REF / REF Code
	Non sterile / Non-sterile		Avvertenze / Warnings
	Non contiene ftalati / Does not contain phthalates		Non contiene lattice / Does not contain latex

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