



STANDING FRAME
PARAPION™



USER MANUAL





Manufacturer takes responsibility for proper usage of the device only when the product was purchased from qualified Akces-Med employee or at specialized medical store!

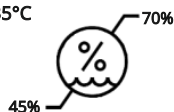
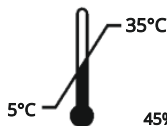
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Product marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.



Akces-Med. Sp. z o.o. Company introduced quality management system ISO 13485 regarding production, sales and service. The system is certified by Det Norske Veritas.





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INTRODUCTION

We know very well how important it is for the user to adopt the standing position, that is why we have created a product called **PARAPION™** which is ideally suited for this purpose. **PARAPION™** allows you for full and safe upright standing.

Stable construction, ergonomic knee supports, wide pelvic and chest belts are the basic elements ensuring safety and comfort during the therapy. The user, who is placed in this device, is able to perform rehabilitation treatment as well as simple domestic or professional activities. The standing frame is equipped with four noiseless castors which enable easy relocation of the user.

Remember to read this user manual carefully. You will find not only useful information but also guidelines regarding safe and effective use of the product.

If you have any questions or remarks, do not hesitate to contact with us:

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Akces-MED Sp. z o.o.: ph. +48 17 864 04 77

e-mail: export@akces-med.com

Thank you for purchasing our product.



CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual. Remember that complying with guidelines is highly important. It assures safety and extends durability as well as aesthetics of the device.





1 THE PURPOSE OF USER MANUAL



The present user manual contains basic information which is essential for :

- preparation before use,
- proper usage,
- maintenance, cleaning and guarantee conditions.

User manual should be kept in easily accessible place. It is designed for people who look after the disabled , and for both doctors as well as physiotherapists who operate the device. Before using the **PARAPION™** standing frame, user is obliged to familiarize himself/herself with user manual.

2 INDICATIONS AND CONTRINDICATIONS FOR USE

The standing frames are intended for people with orthopedic, neurological and cardiological diseases and for people after surgery who are unable to adopt and maintain a standing position on their own as a result of prolonged immobilization. The device is an irreplaceable aid in the rehabilitation process, both in terms of movement and social integration. It is great help in everyday activities such as rehabilitation but also during playing or studying. The selection of the appropriate size of the device depends on medical indications and anatomical parameters, regardless of the age of the user.

The device is recommended for people in the following cases:

- cerebral palsy – various types and forms,
- brain and spinal cord injuries with lower limbs paralysis and weakness,
- balance and motor coordination disorders with different etiology,
- demyelinating disease (e.g. multiple sclerosis – SM),
- meningocele,
- muscles diseases with weakness and paralysis (dystrophy, myasthenia gravis, myositis),
- genetic disorders,
- degeneration and neurological diseases,
- other condition connected with muscles weakness, paralysis and
- musculoskeletal disorders,
- after head and spinal cord injuries and spine trauma with paralysis and
- paresis.





Contraindications:

While standing upright, the user who is in a standing position should be closely monitored. The therapy should be discontinued in case of such side effects as: turning pale, sweating or fainting, joint strain and the resulting deformities of the body. Further proceeding should be consulted with the medical specialist or a physiotherapist who prescribed the treatment. The critical condition of the user is an absolute contraindication to standing upright.

- Relative contraindications for upright standing are: arterial hypertension at rest above 200/110 mmHg, pulmonary hypertension, cardiac arrhythmias, unstable asthma, unstable metabolic disorders, moderate heart valve disease.
- Any condition, such as a healing fracture or severe osteoporosis, that makes it impossible to bear the user's own bodyweight.
- Bone fracture with incomplete union, unless approved by a doctor.
- Postoperative restrictions on joint loading.
- Pain while standing in the standing frame (caused by subluxation or dislocation of the hip joint, overstretching of soft tissues or excessive pressure). Subluxation or dislocation of the hip joint in the absence of pain is not a contraindication.

People with significant flexion in the hip or knee joints, as well as with contractures in the ankle joint, may not be able to use the standing frame. Make sure that the position of the user in the standing frame does not cause excessive pressure or stretching of affected areas of the body. In such cases, standing upright may be contraindicated until a greater range of motion is achieved in the contracted joints.

