HULK
BARIATRIC

INSTRUCTIONS FOR USE
BARIATRIC EVACUATION MATTRESS



EnSafe.One
A world open to all

This is a medical device.
Use it in accordance with the instructions for use or the label.

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Thank you for choosing ENSAFE.ONE products.

1. PURPOSE OF THESE INSTRUCTIONS FOR USE

These instructions provide all the information required for the correct and safe use of the device. Read these instructions carefully before use and follow all recommendations they contain.
These instructions include:

- a description of the evacuation mattress and its design,
- its scope of application,
- how to prepare it for use,
- rules for safe use,
- information on technical inspections, maintenance and cleaning,
- warranty terms, the warranty card and the maintenance log.

If you have any questions, please contact the seller or the manufacturer.

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2. DEFINITIONS

Operator – a person who has acquired the knowledge and competence to operate the device during training delivered by an Authorized Trainer. With these skills, the Operator is able to use the device safely. The Operator is authorized to use the device during an evacuation or whenever transport is required.

User – a person using the device in emergencies, during evacuation drills or for medical transport. This may be a person with special needs who requires assistance to evacuate a building, a patient being moved to another location, or a person who requires safe transport for health reasons.

Person with special needs – a person who, due to their health condition or other limitations, is unable to move independently and requires assistance during evacuation or transport.

Administrator – a person appointed by the customer who oversees the technical condition, technical inspection schedule and cleanliness of the devices.

Authorized Trainer – a person authorized by the Manufacturer to provide training in the use of the device. The Authorized Trainer has the technical knowledge and practical experience required to communicate information about the device reliably and comprehensively.

Authorized Service – a location or entity designated by the Manufacturer to carry out servicing, maintenance and repair of the device.

Service Technician – a person authorized by the Manufacturer who has the knowledge required to service, maintain and repair the device.

Medical device (as defined in Regulation (EU) 2017/745) – means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Incident (as defined in Regulation (EU) 2017/745) – means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Serious incident (as defined in Regulation (EU) 2017/745) – means any incident that directly or indirectly led, might have led or might lead to any of the following:
a) the death of a patient, user or other person;
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health;
c) a serious public health threat.

Serious public health threat (as defined in Regulation (EU) 2017/745) – means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

2. WARNINGS

• Use the device only for its intended purpose.

• The device may be operated only by suitably trained persons who are included on the list of personnel authorized to carry out evacuations.

• Operator authorization is granted for a specific device and does not extend to similar devices.

• Before each use:

- read these Instructions for Use,
- check the technical condition of the device in accordance with the Manufacturer's recommendations.

• If any damage or technical defect is found, immediately take the device out of service and contact the Manufacturer.

• Never exceed the maximum load (max. 300 kg).

• The Operator must:

- secure the evacuee correctly in accordance with these Instructions,
- supervise the person being transported at all times,
- avoid sudden movements, as these may cause injury (to the User and/or the Operator),
- keep hold of the mattress at all times when descending stairs.

• The device may become hot when exposed to sunlight – take care when touching its surface.

• During procedures involving the person being transported, the Operator should wear appropriate personal protective equipment (e.g. gloves, mask) to minimize the risk of contact with body fluids.

• Do not use direct heat sources or open flames near the device.

• Store the device in accordance with the Manufacturer's recommendations.

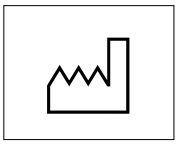
• Carry out technical inspections in accordance with the schedule and rules set out in the Warranty Card attached to these Instructions for Use.

In the event of a medical incident involving the device, notify the Manufacturer in writing without delay via the website **www.ensafe.one** or by registered mail.

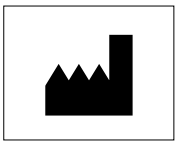
WARNING!

