

sofie.



Instructions for use.

sofie. The versatile seat unit that grows with the child.




schuchmann®

Many thanks.



Dear Customer

At this point we would like to thank you for placing your trust in our company and for purchasing our product. We ask you to read through the Instructions for use carefully prior to initial commissioning of the product, and to observe them. Please note that guidelines and representations in these Instructions for use may deviate from your product due to differing equipment. We reserve the right to make technical modifications.

Important information!

Ensure that these Instructions for use remain with the product.

Your **schuchmann** Team



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1. Preparation.

1.1 Delivery

On receiving the product, please check it for completeness, lack of faults and any transport damage. Inspect the goods in the presence of your forwarder. Should transport damage have occurred, please arrange for an inventory (determination of the faults) to be made in the presence of the forwarder. Please send a complaint in writing to the specialist dealer responsible.

1.2 Safety measures prior to use

The correct use of the product requires detailed and thorough instruction of the user or the accompanying person. We ask you to read through the Instructions for use carefully prior to initial commissioning of the product, and to observe them. It is possible that product parts that get in contact with the skin may heat up in the sun. Depending on the duration and intensity of solar radiation, the surfaces of individual parts can heat up to over 41°C and thus lead to slight burns in the event of direct skin contact. Therefore cover these areas or protect the device from direct sunlight.

1.3 Safe disposal

In order to preserve and protect the environment, to prevent environmental pollution and to improve the recycling of raw materials, please note the disposal instructions in **points 1.3.1 and 1.3.2**.

1.3.1 Packaging

The product packaging should be stored in case the product needs to be transported again. Should you have to return the product for repairs or in case of a guarantee claim, please if possible use the original box so that the product is optimally packaged. Otherwise, separate the packaging materials for recycling according to their classification.



Do not leave packaging materials unattended, as they are a possible source of danger.

1.3.2 Product

At the end of the product life cycle, recycle the raw materials used in the product according to their nature (see material information under **point 2.1**).

1.4 Where to store the Instructions for use

Please store these Instructions for use carefully and ensure that these Instructions for use remain with the product in case of re-use. Should you lose the instructions, you can always download an updated version at www.schuchmann.de.



2. Product description.

2.1 Material information

The base frame and the individual elements are made of steel which is non-corroding and powder-coated. All body supports (pelotte pads) are padded and covered. The covers are made of 100% polyester and are flame resistant (according to DIN EN 1021-1+2).

2.2 Handling / transport

Should you have to carry the equipment due to obstacles, ensure that all moving parts are tightened. Then position yourself next to the seat unit, grip it by the front lower part and back of the unit and carry it to the required location. To transport the seat unit, reduce all adjustments to their most compact size (set lowest seat height, push in foot support, etc.).

2.3 Application areas, use according to the intended purpose

The **sofie** seat unit is a medical product of risk class 1 and designed for children and youths who cannot sit or stand unaided, however whose limited torso posture does not require permanent sitting in a seat pan.

2.3.1 Indication

Paralysis or substantial reduction in the torso musculature, so that sitting erect without comprehensive support is not possible or leads to incorrect posture, deformation and pain. Malformation and/or deformity of the body that makes it impossible or considerably more difficult to sit without special support and positioning. Deformative diseases to guide body growth in children and teenagers. There may be a medical necessity for the prescription of seat units in case of:

- infantile cerebral palsy
- Myelodysplasia
- muscular dystrophy
- various disease patterns with scoliotic deformations of the spine

Use of these units is indicated when the symptoms/disability or growth spurts necessitate frequent subsequent adjustments to the seat elements and accessory parts.

2. Product description.

2.3.2 Contraindications

In general, the indications for sitting should be approved by a doctor or orthopaedist. It should therefore be clarified prior to procurement whether contraindications exist for the patient. In general, any type of pain represents a contraindication.



