ASTRIDE Pro[™]

Standing frame



CE

ATTENTION!

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

Akces-MED Ltd. reserve the right to introduce technical and trading changes in the content of the instruction without warning.



Product 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 Ltd. company introduced quality management system ISO 13485 regarding production, sales and service.

The system is certified by SGS.



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Introduction

ASTRIDE Pro[™] is a modern single-column static standing frame with leg abduction function. The standing frame offers a wide range of adjustments for the feet, knees, and trunk. Innovative solutions used in this standing frame such as sliding sleeves, enable smooth and stepless adjustments so it's easier to fit the standing frame to the user. Thanks to the implemented solutions, using the device is simple and intuitive, requiring no additional tools.

ASTRIDE Pro[™] stander allows for:

- 1. CORRECT AND SAFE BODY POSITIONING OF THE CHILD BY:
- Leg abduction function, facilitating muscle stretching and preventing contractures. It correctly positions the lower limbs, preventing
 dislocation of hip joints.
- Adjustment of foot positioning in the forward/backward direction and in adduction/abduction range to prevent valgus or varus
 deformities. This adjustment is applicable in cases of equinovarus foot associated with hemiparetic cerebral palsy. Additionally, the
 footers are equipped with side protections, ensuring stable foot positioning and, consequently, lower limb stability.
- Rotating knee supports eliminate pressure on the knee cap, stabilizing and securing correct lower limb positioning during standing.
 With independent height, width, and depth adjustments, it allows individual adaptation for children with flexion or extension contractures of the knees, which is extremely useful in case of various forms of cerebral palsy.
- Due to independent chest and pelvic supports, it's easy to put the user in and take them out of the standing frame, ensuring proper stabilization.
- Comfortable belts and supports, which guarantee safety and comfort during standing, provide the ability to set full hip extension
 with the pelvic position secured.
- 2. FUNCTIONALITY AND ERGONOMICS OF THE STANDER THROUGH:
- Smooth table height adjustment supported by a gas spring, enhancing the child's functionality during daily activities such as eating, playing, or therapy. Improvement in functional reaching, fine motor skills, and precise movements, which contributes to the development of more complex forms of play and social interaction. Thanks to its functionality, the standing frame is a device that helps directly in the process of reeducation of an upright position and body control and indirectly supports reeducation of daily activities.
- The use of sliding sleeves protects the frame from damage and enables smooth and stepless adjustments necessary for the proper
 customization of the stander and effective rehabilitation.
- Stable base equipped with wheels and independent brakes, allowing easy movement of the stander between rooms.

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: Medical consultant: mobile +48 516 183 883 Akces-MED Ltd.: ph. +48 17 864 04 77 e-mail: export@akces-med.com

ATTENTION!

Before using the stander, read this user manual which is essential for proper and safe usage of the stander.

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

ATTENTION!

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 ASTRIDE Pro[™] standing frame, the user (or caregiver) is obliged to read the contents of this manual and to follow the instructions in it.

2. Indications and contraindications 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.

It is recommended for users 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.

2. Indications and contraindications for use

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 arrythmias, 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 arrythmias, 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 characteristic





A SCALE THAT MAKES IT EASIER TO ADJUST THE HEIGHT OF THE TABLE TO THE USER



TABLE OF FOOT ABDUCTION ANGLES



CHEST BELT WITH CHEST ROTATION FUNCTION

AVAILABLE IN ACCESSORIES

4. Size table

Symbol	Measurement	Unit	Size 1
	indicative user height *	[cm]	90 - 130
А	chest belt height (accessories)	[cm]	67 - 97
В	chest belt width (accessories)	[cm]	16 - 38
	chest belt parimeter (accessories)	[cm]	54 - 96
С	pelvic belt height	[cm]	43 - 75
D	pelvic belt width	[cm]	16 - 38
	pelvic belt parimeter	[cm]	54 - 98
E	knee supports height	[cm]	23 - 54
F	spacing between the middle of the knee supports	[cm]	16 - 43
Н	tray height	[cm]	61 - 81
I	footer width	[cm]	8 (size S) 10 (size M)**
J	footer spacing	[cm]	12 - 63
К	footer length	[cm]	19 (size S) 23 (size M)**
	max. user weight	[kg]	50
Symbol	Weight and dimensions	Unit	Size 1
x	width	[cm]	70
Y	długość	[cm]	70
Z	height	[cm]	88 - 118
Z1	tray height	[cm]	82 - 102
	weight	[kg]	19

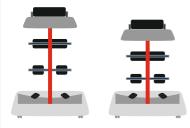
Note: Measurement tolerance range is +/- 1 cm / 1/2 in.

* Height cannot be the main parameter while choosing the product size.

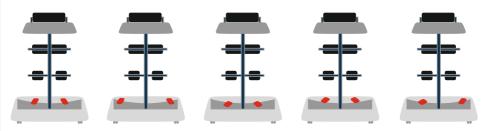
** The stander is equipped with feet in size S as standard. (It is possible to change to size M when placing an order).