- **DO NOT EXCEED THE MAXIMUM LOAD (MAX. 300 KG)**
- **NEVER LEAVE THE USER UNATTENDED!**
- **THE DEVICE MUST BE OPERATED ONLY BY SUITABLY TRAINED AND COMPETENT OPERATORS.**

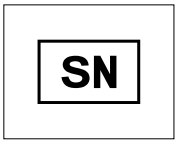
4. EXPLANATION OF SYMBOLS



MANUFACTURE DATE



MANUFACTURER NAME



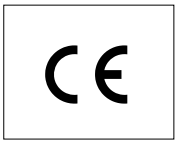
PRODUCT SERIAL NUMBER



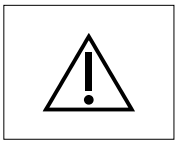
MEDICAL DEVICE



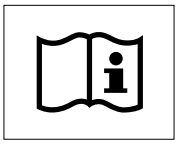
PERMISSIBLE USER WEIGHT



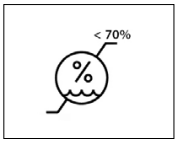
CONFORMITY ASSESSMENT



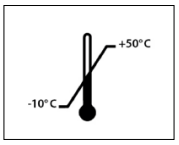
WARNINGS



PRODUCT INSTRUCTIONS FOR USE



AIR HUMIDITY

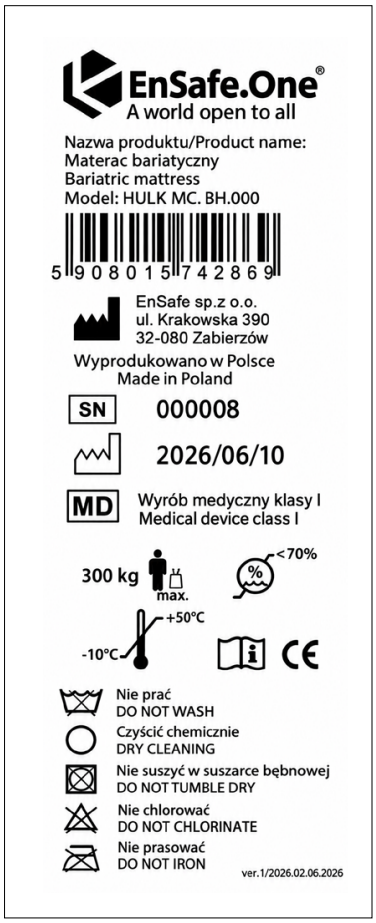


STORAGE TEMPERATURE

5. LABEL

Label – contains the required information identifying and describing the medical device, including:

- the Manufacturer's name,
- the device model,
- the date of manufacture,
- the serial number,
- the maximum permissible load (User weight),
- the CE conformity marking,
- the marking classifying the product as a medical device,
- the UDI code,
- a pictogram indicating that the Instructions for Use must be read before using the device,
- cleaning instructions for the device.



The label is located on the inside of the mattress, under flap no. 1.
Never remove or cover the label.

6. INTENDED PURPOSE AND SCOPE OF USE OF THE HULK BARIATRIC EVACUATION MATTRESS

The HULK Bariatric mattress is a Class I medical device intended for the evacuation and/or transport of persons with special needs. It is designed for the transport and/or evacuation of one person in a lying position down and up stairs, for transport across level surfaces and for carrying over obstacles.

It enables people to be transported and/or evacuated from a building in emergencies when elevators cannot be used or when other devices, such as evacuation chairs, cannot be used.

Persons with special needs include: persons with a physical disability (permanent or temporary) or an intellectual disability (a person who cannot make decisions independently and remains under the supervision of a caregiver), older adults, pregnant women, persons with temporary injuries (e.g. lower-limb fractures), and persons with excess body weight who are unable to move independently (the weight of the person with special needs must not exceed 300 kg).

Contraindications:

A person operating the evacuation mattress (Operator) must not perform this role if they:

- have not completed the required training in the operation of the device;
- have physical limitations that may prevent safe use (e.g. balance problems, impaired coordination, musculoskeletal disorders), or do not have sufficient physical strength to maneuver the device, especially on stairs;
- have medical conditions that may affect their ability to operate the device steadily (e.g. epilepsy, vestibular disorders), or have an implanted pacemaker;
- are not suitably dressed: lacking stable, flat-soled footwear; wearing clothing that is too loose, flowing or ill-fitting, which may increase the risk of catching on parts of the device; or wearing clothing that restricts the Operator's movement or reduces their ability to maneuver the device;
- cannot cope with working under high stress or time pressure;
- are under the influence of alcohol, narcotics or medications that affect consciousness, reflexes or motor coordination.