2.4 Use not in accordance with the intended purpose / warning guidelines

- Ensure that the seat unit is only used by one user.
- Do not use the seat unit to transport people.
- In order to guarantee safe lifting when transporting the seat unit, stand at the side of the seat unit and grasp the front and back of the seat surface. Here all movable parts should be tightened, e.g. seat depth adjustment.
- Never leave the user unattended in the seat unit.
- Correct usage of the seat unit requires precise and careful training of the accompanying person.
- The max. load (**see Point 6**) may not be exceeded.
- Do not use the seat unit if it has defective, worn or missing parts.
- For reasons of fire safety, the seat unit may not be placed close to an open fire or any other strong source of heat such as electric or gas heaters.
- Use only accessories and spare parts made by Schuchmann, otherwise you will compromise the safety of the user.
- Only use the seat unit if all components have been correctly mounted and adjusted.
- When adjusting the seat unit, there is the risk of trapping or crushing limbs.
- Users who have difficult reading must have someone read these instructions for use aloud so that they understand how to use the therapy chair. Adjustments may only be made when the user is not in the seat unit.

2.5 Equipment for basic model

- Incl. removable armrests with adjustable height, width and angle
- Incl. standard seat pad with cover
- Adjustment options: back angle, back height, seat depth, seat width
- Adaptable to all standard exterior and interior chassis



2. Product description.

2.6 List of accessories

- Headrest, padded
- Removable back
- Thorax pelotte pads (also foldable), padded
- Thigh guide, padded
- adjustable pelvic guide, padded
- Therapy table
- Knee abduction wedge, padded
- Strap assembly kit for the seat area
- Strap assembly kit for the back area
- Incontinence coating
- Positioning aids

2.7 Product overview

The Fig. below is intended to show you the designation of the most important components as well as the terms which you will find in these Instructions for use.

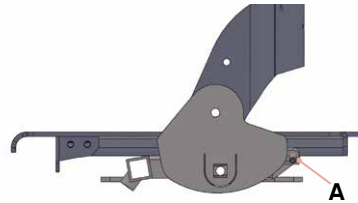


3. Settings.

Settings and adjustments to the product or accessories may only be made by people who have been given the necessary instructions by a medical product advisor. Please ensure that none of the user's extremities are in the respective area when making adjustments of any kind to minimise the risk of injury. All adjustments can be made with standard tools (e.g. Allen key, screwdriver or spanner).

3.1 Seat depth

After loosening the cylinder head screws on both sides of the seat unit with a hexagonal wrench (**A**), the seat surface can be moved continuously forwards or backwards. After each adjustment, please retighten all screw connections!



3.2 Back inclination

The back can be adjusted to the correct angle after loosening of the clamping lever (**B**) on the right-hand side of the seat unit.



Ensure that, during setting / adjustment of the back inclination, no body parts are trapped in the area of the setting / adjustment mechanism in order to avoid injuries.

3.3 Back height

Loosen the cylinder head screw (**C**) with the hexagonal wrench (M8) at the rear and bring the back into the required height.



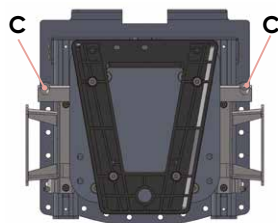
3. Settings.

3.4 Armrests

The armrests can be adjusted in angle, height and width. The angle is adjusted after loosening the star knob (A). The height can be adjusted through loosening the star knob (B).

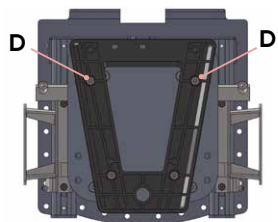


The width adjustment takes place after loosening the two grub screws (C), which are located on the underside of the seat unit.



3.5 Adapter / adaptation to the seat depth

With our adapter systems it is possible to adapt the **sofie.** seat unit to all standard sub-frames for indoors as well as for outdoors. After loosening the 4 countersunk head screws on the underside of the seat unit using a hexagonal wrench (D) the position of the adapter (here our trapezoidal adapter upper part) can be adapted to the seat depth or to the sub-frame.



After each adjustment, please retighten all screw connections!

3.6 Trapezoidal adapter

Place the seat pan with the trapezoidal shaped mounted adapter piece on the trapezoidal shaped seat pan adapter plate and push back. The patented closure automatically clicks into place. Now tighten the knurled head (E) of the patented closure. When removing the seat unit, untwist the knurled head first; as it is pulled downwards, the connection between the adapter and seat unit adapter is released. The seat unit can now be pulled away to the front.