In case of people with impaired cardiovascular system (arterial hypertension at rest above 200/110 mmHg, pulmonary hypertension, cardiac arrhythmias, moderate heart valve disease); respiratory system (unstable asthma) and unstable metabolic disorders, it is necessary to monitor the user while standing in order to prevent serious complications.





3 GENERAL CHARACTERISTICS OF STANDING FRAME

3.1. Standard equipment

1. Frame with castors and brakes,
2. Foot plate with foot stabilization,
3. Adjustable knee support,
4. Chest brace with chest belt (adjustable),
5. Pelvic brace with pelvic belt (adjustable),
6. Low armpit supports,
7. Tray with plate (size 1)





3.2. Additional equipment



PPN_002

**Belt for moving patients
AM-P**



PPN_003

Soft cover for tray



PPN_015
PPN_016
PPN_020

Tango Wheel 75 /100/125 mm



PPN_111

**Independently adjustable knee
supports**



PPN_112

Forearm supports



PPN_116

Longer pelvic belt



PPN_140

High armpit supports



PPN_157

Chest support



PPN_158

Pelvic support



PPN_159

Longer chest belt



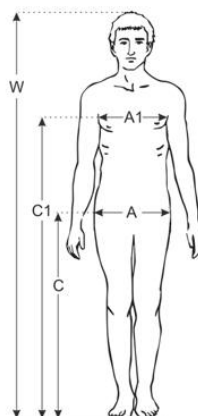
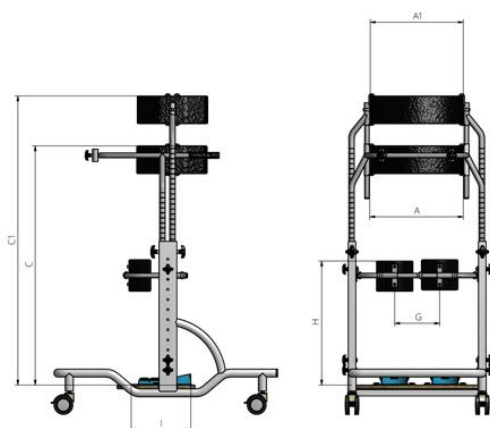
PPN_401

Tray





4 SIZE TABLE



Symbol	Measurement	Unit	Size 1	Size 2	Size 3
W	Indicative user height*	[cm]	90 – 140	110 – 170	140 – 200
A/A ₁	Pelvic/chest support width	[cm]	23	31	38
C	Pelvic support height	[cm]	61 – 90	80 – 104	92 – 122
C ₁	Chest support height	[cm]	73 – 111	92 – 126	107 – 163
	Pelvic/chest support circumference	[cm]	56 – 76	80 – 102	95 – 124
G	Knee supports width	[cm]	12 – 22	16 – 24	20 – 31
H	Knee supports height	[cm]	18 – 45	24 – 49	31 – 71
I	Footer length	[cm]	23	27	30,5
	Max. user weight	[kg]	30	55	95

Note: Measurement tolerance range is +/- 1 cm / 1/2 in.

*This measurement cannot be the main parameter while choosing the product size.

Weight and dimensions	Unit	Size 1	Size 2	Size 3
Width	[cm]	56	56	67
Length	[cm]	75	87	93
Height	[cm]	73	92	107
Weight	[kg]	17	21,5	27,5