ADJUSTMENTS

HEIGHT ADJUSTMENT

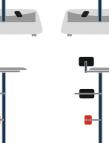


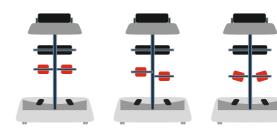
FEET ADJUSTMENT



KNEE SUPPORTS ADJUSTMENT







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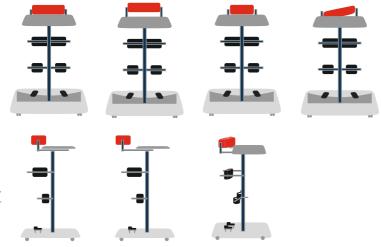
ADJUSTMENTS

PELVIC BELT ADJUSTMENT





CHEST BELT ADJUSTMENT - ACCESSORIES



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ATTENTION!

The column of the standing frame and the elements that stabilize the user are adjusted by knobs.

After the adjustment is completed, remember to tighten them firmly, and before using them, it is essential to check whether the adjustable elements do not change their position under the load.

5.1 Height adjustment



1 INFORMATION!

There is a pictogram on the column with a scale that indicates the height from the feet to the tray.

5.1 Height adjustment



INFORMATION!

To decrease the height of the standing frame, loosen the knobs and, pressing down on the table, lower it. While pressing the table, tighten the knobs.



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5.2 Foot stabilizers adjustment

INFORMATION!

The feet are independently adjustable:

- spacing,
- front and back movement,
- rotation.

On the platform there is an infographic telling the value of the angle of the lower limbs abduction depending on the height of the user and the points of attachment of the feet to the slides.







SPACING ADJUSTMENT





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5.2 Foot stabilizers adjustment









5.3 Knee supports adjustment



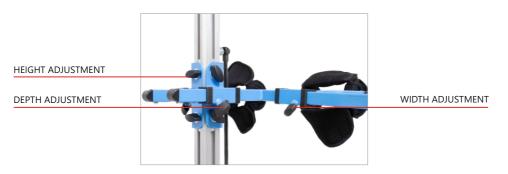
INFORMATION!

Knee supports are independently adjustable::

- in height,
- in width (spacing of the supports),
- in depth.

They also have independent adjustment of rotation in the frontal plane.

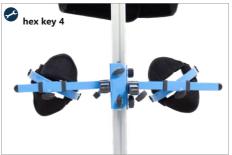
5.3 Knee supports adjustment











INFORMATION!

The soft element of the knee support can be adjusted by the included hex key.



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5.4 Pelvic belt adjustment

1 INFORMATION!

Pelvic belt can be independently adjusted:

- in width,
- in depth,
- in height.

The belt's circumference is regulated by velcro elements and additional belts fastened circumferentially with adjusters.





5.4 Pelvic belt adjustment





The pelvic belt can be moved freely on the slides, adjusting its displacement in the frontal plane, as well as adjusting the level of rotation of the belt according to the user's needs.













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5.5 Chest belt adjustment - accessories

1 INFORMATION!

Chest belt can be independently adjusted:

- in height,
- in width,
- in depth.

The belt's circumference is regulated by velcro elements and additional belts fastened circumferentially with adjusters.

The chest belt is not standard equipment of the product. To mount the chest belt, it is necessary to remove the tray first.

REQUIREMENT TOOLS

hex key 3



5.5 Chest belt adjustment - accessories



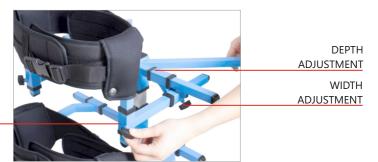








5.5 Chest belt adjustment - accessories



HEIGHT ADJUSTMENT













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6. The use of standing frame

ATTENTION!

Before using the ASTRIDE Pro[™] standing frame, read the instruction manual and follow the information included therein.

Before each use, prepare the user and the device.

6.1 Preparation of the user

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

- user's outfit is light and comfortable, not restrictive of movement,
- · shoes should be comfortable and, moreover, they should stabilize ankle,
- due to hygienic reason and to avoid abrasion it is advisable for the user 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 user to wear orthopedic supply (collar, corset, orthesis, shoes) if it is recommended by doctor.

ATTENTION!

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

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

6. The use of standing frame

6.2 Preparation of the product

1. How to prepare the standing frame for use:

- assemble the standing frame,
- place the standing frame on an even and flat surface, away from sources of fire and high temperature,
- make sure that all the elements are undamaged, properly mounted and stable,
- push the brakes,
- adjust the standing frame to the user's size and needs,
- place the user in the standing frame,
- fasten the elements which stabilize the user the chest (if any) and pelvic belts,
- start uprighting.