4. Accessories.

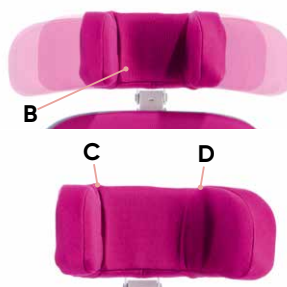
4.1 Headrest

The headrest can be adjusted in height, depth and angle. In order to do this, please loosen the 2 cylinder head screws (A) with a hexagonal wrench and bring the headrest into the required position.



4.1.1 Headrests with angle-adjustable lateral guide

The headrest with angle-adjustable lateral guide (B) can be adjusted in height, depth and angle (see **Point 4.1**). In addition, the angle of the lateral guide can be adjusted individually. To adjust the lateral guide, loosen the hexagon socket screw (C+D) and bring the respective lateral guide into the desired position.



Tighten the twist grip / clamping lever again after each adjustment!



Support the head of the user with one hand when you make an adjustment to the headrest during use!

4.2 Removable back

The removable back can be operated on the back of the therapy chair. Loosen the twist grip (E), press the locking lever (F) together and then remove the back. The function of the removable back can be integrated into the therapy plan and also used for short periods of time, as the back, including the headrest, is quickly plugged in again, and provides the user with a positioner and support when they are tired.



After each adjustment, please retighten all screw connections!



4. Accessories.

4.3 Thorax pelotte pads

The thorax pelotte pads are individually adjustable in height and width. In order to do this, please loosen the 2 pan head screws with a hexagonal wrench (**A**) and bring the thorax pelotte pads into the required position.



4.4 Foldable thorax pelotte pads

The foldable thorax pelotte pads can be folded to the sides to ease placement of the child.

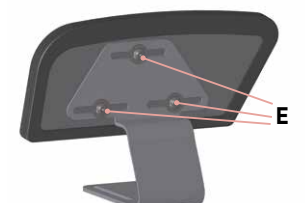
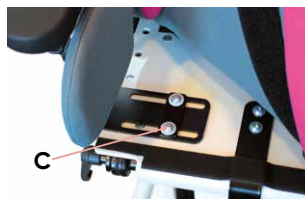
To do this, please press the red pushbutton (**B**) on the side of the thorax pelotte pad over the joint, and swivel the pelotte pad away from the side.



When folding back, ensure that the thorax pelotte pad engages!

4.5 Thigh guide

The thigh guide pads are individually adjustable in height and depth. In order to adjust the depth, loosen the pan head screws with a hexagonal wrench (**C**) under the seat pad and bring the thigh guide pad into the required position. The depth adjustment is possible on any thigh guide except on the standard version for Size 0 with adjustable pelvic guide. In order to adjust the depth, please open the zips (**D**), loosen the 3 pan head screws with a hexagonal wrench (**E**) and bring the pad into the required position.

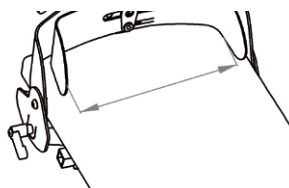
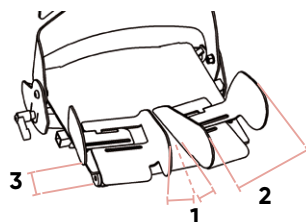
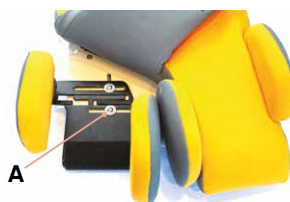


After each adjustment, please retighten all screw connections!

4. Accessories.

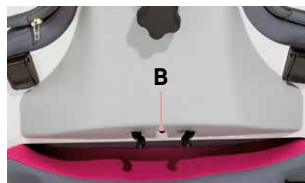
4.6 Abducting leg guides

The abducting leg guides permit the medically necessary abduction of the thighs and the compensation of a seat depth difference. In order to adjust the leg guides, please loosen the pan head screws with a hexagonal wrench (**A**) below the seat pad, and bring the leg guides into the required position. You can then easily adjust the abduction angle (**1**), the thigh width (**2**) and also the leg length compensation or seat depth difference (**3**) via the slotted holes.