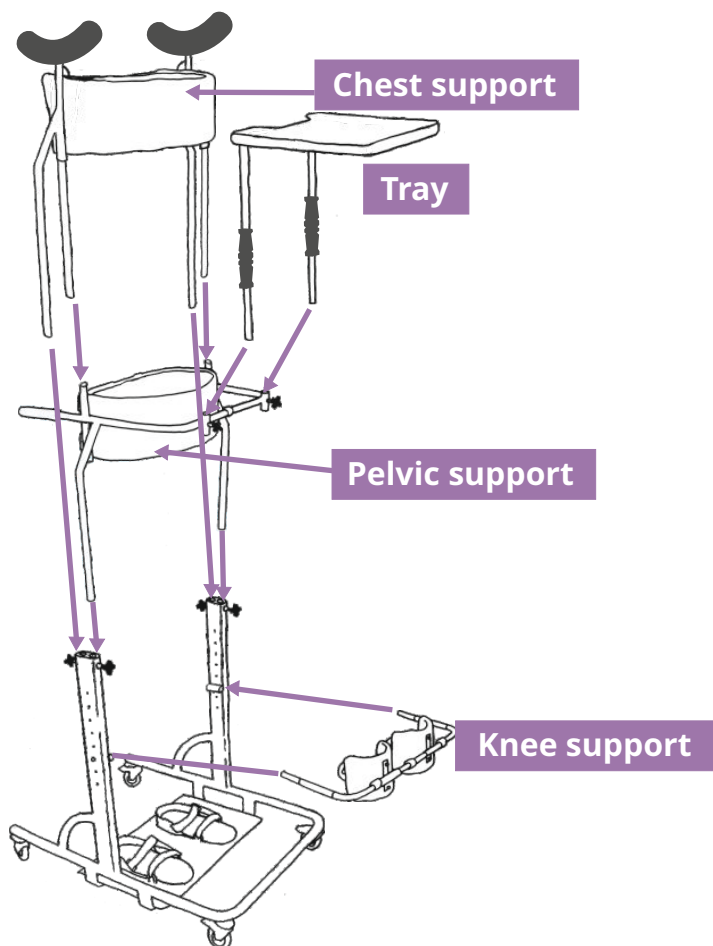
Note: Measurement tolerance range is +/- 1 cm / 1/2 in.

Note: Approximate values, depending on the product configuration.





5 MOUNTING THE STANDING FRAME



ATTENTION! Assembly of the standing frame should begin by inserting the pelvic support (hip support) into the guides placed in the frame (as seen in the figure). Next, we mount the chest support in a similar way. Afterwards we mount the table and foot stabilizer (in any order) as shown in the picture.





6 RULES OF ADJUSTING THE STANDING FRAME TO THE USER



WARNING! Adjustment of the standing frame to the patient is done by trained personnel only! All exercises must be performed only in the company of appropriately trained personnel.

Adjusting the device to the patient:

1. Measure the length from the ground to the knee joints. Set the knee support at this height.
2. Measure the distance between the ground and the trochanter of the thighbone. At this height set the pelvis(hip)support.
3. Measure the distance between the ground and axillary(armpit). Set the chest support at this height.
4. We approach the standing frame with the patient in his chair.





5. Stabilize feet on the foot stabilizer with the straps.



Straps in the knee stabilizer and knee supports should be unfastened. Place the feet in the foot stabilizer, retracting the foot (pushing it back) to the metal clamp/support and fastening the straps.



In the case of occurrence of abduction-adduction in the forefoot of the patient, the feet in the foot stabilizer should be set at an appropriate angle.

6. Stabilize the knees in previously set knee supports by additionally fastening the stabilization straps.



7. Open the hip and chest supports.





8. We position the patient in standing frame.



9. Fasten the hip and chest supports , additionally securing with belts.



Chest support fastening

Pelvic support fastening





10. Check if the patient is standing straight, and if the projections of shoulders, hips and knees coincide in a straight line. If not then we should adjust the hip, knees and chest support, so that the patient stands straight. This is very important as it prevents the formation of contractures in the ankle joints, knees and hips.





7 THE USE OF STANDING FRAME



CAUTION! PARAPION™ has to be used with compliance to guidelines included in this user manual. Remember to use the product only with someone who is trained and knowledgeable. Do not forget to prepare both product as well as patient before using PARAPION™!

9.1. Preparation of the patient

Before using the product, it is essential to make sure that:

- patient's outfit is light and comfortable sporty clothes are advisable;
- shoes should be comfortable and, moreover, they should stabilize ankle;
- due to hygienic reason and to avoid abrasion it is advisable for the patient to always wear clothes when using the device, skin must not be naked especially in places of regular contact with upholstery;
- drains, bags, catheters etc. if applied, have to be secured to function properly and not to disturb during using the product;
- if it is necessary for a patient to wear orthopedic supply (collar, corset, orthosis, shoes) if it is recommended by doctor.



CAUTION! Outfit should protect patient's skin from direct contact with upholstery as well as other parts of equipment.

CAUTION! Only doctor can make a decision concerning using any kind of orthopedic supply!