The evacuation mattress should not be used for persons:

- who experience sudden, uncontrolled muscle spasms,
- who have violent tics or seizures,
- whose body weight exceeds the permissible load of the device specified in the technical specifications.



If there is any doubt about using the device for a particular User, consult the User, their caregiver (if present) or the person responsible for their medical care – e.g. a paramedic, physician or qualified personnel.



Use of the device for any purpose other than its intended purpose is prohibited.

The device may be used in accordance with these Instructions for Use by suitably trained and competent operators solely as an aid to ensuring the safe evacuation and/or transport of persons with special needs. The owner, manager or person in actual control of the building must provide the necessary evacuation procedures, trained personnel and periodic technical inspections of the equipment used during evacuation, including the HULK Bariatric mattress (inspections should be carried out by an Authorized Service designated by the Manufacturer), as well as maintenance. This will ensure the safe evacuation of all Users from the premises in situations that threaten life or health before the emergency services arrive.

7. TECHNICAL SPECIFICATIONS





TECHNICAL SPECIFICATIONS		
Manufacturer:	EnSafe sp. z o.o.	
Address:	ul. Krakowska 390, 32-080 Zabierzów, Poland	
Device type:	Bariatric mattress	
Model:	HULK Bariatric	
Device class:	I	
Maximum permissible User weight:	300 kg	
Total device weight (without cover):	7 kg	
Mattress dimensions [L x W x T]:	205 x 85 x 7 cm	
Dimensions folded in half [L x W x T]:	106 x 85 x 15 cm	
Safety belts:	3 pcs.	
Securing flaps:	3 pcs.	
Carrying handles:	2 main and 12 side handles	
Head immobilizer:	1 pc.	
Mattress material:	Rubberized Poliester	
Storage and operating temperature:	-10°C	+50°C
Storage and operating humidity:	< 70%	
Storage method:	Transport bag or wall mounting cover	

8. HOW TO USE THE HULK BARIATRIC MATTRESS



The HULK Bariatric evacuation mattress may only be used by authorized persons, i.e. Operators.

Before use, the Operator must visually inspect the evacuation mattress, i.e. check that the material is undamaged and that the seams are intact.

The device must not be used if any defect in its technical condition is found.

The Operator should be dressed in a way that allows complete freedom of movement. Flat-soled footwear that fits well, is comfortable and will not slip off accidentally is required (flip-flops, among others, are not permitted). Clothing should be ergonomic and must not restrict movement while operating the device. Excessively loose or flowing items of clothing must not be worn.

Before positioning the person to be transported, assess whether additional Operators are needed.

If there is any doubt about using the device for a particular User, obtain information directly from the User, their caregiver (if present) or medical personnel, e.g. a paramedic, nurse or physician.