4.7 Adjustable pelvic guide

The adjustable pelvic guide can be adjusted in width, provides the user with a high level of security and positions the pelvis. First loosen the cylinder head screw on the rear of the seat unit at the lower edge of the cover (**B**). Then push the front of the pad down slightly and loosen the pan head screw with a hexagonal wrench (**C**). Now please position the user in the chair and bring the pelvic guide into the desired position. First tighten again the cylinder head screw with a hexagonal wrench (**B**) and only then lift out the user. Now you only need to tighten again the pan head screw with a hexagon socket (**C**) and then you can position the user back into the seat unit.



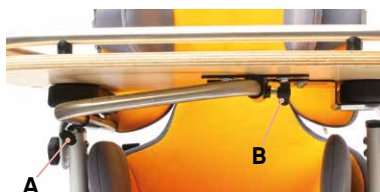
After each adjustment, please retighten all screw connections!



4. Accessories.

4.8 Therapy table

The therapy table can be adjusted in height and depth. Height adjustment takes place via adjustment of the armrests (see **Point 3.4**). For adjustment of the depth, loosen the wing screw (**A**) and bring the therapy table into the required position. To fold the therapy table to the side, e.g. when the user sits down or gets up, loosen the wing screws (**A+B**), pivot the table upwards and move it to the side of the seat unit (**C**).



4.9 Knee abduction wedge

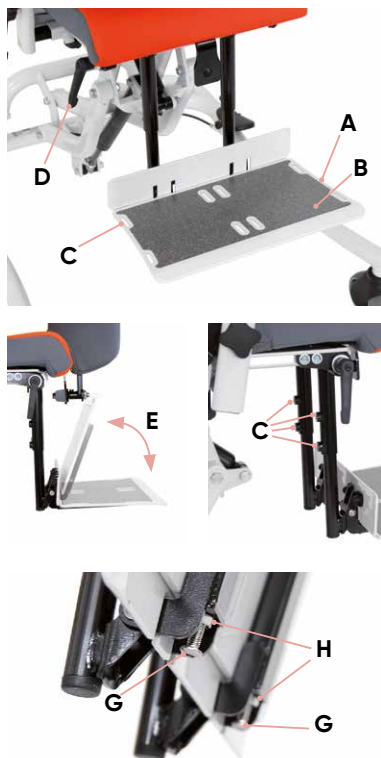
The knee abduction wedge must be mounted onto the front of the seat plate using a quick-release axle. To do this, please press the knob on the quick-release axle (**D**), and the abduction wedge can easily be removed or inserted. When inserting the abduction wedge, you should be able to hear it engage with an audible "click".



4. Accessories.

4.10 Foot support (fixed-mounted onto the seat unit)

An optional foot support (A) is available for **sofie**. It has a non-slip surface (B) and has 8 slits (C) to attach straps such as foot cuffs or foot positioning aids. In order to adjust the knee angle, please loosen the clamping lever (D) under the seat surface, bring the foot support into the required position and retighten the clamping lever (D). The foot support can be folded up in order, for example, to facilitate climbing in (E). In order to continuously adjust the height, please loosen the four grub screws (F), bring the foot support into the required position and retighten the grub screws (F). The foot angle can also be adjusted for optimum positioning of the feet. To do this, first fold the foot support upwards and then screw the hexagon socket screws (G) in or out. Counter the nuts (H) after each foot angle adjustment.



Counter the nuts (H) after each foot angle adjustment!



After each adjustment, please retighten the clamping lever and the grub screws!

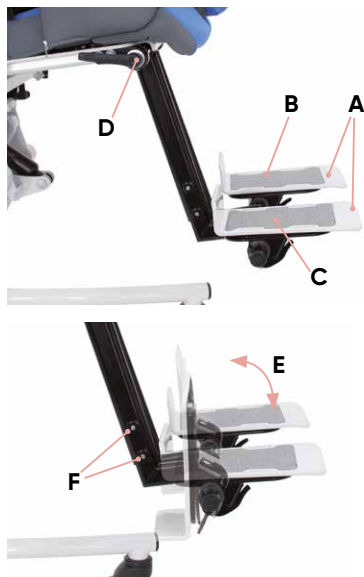


For „Shortening the foot support tubes“ see assembly instructions. These can be found at www.schuchmann.de/mediathek.