8.2. How to use PARAPION

1. Before use it is necessary to:

- Unfold the device;
- Place the device on even ground;
- Make sure that all parts are serviceable, correctly mounted and stable;
- Block brakes;
- Adjust the device to patient's measurements;
- Undo vest, trunk belts etc so as to place easily the patient in the device;
- Place patient in the device;
- Fasten all elements which stabilize patient e.g. vest, trunk belts, feet stabilizing belts etc.;
- Mount additional equipment e.g. tray.



Equipment works correctly only when the device is adjusted according to patient's height as well as weight. Remember to take all these measurements into account while purchasing the product. Correct adjustment is the most important due to the fact that only then the product is safe. It is forbidden to force child to keep specific position because he/she will feel uncomfortable and it may lead to wrong posture.

Remember to make sure that all belts and locking are correctly adjusted and fastened. Check also if fastenings from adjustable elements are firmly tightened.





8.3. Upright position

CAUTION!

The length of time for upright position process is different for each patient. It is recommended to extend this time during the initial period (adaption period for the change of position). Either doctor or physiotherapist can make decision concerning the length of upright position process. Upright position process has to be always performed under the supervision of trained person!

It is recommended to divert patient's attention during upright position process by:

- manipulation games
- educational games
- touch stimulation and others



It is highly important to adjust the device to the patient before using it!

Make sure that all belts as well as fastenings from adjustable elements are correctly adjusted and fastened.

It is forbidden to leave the patient unattended!

Only trained staff can adjust standing frame to the patient!

As far as first upright standing is concerned, it takes place in rehabilitation, neurosurgery or orthopedics wards. Moreover, it has to be performed together with doctor and physiotherapist due to the fact that medical problems may appear during first treatments such as fainting, drop in blood pressure, dizziness etc. Upright standing is continued in home together with trained staff (rehabilitation technician, district nurse, trained family members).





Incorrect adjustment of the device can lead to side effects such as: fainting, body deformities, overloading joints. It is highly advisable to adjust the device before every use of a standing frame. This adjustment has to be done only by a trained person or therapist. If any of these side effects appear, it is highly important to stop the upright position process, take out the patient from the device and lie him/her down. If these undesirable side-effects still occur it is necessary to contact doctor. If these side effects disappeared, remember to inform doctor so as to make decision concerning further upright position process.





8 SAFETY RULES



CAUTION! Standing frame **PARAPION™** has to be used in compliance with guidelines in this user manual.

It is highly important to consult either doctor or physiotherapist in order to make right decision concerning the choice of **PARAPION™** and its size. It is also essential to familiarize with the guidelines described in user manual before using the device.

1. Before use it is necessary to:

- make sure that there are no damages or different faults which could endanger patient's life; check if all parts are working and are correctly mounted and, moreover, check if they are not broken;
- check if all screws, knobs and all glued, sewed or tapped parts are tightened;
- check if brakes are operating correctly;
- check if buckles are operating correctly;
- always use safety belts, Velcro tapes should overlap min. 8cm;
- adjust the device according to patient's measurements and needs;
- make sure that all movable parts and knobs for adjustments are stable and locked;
- secure patient with the aid of elements such as pelvic harness. It is highly important to secure patient because it safeguards him/her from falling out.





2. It is forbidden to use the device for different purposes that it is intended to.
3. It is forbidden to use the device when it is damaged or any part is missing.
4. It is forbidden to leave the patient unattended.
5. The device should be used only when there is someone who is trained and knowledgeable.
6. It is forbidden to leave the device and the patient on unstable ground unattended, even if the brake is engaged.
7. It is forbidden to either go up or down the stairs; it doesn't matter if the patient is placed in the device or not.
8. It is important to engage brake during getting into and getting out the device.
9. Make sure that all limbs are not close to spokes or other adjustable elements.
10. Please pay your attention when approaching to sources of fire or sources of high temperature during using the device. Moreover, device shouldn't be stored in rooms with high humidity.
11. Secure the device during transportation in order to avoid any possible damages. Manufacturer doesn't take responsibility for damages which appeared due to improper preparation of the device during transportation.
12. Before using the stander, remove all paper and plastic packaging. The packaging is not a toy! Keep away from children and animals



Incorrect product adjustment can lead to such side effects as fainting, body deformities, joint overload, etc. If the abovementioned symptoms occur, stop using the product immediately, take the user out of the product and lay them down. If the undesirable symptoms persist, contact a physician immediately. If the symptoms have disappeared, inform the attending physician about this fact in order to make a decision about the further rehabilitation process.