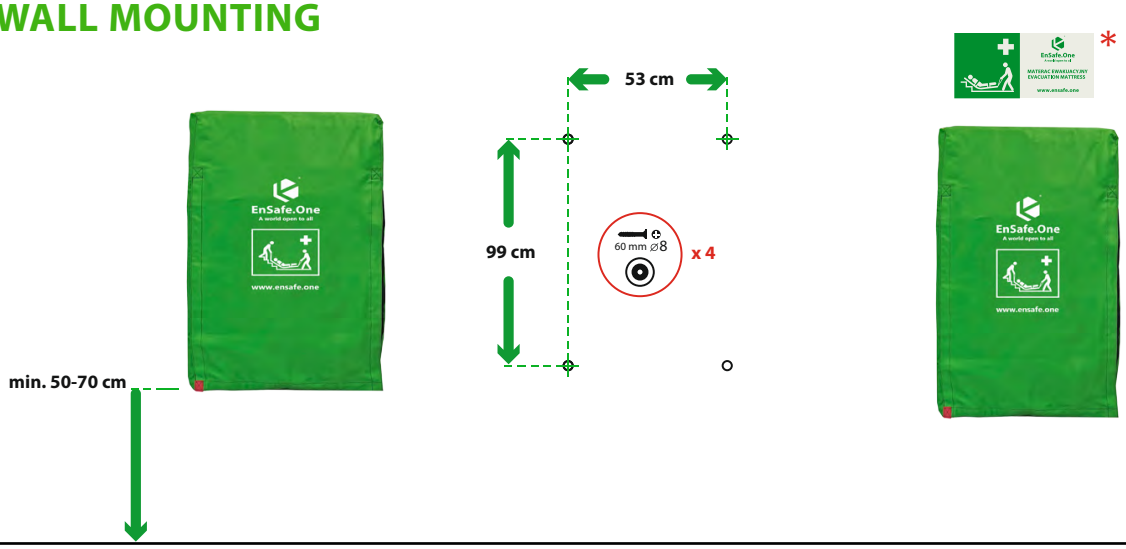


The person being transported must have their belts correctly fastened and must not lean to either side.



The Operator must never leave the User unattended on the evacuation mattress.
The Operator must never let go of the evacuation mattress when descending stairs or when transporting the User between obstacles. The Operator must avoid sudden movements of the mattress, as these may cause injury to the User.

9. WALL MOUNTING



1. Unpack the package and check that the contents are complete. Choose an installation location for the mattress (installation near stairwells is recommended). Check the chosen location for building services (gas, water and sewage, electrical, etc.). Install in a location where these services do not run. The mattress brackets must be installed at a height of at least 50–70 cm, measured from floor level.

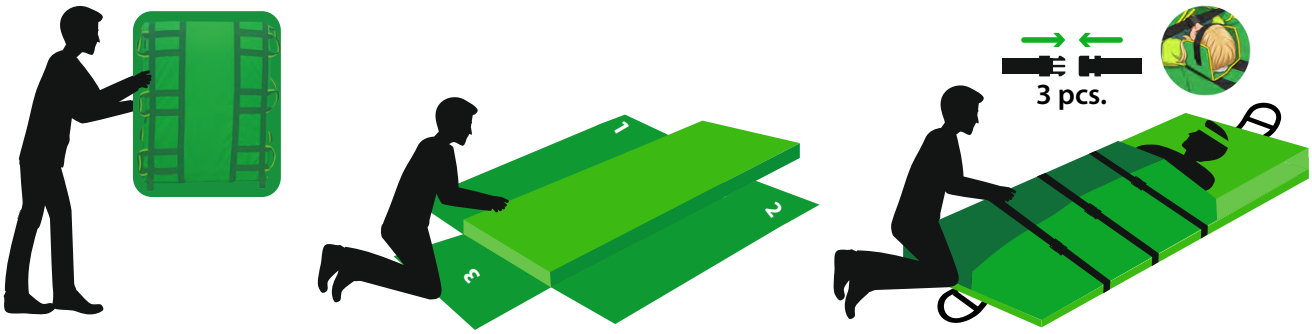
2. Hold the supplied mounting brackets against the wall and mark the hole positions. Select a drill bit to match the supplied wall plugs, then drill four holes (wall plug spacing: 53 cm horizontally, 99 cm vertically). Insert the wall plugs, then screw the cover to the wall using the washers.

3. Place the mattress in the wall mounting cover. Affix the evacuation mattress sign above the installation location.

* The product is supplied with either a wall-mounted cover or a transport bag, depending on the customer's choice.
The photoluminescent sign is an optional accessory.

10. UNFOLDING, POSITIONING THE EVACUEE AND TRANSPORT DOWNSTAIRS AND UPSTAIRS

⚠ Unfold the mattress on a flat surface. The person must be placed on and removed from the evacuation mattress on a stable, level surface.