4. Accessories.

4.11 Footrests

Optionally, **sofie.** can also be equipped with footrests (**A**). They have an anti-slip surface (**B**) and have 4 slits each (**C**) to mount straps such as foot cuffs or foot positioning aids. For adjustment of the knee angle, please loosen the clamping lever (**D**) under the seat surface on both sides, bring the footrests into the required position and retighten the clamping lever (**D**). The footrests can be folded up, for example in order to facilitate climbing in (**E**). For continuous height adjustment, please loosen the two grub screws (**F**) on each footrest, bring the footrests into the required position and retighten the grub screws (**F**). During height adjustment, please ensure that the markings (**G**) on the adapter tubes of the footrests are not exceeded in order to guarantee secure clamping through the grub screws (**F**).



After each adjustment, please retighten the clamping lever and the grub screws!

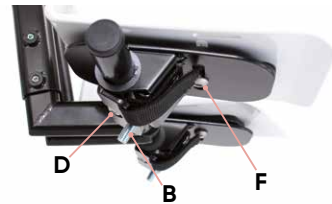
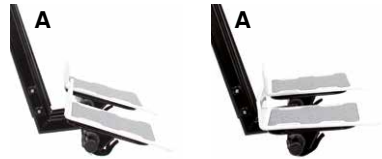
4. Accessories.

4.11.1 Positioning of the footrests

For optimum positioning of the feet, the footrests can be adjusted independently of each other in width, angle and depth.

Foot angle

The foot angle (A) of the respective footrest can be adjusted from $(-15^{\circ}$ to 5° . To achieve this, please screw the grub screws (B) under the footrests in or out, thus adjusting the required foot angle.



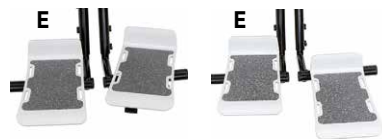
Width

In order to adjust the width (C), please loosen the pan head screws (D) under the footrests, bring the footrest into the required position and retighten the pan head screws (D).



Angle / depth

In order to adjust the angle and the depth (E), please loosen the pan head screws (F) under the footrests, bring the footrest into the required position and retighten the pan head screws (F). In addition, additional width adjustments can also be made in this way. Securing against folding up. The footrests can be secured against unintentional folding up. To do this, simply loosen the hook and eye fastener (G) under the footrest, bring the footrest into the required position and close the hook and eye fastener (G) again.

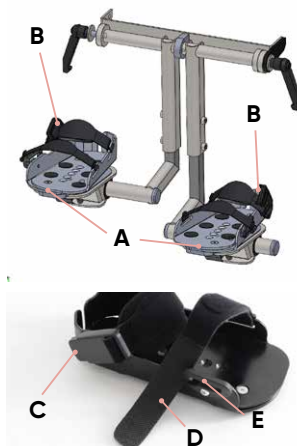


After each adjustment, please retighten all screw connections!

4. Accessories.

4.12 Footrests with foot pans

Optionally, the footrests can also be equipped with foot pans (A). Here, as on the standard design, the knee angle can be adjusted, the foot pans folded up and the height adjusted (see **Point 4.11**). For optimum positioning of the feet, the footrests with foot pans can be adjusted independently of each other in width, angle and depth (see **Point 4.11.1**). In order to secure the user in the foot pan, the foot pans are equipped with straps. These can be closed using the magnetic locks. If you guide the strap end (B) in direction of the lock, it will engage automatically. To open the straps, press the button (C). For the length adjustment, the hook and loop closure of the strap (D) can be opened on both sides and adjusted in length. To close the strap in the forefoot area, guide it through the opening (E) and close the strap with hook and loop closure.



After each adjustment, please retighten all screw connections!

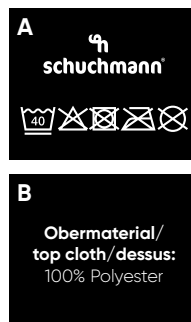
5. Cleaning and servicing.

5.1 Cleaning and disinfecting

5.1.1 Cleaning

Please clean all frame elements regularly with a sponge or damp cloth; making sure that water droplets are removed. Please clean with a mild household detergent for severer dirt. Thorough drying of the cleaned areas is important.