This device can be only used inside the buildings.

The device contains small parts which children may swallow.

Do not use a product that has any signs of damage, tearing or wear. Only an undamaged product and proper use guarantee its right and safe working. If the product is damaged, discontinue use and contact the manufacturer.





It is forbidden to make any changes concerning device's structure due to the fact that it is dangerous and it results in losing warranty.

Under no circumstances should an unqualified person repair or alter the product and its construction, as the health and safety of the user depend on it as well as it will lead to the loss of warranty.

The weight of user should not be bigger than maximal weight described on page 9 where you will find information regarding this issue.

Serious incidents involving this device should be reported both to manufacturer and to the competent authority in your country.

10 TERMS OF WARRANTY

- 1) **Akces-MED Sp. z. o. o** sells products free from manufacturing defects or faults.
- 2) Manufacturer gives the purchaser **24-month** guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
- 3) All defects which appear after warranty period can be repaired only when the user will pay for it. This rule doesn't apply to refunded products - user can ask National Health Refund for refund.
- 4) Manufacturer claims that the product can be used for **36 months**. User can use this product after this period only when he/she will send the device to manufacturer so as to service it. Next, manufacturer determines again how long the product can be used and, moreover, the date of the next service will be determined.
- 5) If product is damaged, please contact our dealer or **Akces-MED Sp. z. o. o** customer service (ph. 17/864 04 77)





11 MAINTENANCE AND CLEANING

The standing frame **PARAPION™**, which is a medical device, should always be kept clean and should be used in accordance with the manufacturer's instructions. The standing frame should be kept in a clean, dry and ventilated room. Maintenance and cleaning must be done at least once a month. Periodic cleaning and maintenance of the device is essential to keep its proper functioning and safety.

Recommendations for cleaning the upholstery and other elements of the device:

1. Wash with warm water using a soft cloth and mild cleaners.
2. Make sure the cloth is not too wet, as this may enlarge the stain and damage the upholstery or foam inside the upholstery.
3. Remember to remove excess moisture from the upholstery before the next cleaning.
4. The upholstery must not get wet during cleaning.
5. You must not soak the upholstery.!
6. After cleaning the stains, the upholstery should be rinsed with lukewarm water and dried with a clean cloth.
7. Do not use hard brushes for cleaning the upholstery.
8. Do not clean the upholstery with strong chemicals, e.g. solvents or chlorine-based caustics.
9. Do not clean, replace any elements or maintain the standing frame during use.
10. Metal and plastic elements should be cleaned by hand with suitable cleaners, after having read the recommendations of the manufacturer of the given cleaner
11. It is possible to disinfect metal, plastic, wooden and upholstery elements of the product with a generally available disinfectant. In order to disinfect the selected element, spray its surface with a disinfectant generally available on the market and wipe with a dry, clean cloth. After disinfection, wait until the element is completely dry, especially in the case of upholstery. Before using the disinfectant, first check in an invisible place whether the product will not discolor or damage the disinfected surface.





Remember that upholstery has to be always dry before using!

The manufacturer of the standing frame, Akces-MED Sp. z o. o., is not responsible for any damages caused by using unsuitable cleaners.

Before using it is necessary to:

- clean wheels;
- check if base as well as wheels are correctly mounted; check if brake stops turning wheel;
- check if standing frame construction is free of breaks or any kinds of deformities;
- check if all movable parts are working and all screws, nuts, knobs etc. are correctly tightened;
- check if belts are not frayed; check if buckles and clamps work correctly.



Manufacturer takes responsibility only for hidden faults or damages which appeared despite the fact that user complied with the guidelines.

In case of any damages, it is essential to contact the person who sold you the product.





TECHNICAL INSPECTION

Technical inspections should be performed regularly. Before servicing, the product should be thoroughly cleaned to reveal any hidden damage.