ATTENTION!

Before using the standing frame, make sure that all the belts and other elements have been properly adjusted, and all the knobs and fastenings of the adjustable elements are firmly tightened.

The standing frame will fulfil its function properly only when it is adjusted to the size and needs of the user. The most important thing, while adjusting the standing frame to the user, is to provide the user with the maximum feeling of safety. The improper use of the standing frame may lead to strengthening the incorrect posture patterns.

The initial adjustment of the standing frame to the user is carried out only by properly trained staff, and continued by trained persons. Correct adjustment of the device is essential for safety and determines the correct course of rehabilitation of the user.

6. The use of standing frame

6.3 Upright position

The length of time for upright position process is different for each user. 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 user's attention during upright position process by: manipulation games, educational games, touch stimulation and others.

ATTENTION!

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

Make sure that all belts as well as fasteningsfrom adjustable elements are correctly adjusted and fastened! It is forbidden to leave the user unattended!

It is forbidden to leave the user unattended!

The initial adjustment of the standing frame to the user is carried out only by properly trained staff.

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).

7. Safety rules

ATTENTION!

The standing frame ASTRIDE Pro[™] has to be used in compliance with guidelines in this use manual. Before each use, prepare the user and the device.

It is highly important to consult either doctor or physiotherapist in order to make right decision concerning the choice of ASTRIDE Pro^{TM} 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 user'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 the condition of the upholstery for any signs of damage,
 - 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 user's measurements and needs e.g. the adjustment of pelvic belt, chst belt (if any), knee supports, etc.,
 - make sure that all movable parts and knobs for adjustments are stable and locked,
 - secure the user with available stabilizing aids of the standing frame. It is highly important to secure user because it safeguards him/her from falling out.
- 2. It is forbidden to use standing frame for different purposes that it is intended.
- 3. It is forbidden to use standing frame when it is damaged or any part is missing.
- 4. It is forbidden to leave the user unattended.
- 5. Device should be used only when there is someone who is trained an knowledgeable.
- 6. It is forbidden to leave standing frame and the user on unstable ground unattended, even if the brakes are engaged.
- 7. It is forbidden to either go up or down the stairs; it doesn't matter if the user is placed in the device or not.
- 8. It is important to engage brake during getting into and getting out the standing frame.
- 9. Make sure that all limbs are not close to spokes or other adjustable elements.
- 10. The standing frame should be stored and used away from sources of fire or high temperature. Moreover, standing frame shouldn't be stored in rooms with high humidity.
- 11. Secure standing frame 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 standing frame, remove all paper and plastic packaging. The packaging is not a toy! Keep away from children and animals.

7. Safety rules

ATTENTION!

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.

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

The device contains small parts which children may swallow.

Do not use a product that shows any signs of damage, destruction or wear. Only a fully functional product, used in accordance with the instructions for use, is safe for the user. If the product is damaged, discontinue use and contact us with 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 loosing warranty.

The weight of user should not be bigger than maximal weight described on page 8 where you will find information regarding this issue.

8. Terms of warranty

• Akces-MED Ltd. sells products free from manufacturing defects or faults.

- Manufacturer gives the purchaser 24-month guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
- 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.
- The stander is covered by a 36-month warranty on the territory of Canada the details of the rights resulting from the extended warranty are regulated by the warranty card.
- 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.
- If product is damaged, please contact our dealer or Akces-MED Ltd. customer service: (ph. +48 17 864 04 77, e-mail: export@akces-med.com).

9. Maintenance and cleaning

The standing frame ASTRIDE Pro[™], 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.

9. Maintenance and cleaning

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.

ATTENTION!

Remember that upholstery has to be always dry before using!

The manufacturer of the standing frame, Akces-MED Ltd., 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.

ATTENTION!

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.



9. Maintenance and cleaning

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: 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: • 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: • 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 (i fapplicable), • 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: • 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.

9. Maintenance and cleaning

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
Once a month.	Wheel axles, quick connectors (if applicable).	Check: • 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: • 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: • 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: • 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 labelling.	Check: • 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.

10. Labelling



Declaration that the product meets the essential requirements



Catalog number



Serial number



Please read the manual instructions before use

You need to take special precautions



Manufacturer



Production date



Store in a dry place



Prohibition of use without fastened safety belts

The product does not contain latex



Protect from sunlight

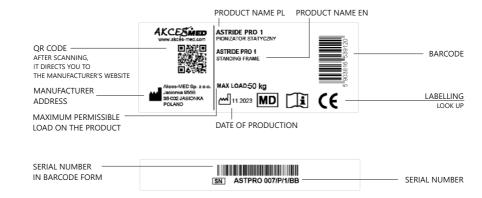


Storage temperature limitation



Relative humidity storage









MD

Medical device

description

astride pro ™

akces-med.com

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www.akces-med.com

Akces-MED Ltd.

MANUFACTURER

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