All fabrics that cannot be removed can be wiped with a moist cloth. For all removable fabrics please pay attention to the sewn-in care labels (such as **A + B**) on the respective element. Please also pay attention to our general cleaning and hygiene advice. This can be found at **www.schuchmann.de/mediathek**.



5.1.2 Disinfection

Various products can be used for surface disinfection of wood, metal and plastic parts.

Liquid disinfectants are available as ready-to-use solutions that are sprayed on and evenly applied with a soft cloth. Alternatively, wipes pre-soaked with disinfectant can be used to wipe the products over the entire surface. In both cases, care must be taken to ensure complete wetting. Disinfection in fully automatic disinfection systems is also possible and recommended. The exposure times may vary and can be found in the manufacturer's instructions for the products used.

5.2 Servicing

Please carry out a visual inspection on a daily basis and regularly check the product for cracks, breaks, missing parts and malfunctions. In case of a defect or malfunction, please contact the specialist dealer who supplied you with the product (see **Point 8.5**).

5.3 Maintenance

For reasons of user safety and to retain product liability, the product must be subjected to maintenance by a specialist dealer at least once a year (see **Point 8.5**). The maintenance work carried out must be documented in the maintenance plan (see **Point 5.3.2**).

5. Cleaning and servicing.

5.3.1 Maintenance specifications

- Basic cleaning according to the manufacturer's specifications
- Disinfect according to the manufacturer's specifications as required
- Damages to the frame, mounting parts and accessories (cracks, breaks, corrosion, bent or missing parts)
- Strength of the connections (tighten loose screws, replace missing screws)
- Functionality of the adjustment elements (screws, release lever)
- Functionality of other adjustment elements (back, headrest, pelotte pads, armrests, footrests, table and guides in the leg area)
- Check the harness for damage (clamping device, closures, seams)
- Check the pads and covers for damage
- Legibility of the type label
- Final complete functional check of the aid
- Check that all mounting parts and associated accessories are correctly fastened

5.3.2 Maintenance plan

Maintenance specifications of the manufacturer (see **Point 5.3.1**) were carried out:

Date	Company	Name	signature



Any defects or damage found must be repaired by the specialist dealer or the manufacturer before reuse.

5. Cleaning and maintaining.

5.4 Spare parts

Use only original accessories and original spare parts from Schuchmann, as otherwise the safety of the user is endangered and the warranty expires. Should you wish to order spare parts, please contact the specialist dealer who supplied you with the product, stating the serial number of the therapy chair (see **Point 8.5**). Necessary spare parts and accessories must only be installed by trained personnel.

5.5 Duration of use and re-use

The expected duration of use of our product, dependent on the usage intensity and amount of re-use, totals up to "8" years if the usage takes place in accordance with the information in these Instructions for use. It may be possible to use the product over and above this time period if it is in a safe condition. The expected duration of use does not refer to wear parts, such as for example wheels, gas pressure springs,... . The maintenance and evaluation of the condition, and if applicable the potential for re-use, must be decided by the specialist dealer.

The product is suited for re-use. Prior to forwarding, please follow the cleaning and disinfection instructions stated in **Point 5.1**. Accompanying documents such as these Instructions for use are part of the product and must be passed on to the new user. No disassembly is required prior to re-use. In the case of storage, it is recommended to fold the product to the smallest dimension to save space.

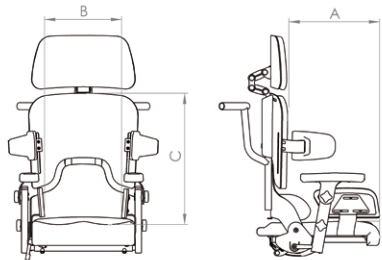


Should a serious incident occur during the service life of the product despite being used as intended, this must be reported immediately to the manufacturer and the competent authority.