Frequency	What should be checked? What should be done?		Remarks
Before each use.	General condition of the product.	Check: <ul style="list-style-type: none"> the entire product for any visible damage, cracks or mechanical defects,, if the product complete, if all bolts, screws, knobs, nuts and other elements of the construction are complete and tightened.. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Wheels and brakes.	Check: <ul style="list-style-type: none"> if the wheels are properly mounted and if they are not damaged, if the brake is blocking the spinning wheel, if the wheels are not dirty. If necessary, clean the wheels. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Fastening of the construction elements.	Check all the mechanisms of the product and its moving parts. Check in particular: <ul style="list-style-type: none"> if the seat is properly mounted (if applicable), if the wheels are properly mounted (if applicable), if the elements securing the user are properly mounted and if they work well (if applicable), if all the moving parts are complete, work properly, do not jam, if the adjustment mechanisms of the following elements work properly (if applicable): headrest, backrest, seat, abduction block, armrests, footrests. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Upholstery elements.	Check: <ul style="list-style-type: none"> if there is any damage, tears, rips, loose seams or deformations on the upholstery elements, if the stabilizing straps, vests or safety belts are not frayed or twisted and if the buckles work properly, if the stabilizing straps, vests or safety belts work correctly and do not unfasten under pressure or when pulled. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
Once a week.	Product cleaning.	If the frame and upholstery get dirty (dusty, muddy, etc.) during everyday use, wipe them with a damp cloth without detergents. Remove dirt (e.g. hair, food remains, etc.) from the moving parts of the product.	The product should be cleaned when necessary, but at least once a week. Do not use any chlorine based cleaners or methylated spirit. Before using the product, check if the upholstery is dry.





Frequency	What should be checked? What should be done?		Remarks
Once a month.	Wheel axles, quick connectors (if applicable).	Check: <ul style="list-style-type: none"> if the wheels are rolling and if they are not loose. To maintain the wheels, apply a small amount of a preservative-lubricant between the axle and the wheel hub. Check if you can easily remove and attach the wheels. 	Clean the wheels when dirty. In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Product construction connectors (welding, threading, soldering)	Check: <ul style="list-style-type: none"> the condition of the product frame in the places of joining (welds, threads, soldering). 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Tires/innertubes (if applicable).	Check: <ul style="list-style-type: none"> tire wear condition. Check for visible damage. Check tire pressure (if applicable). 	If the tire pressure is too low, inflate them to the correct level. In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
Once every 6 months.	Construction moving parts.	Check: <ul style="list-style-type: none"> if the moving parts of the construction have not been damaged. Maintain them using a proper cleaning agent. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Product labeling.	Check: <ul style="list-style-type: none"> if the marking and labels are readable. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
After the life time of the product finishes.	Detailed product check.	Check the product.	The manufacturer specifies the life time of the product, which is given in the user manual. After the given period, the user may use the product only if it is sent back to the manufacturer to be checked first. After that, the manufacturer will re-define the life time of the product and the date of the next check.

The list of all spare parts is available for download after selecting a product on www.akces-med.com.





12 LABELLING

12.1. Symbols

	Declaration that the product meets the essential requirements		Dry vertically
	Catalog number		Do not chlorinate
	Serial number		Do not iron
	Please read the manual instructions before use		Do not dry in a drum dryer
	You need to take special precautions		Do not bleach
	Manufacturer		The product is intended for indoor use
	Production date		Prohibition of use without fastened safety belts
	The product does not contain latex		Prohibition to leave the patient without care during use of the product
	Store in a dry place		You need to read the additional information
	Careful! Delicate content		You need to use the tools indicated in the assembly description
	Protect from sunlight		
	Storage temperature limitation		
	Relative humidity storage		

12.2. Example of identification plate

QR code - after scan you are directed to the website of the product

Producers address

Name of product

Name of product in English

Date of production

Maximum allowable product loading

Labeling - look above

Serial number in the form of a bar code

Serial number

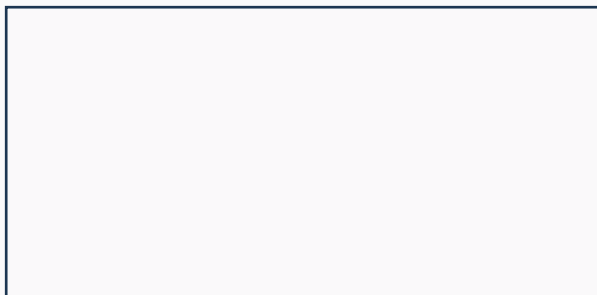


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