01 Remove the mattress from the cover mounted on the brackets.
Check that the mattress is undamaged and in good working order (no visible damage or tears).
Check the carrying handles.
Check that the safety belt and hook-and-loop fasteners are complete and in good condition.

02 Unfold the mattress with all its flaps.
After placing the person to be transported on the mattress, close all flaps with the hook-and-loop fasteners in their numbered order (1–3).
Secure the person being transported using the 3 safety belts.

03 Check that all flaps and safety belts are fastened and that the head stabilizer is in place.
Using two carrying handles, two Operators can begin transporting the person on the mattress.

⚠ Transport and/or evacuation may begin only after confirming that the safety belt is correctly fastened.

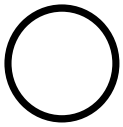
⚠ When transporting/evacuating down stairs or on a level surface, the HULK Bariatric evacuation mattress should be operated by **at least two persons**.

11. CLEANING AND STORAGE

Dry clean only. Maximum washing temperature: 40°C. Do not bleach or use chlorine. Do not tumble dry. Do not iron at temperatures exceeding 150°C.



Do not tumble dry



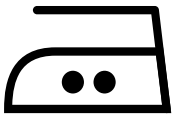
Dry cleaning



Max. wash temperature 40°C



Do not bleach or chlorinate



Max. ironing temperature 150°C

Disinfect the structure using commercially available surface disinfectants.

Due to the risk of contact with the body fluids of the person being transported, the Operator or Administrator must always wear appropriate personal protective equipment, such as gloves, a mask, etc., during all inspection and cleaning procedures.

Do not use high-pressure water – it may damage the protective coating.
Failure to follow this recommendation may compromise the device and its service life.

Do not use direct heat sources or flames.

Clean the device after each use. Allow the device to dry completely before storage. Store the device in a dry, clean, ventilated place at a temperature between -10°C and +50°C and a relative humidity of <70%.

After cleaning, fold the HULK Bariatric evacuation mattress, place it in the bag or cover and store it in a designated location.

12. TECHNICAL INSPECTIONS

The device must undergo annual inspections to verify that it functions correctly and meets the safety requirements guaranteed by the Manufacturer at the time the device was placed on the market. Inspections must be carried out by an Authorized Service designated by the Manufacturer, using specialized Service Technicians.

EnSafe sp. z o.o. accepts no liability for any device that has not undergone a technical inspection approving it for further use.

The Manufacturer accepts no liability for damage resulting from improper use or from maintenance and technical inspections carried out by persons not authorized to perform them.

To keep medical devices fit for use, the Manufacturer recommends appointing an Administrator responsible for ensuring that technical inspections are up to date and for overseeing the technical condition and cleanliness of the device.

The following maintenance tasks may be carried out by a trained Operator:

- Safety belts – check fastening, check for damage, check that they do not open unintentionally;
- Fabrics – general condition, degree of wear, no abrasion, cracks or seam tears;
- General technical condition – no damage, full functionality of the device retained.

Carry out the inspection before each use or at least once a year (if the device is stored correctly).



If any defect is found in the technical condition of the mattress or any of its components, immediately take the device out of service and contact the Manufacturer.

If the above recommendations are not followed, the device must be disposed of and the Manufacturer notified, or the device must be withdrawn from service.

13. MALFUNCTION



In the event of a malfunction, secure the device and label it appropriately to prevent its use. Then report the malfunction to the seller and/or the Manufacturer, who will arrange a visit by an Authorized Service Technician.

Contact details are available at **www.ensafe.one**

14. SERVICE LIFE AND DISPOSAL

A worn-out device must be recycled in accordance with national regulations.

15. WARRANTY

Warranty details are provided on the enclosed warranty card.

Manufacturer:
EnSafe sp. z o.o.
ul. Krakowska 390
32-080 Zabierzów, Poland

Trade name of the device: **HULK Bariatric Mattress**
Country of origin: Poland

Product information:
Class I medical device in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, as amended).

Contact the Manufacturer: biuro@ensafe.one

MD CE

Instructions issued: 26.10.2026
Version no.: HULK Bariatric WER. 01