6. Technical data.

Dimensions



		Size 0	Size 1	Size 1 b	Size 2
A	Seat depth*	15 – 25 cm	21 – 30 cm	26 – 36 cm	30 – 42 cm
b	Seat width	16 – 26 cm	20 – 30 cm	20 – 30 cm	28 – 38 cm
c	Back height (short back)	35 – 43 cm	35 – 43 cm	42 – 52 cm	42 – 52 cm
c	Back height (long back)	42 – 52 cm	42 – 52 cm	53 – 63 cm	53 – 63 cm
	Back angle	(-)5° – 25°	(-)5° – 25°	(-)5° – 25°	(-)5° – 25°
	max. load	30 kg	30 kg	45 kg	50 kg
	Weight	9 kg	10 kg	10 kg	12 kg
	Recommended for sub-frame(s)	freddy. Size 0	freddy. Size 0	freddy. Size 1 + Anti-tip mechanism, franka. Size 2 fridolin 1+2 size 2	freddy. Size 2 + Anti-tip mechanism, franka. Size 2 fridolin 1+2 size 2
* reduced by 1 cm in combination with adjustable pelvic guide					

7. Guarantee.

The two-year statutory guarantee period shall apply for all products. This begins with the delivery or handover of the goods. Should a verifiable material or manufacturing fault occur within this time period, we shall, after carriage paid return to us, view the indicated damage and, if applicable, either repair or deliver a new product at our discretion.

8. Identification.

8.1 EU Declaration of Conformity



EU Konformitätserklärung EU Declaration of Conformity



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erklärt in alleiniger Verantwortung, dass das nachfolgend genannte Produkt der Risikoklasse 1
declares under our sole responsibility that the following product(s) of Class 1 Medical Devices

„sofie.“ Therapiestuhl / *therapy chair*

Art.-Nr. / Item-No.: 17 00 100, 17 01 100, 17 01 200, 17 02 100

Basis UDI-DI / Basic UDI-DI: 4251040200004000170XXXXA6

den einschlägigen Bestimmungen der im folgenden aufgeführten Richtlinien und Standards entspricht:
is / are in conformity with the requirements of the below listed directives and standards:

Verordnung (EU) 2017/745 über Medizinprodukte vom 05. April 2017
Regulation (EU) 2017/745 on medical devices of 5 April 2017

DIN EN 12182:2012 Technische Hilfen für behinderte Menschen
Technical aids for disabled persons

DIN EN ISO 14971:2013 Medizinprodukte – Anwendung des Risikomanagements auf Medizinprodukte
Medical devices – Application of risk management to medical devices

Diese Konformitätserklärung gilt nur für Produkte mit den oben genannten Artikelnummern und
ist gültig bis zum 31.12.2023.

*This declaration of conformity applies only for products with above-named Item-numbers
and is valid until 31.12.2023.*

Datum / Date: 01.04.2020

Unterschrift / Sign:

Name / Name: Torsten Schuchmann

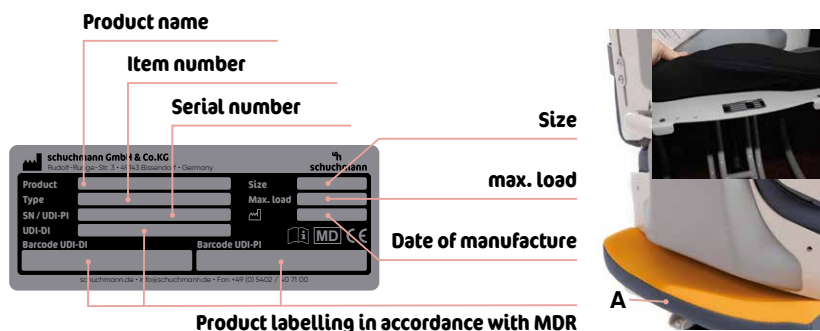
Funktion / Function: Sicherheitsbeauftragter für Medizinprodukte / *Safety officer for medical devices*



8. Identification.

8.2 Serial number / date of manufacture

The serial number, the date of manufacture and other information can be found on the type plate, which is located on all of our products (**A**).



8.3 Product version

The **sofie.** seat system is available in four sizes and can be supplemented through a diverse range of accessories (see **Point 4**).

8.4 Issue of the document

Instructions for use **sofie.** – Change status J; issue 08.2021

8.5 Name and address of the manufacturer, specialist dealer supplying the product

This product was manufactured by:



Schuchmann GmbH & Co. KG

Rudolf-Runge-Str. 3 · 49143 Bissendorf · Germany
 Phone +49 (0) 5402 / 40 71 00 · Fax +49 (0) 5402 / 40 71 109
 info@schuchmann.de · www.schuchmann.de

This product has been delivered by the following specialist dealer: