

Stehgeräte



Instructions for use

Status: 04/2025

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1 Foreword

Dear customer!






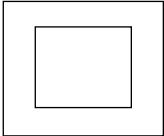
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical device with great care.








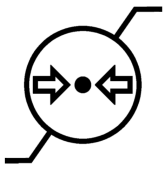

Please read the instructions for use carefully before first use and always keep them within easy reach.

For further information or in the event of problems that are not described or not described in sufficient detail in these instructions for use, please contact your specialist dealer or medical supply store. The Levaflex standing device is a Class I medical device and meets the requirements of EU Regulation 2017/745 (MDR) and the applicable national regulations. The EU Declaration of Conformity is available for download on the website.

2 General information

2.1 Symbols used

	Caution!
	Manufacturer
	Conformity symbol
	Medical device
	Type B applied part
	Protection class II device

	<p>Dispose of electrical components in accordance with legal regulations. Do not dispose of with household waste!</p>
	<p>Date of manufacture</p>
	<p>Article number</p>
	<p>Serial number</p>
	<p>Sales partner</p>
	<p>Temperature limit - indicates the temperature limits to which the medical device can be safely exposed.</p>
	<p>Humidity, limit - indicates the humidity range to which the medical device can be safely exposed.</p>
	<p>Air pressure, limit - indicates the range of air pressure to which the medical device can be safely exposed.</p>
	<p>Observe instructions for use</p>


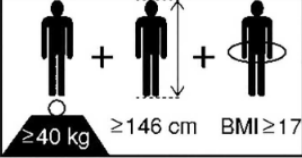
	Unique identifier of a medical device
	Physical description of an adult

Table 1: Symbols used

2.2 Type plate

The product can be clearly identified by the type plate.

MD

REF

Safe working load:



SN

UDI



(01) 0 4251858 50276 5 (11) 220113 (21) 220100FB0005



ISKO KOCH GmbH
95448 Bayreuth
Egerländer Str. 28

ISKmed



13.01.2022

Figure 1 : Exemplary type plate

Figure 1 shows an example of a type plate. Please refer to the attached type plate for the exact specifications of your product

3 Safety instructions

- You should read these instructions for use carefully before using the standing device. They contain important information for the safe and reliable use of the appliance. Keep the operating instructions for future reference.
- Safety, reliability and performance are guaranteed if the following instructions are followed and the appliance is used properly.
- The device may only be operated by medically trained and instructed personnel when starting upright training. Operators must be trained in handling the device and their training and level of knowledge must enable them to assess the risks for the patient.
- All clamping and screw connections must be checked regularly.
- The user must be assisted by 1 or 2 helpers during use.
- Do not use aids outdoors. The device may only be used in protected domestic and clinical areas.
- Leaning out far poses a risk of falling.
- The aid must not be used as a means of transportation.
- Only park the aid with braked wheels.
- In the event of a malfunction, the standing device must be withdrawn from use immediately.
- Parts of the standing device can catch fire if handled incorrectly.
- When standing, the user must always wear sturdy shoes; barefoot use is not permitted. Unless expressly instructed to do so by the therapist.
- Ensure that children only have access to the mobile standing device under supervision.
- The standing appliance should only be set up by authorized personnel.
- The installation-side fuse protection must not exceed 16A. Before connecting the appliance, please ensure that the voltage and frequency of your power supply correspond to the specifications on the type plate.
- When selecting the location, ensure that the floor is level
- Provide a suitable floor covering if the standing device has to be moved frequently. Carpets, rugs and loose floor coverings can be damaged or make it difficult to move the appliance.
- Connect the mains plug firmly to the mains socket. Lay the mains connection cable on the floor. Make sure that the standing device (especially when moving it) does not stand on the cable with its castors. The cable must not be routed through the mechanics of the substructure! (Danger of crushing)
- Damaged mains cables can lead to life-threatening situations. They must be replaced immediately.
- Check the mains cable for damage at regular intervals (weekly).
- Ensure that the electrical specifications of the appliance match the local conditions at the installation site.
- When the hand controls are not in use, ensure that they are attached to the standing appliance to prevent incorrect operation that could cause damage.

4 General product description

4.1 Intended use

The Levaflex standing device is intended exclusively for standing training for people who are unable to walk or have difficulty walking, for independent use with an assistant. Standing training is used in inpatient and outpatient rehabilitation as well as in the home environment. The design of our standing devices enables independent, stable and safe standing. An electric belt retractor is used to bring the patient out of the wheelchair and into a secure standing position.

4.2 Indication

People between 140 and 200 cm tall with various physical and/or psychological limitations can stand safely, firmly and without fatigue every day. Daily standing stabilizes the circulation, prevents bone decalcification (osteoporosis), corrects contractures of the hip and knee joints, stimulates bowel and bladder functions as well as breathing and kidney activity. Targeted promotion of head control is optimized by the precise adjustment options at all levels.

4.3 Contraindications

The following patients are not permitted to use the standing device:

- Decubitus ulcers, particularly in the hip and leg area
- Extreme deformation and inability to bear weight in the lower extremities
- In the case of severe cardiovascular problems
- Severe dizziness that makes it impossible to stand up independently or partially independently
- With severe anxiety

4.4 Equipment features

The Levaflex standing device has the following features:

- Table cut-out with ergonomic abdominal pad
- Foot plate with heel cups and toe fixation
- Double swivel castors with total locking
- Table height adjustment with gas spring support
- Knee pads adjustable in height and depth, as well as with horizontal and angle adjustment
- Stainless steel handrails height-adjustable in parallel

4.5 Scope of delivery

- Pre-installed sturdy base frame
- Support table with height adjustment and electric automatic belt retractor
- Height and depth-adjustable upper body support and knee pads
- Adjustable heel cups with toe Velcro straps

5 Assembly information

5.1 Basic information on assembly

The standing device should only be set up by authorized personnel. The installation-side fuse protection must not exceed 16A.

Before connecting the appliance, please ensure that the voltage and frequency of your power supply correspond to the specifications on the type plate.

Ensure that the floor is level when selecting a location for the standing device. Provide a suitable floor covering if the standing device has to be moved frequently. Carpets, rugs and loose floor coverings can be damaged or make it difficult to move the appliance.

Connect the mains plug firmly to the mains socket. Lay the mains connection cable on the floor. Make sure that the castors of the standing appliance do not rest on the cable (especially when moving it).



Damage to the mains cable caused by driving over it or pinching it can have fatal consequences.

6 Operation

All preliminary settings may only be made on the empty standing device without the patient standing in it. The settings must then be checked again with the patient standing in the aid and corrected if necessary. An assistant is required for the adjustment work. Due to the large number of adjustment options for the standing device, some of the settings described may not be possible for some users or under certain circumstances.



After making adjustments, check that all connections are tight!



The upholstery of the table top must never be adjusted below the top edge of the pelvis!

6.1 Body height

Adjustment to the patient's height is made via the extension height of the table tubes. The adjustment is correct when the therapy table is at arm height or slightly higher if necessary when the patient is standing. The table height adjustment is supported by two built-in gas springs.

Loosen the clamping levers on the vertical support tube and pull it out as required (see Figure 3).



The clamping lever must always be tightened when the standing device is in use!

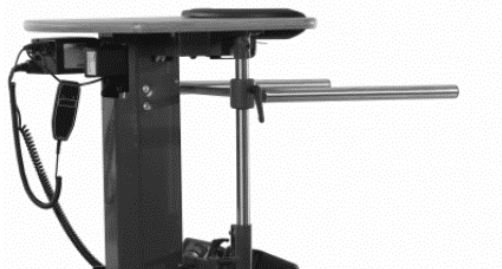


Figure 2 Adjusting the table height

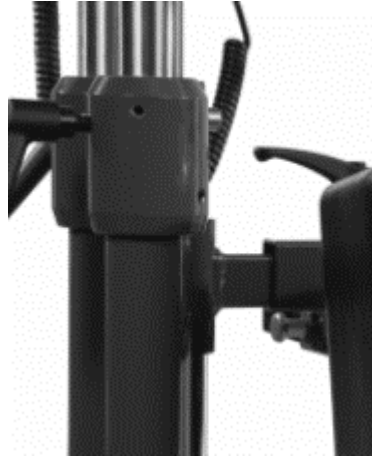


Figure 3 : Clamping lever for table height adjustment

6.2 Hip support



An assistant is required to use the support bar with hip support!

The hip support is adjusted in height by loosening the clamping levers on the main tubes and in depth by loosening the clamping levers on the rear cross tube. Adjustment to the width is made by snapping on the rear cross tube. The pads are positioned above the sacral area in the area of the lumbar vertebrae when the patient is standing (see Figure 4). They should have a stabilizing effect in conjunction with the heel support and knee pad.



The clamping lever must always be tightened when using the standing device!



Figure 4 : Position of the hip support in the sacral area

6.3 Foot and heel support

Adjust the heel holders by repositioning them on the perforated base plate so that the user has a firm hold in them (4 positions are possible).

The patient can get on by opening the Velcro straps on the belts. The straps are closed tightly over the instep. The Velcro straps serve as toe fixation. (see Figure 5)



Check that the foot is firmly secured!

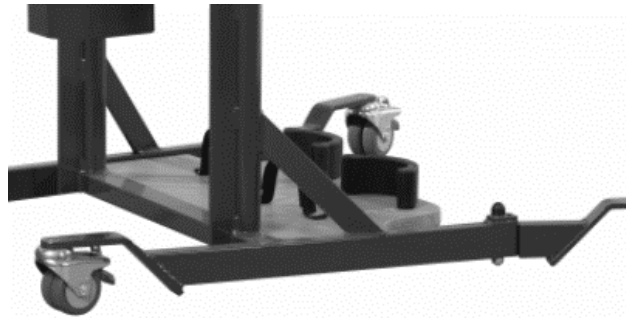


Figure 5 : Adjusting the heel cups and toe fixation

6.4 Knee pads

The height and depth of the knee pads are adjusted by loosening the vertical and horizontal tube catches. The knee pads are correctly adjusted when they are positioned below the knee on the shin. The knee pads should first be preset and corrected if necessary when the patient is standing. They stabilize the patient's stance in conjunction with the heel support and hip support. (see Figure 6)



Figure 6 : Adjusting the knee pads

6.5 Upper body support

6.5.1 Adjusting the back pad

The back pad supports the middle of the back at the height of the shoulder blade. To attach the pad (see Figure 7), turn the knob on the holder a full turn and pull it out. Slide the pad holder into the holder with the holes facing outwards.

Lower the tube into the holder and release the knob as soon as the back pad is at the desired height. Release the button so that the indexing pin integrated in the button engages in the nearest hole in the tube. Tighten the knob to fix the back pad in position.

6.5.2 Lateral arm support

The upper body support is supplemented by side supports. Two width-adjustable arm supports can be attached to the upper body support, which can be positioned on both sides of the chest at the height of the armpits. The height of the arm supports depends on the height adjustment of the upper body support and should be adjusted so that there is a distance of three fingers between the top of the side arm supports and the armpit. See previous instructions for adjusting the height of the upper body support.

6.5.3 Attaching and adjusting the headrest

The headrest supports the head at the level of the back of the head. To attach the headrest, pull out the locking pin on the upper body support. Slide the headrest tube into the holder with the holes facing outwards. When you have reached the desired height, release the indexing plunger so that it engages in the nearest hole in the headrest tube.

The depth of the headrest should be adjusted so that the head is supported but not pushed forward. To adjust the depth of the headrest, pull the plunger on the underside of the headrest upwards and slide the headrest in or out to the desired position. When you have reached the desired position, release the plunger and make sure that it engages in one of the holes in the headrest.



Figure 7: Upper body support

6.6 Chest support

The chest support supports the patient in a standing position. After centering and aligning the chest support on the table, it can be attached to the table of the standing device using two screw clamps. (seeFigure 8)

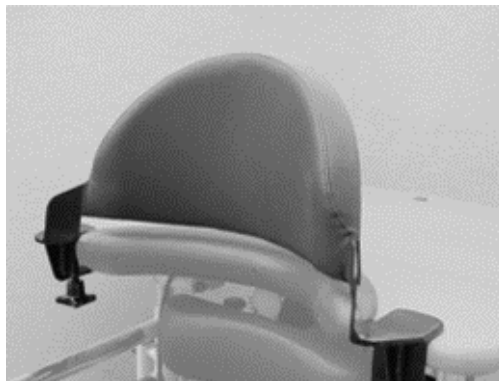


Figure 8 : Breast pad

6.7 General instructions for use



Put on the patient support belt before approaching the standing device.

The patient belt should be fastened so that its lower edge is clamped between the sacral area and the wheelchair seat. Then fasten the abdominal belt (see Figure 9).

Swivel the legrests or footrest to the side. Place the feet in the foot guides. The heel sections can be removed for this purpose. Drive the wheelchair so close that the front wheels touch the recesses provided in the footplate. Secure the wheelchair against rolling away.



Figure 9 : Patient restraint belt

Once the control unit has been connected to the mains using the mains cable, the device is ready for operation. The drive is automatically switched off in the end position of the two belt ropes.

The additional forced switch-off is triggered as long as the black push-button of the interrupter is held down. The device can only be operated again once it has been released. The push button is located underneath the tabletop. (see Figure 10)

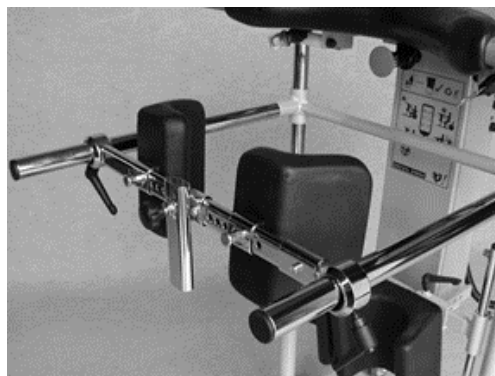


Figure 10 : Position of the breaker push button

Each upward or downward movement of the straps is effected by pressing the respective button on the hand switch. The buttons are marked with arrows according to their function. (see Figure 11)

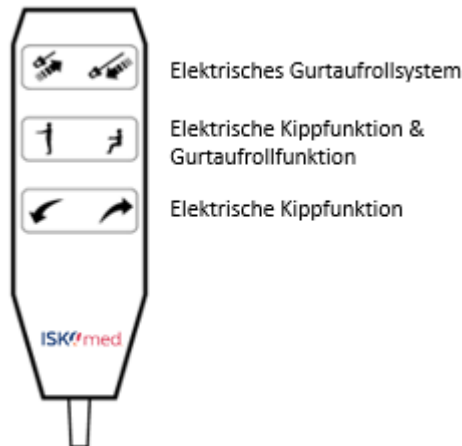


Figure 11 : Hand control for the Levaflex standing device

To give the wheelchair more room to move, the castors can be adjusted outwards using a screw joint. (see Figure 12)

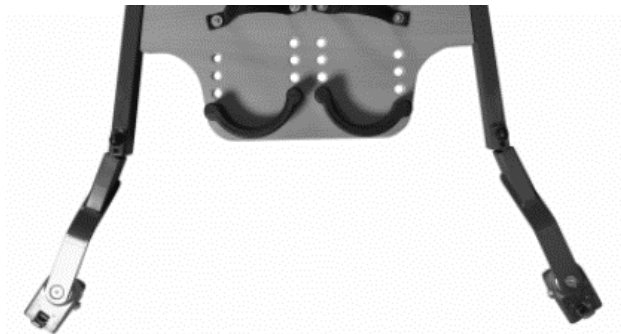


Figure 12 : Adjusting the castors

6.8 Instructions for using the tilt function

The Levaflex standing device offers you more comfort when standing up. (see Figure 13) The tabletop, handrails, knee support and footplate are tilted towards the patient before standing up. Tilting is realized via an additional tilting motor.



Figure 13: Standing up process

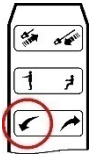
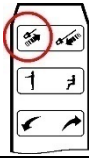
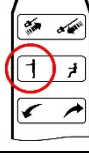
Procedure for standing up		
	Description	Button on the handset
1	Tilt the support tubes back by pressing the hand control. Click in both pull ropes with the patient support belt in place.	
2	Tension the pull cords without lifting the patient.	
3	By pressing the stand-up function button, both motors are activated simultaneously and the raising process initiated.	

Table 2: Sequence for stand-up procedure


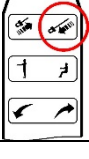
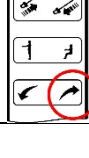
Sequence when resetting:		
	Description	Button on the handset
1	If you press the button on the hand control, the lowering procedure is carried out, both motors move again simultaneously and the patient is gently brought into the sitting position.	
2	Press this button to release the pull cords	
3	After the patient has left the standing device, the table can be returned to the horizontal position by pressing this button.	

Table 3: Procedure for resetting

6.9 Behavior in the event of a power failure

If the power fails while the electric belt retractor is in use, the user must call an assistant to help the patient back into the wheelchair.

The following description assumes that the assistant is right-handed. If the patient is left-handed, the procedure must be mirrored.

First, the wheelchair is turned around the left front wheel just enough so that the assistant can stand behind the patient, but it is still possible to place the patient in the wheelchair. The assistant stands behind the user, opens the Velcro fastener of the abdominal belt, grasps the patient's chest with the

right arm under the patient's right armpit and opens the left buckle of the patient support belt with the left hand (if necessary, relieve the patient restraint belt by applying some pressure over the body buckle). The assistant's left hand now grasps under the patient's buttocks to support them as they slide back into the wheelchair.

6.10 Operating the brake castors

The standing device has four individually braked swivel castors. The standing device should always be braked at the installation site and during use using the castor lock. (see Figure 14)

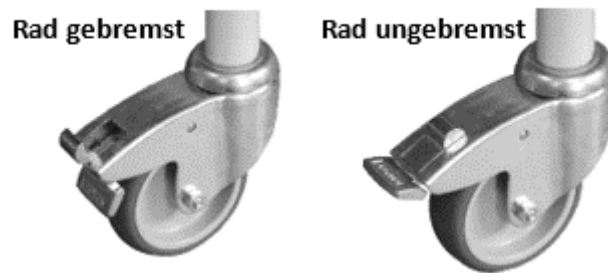


Figure 14: Castors in braked and unbraked state



Standing training with unbraked castors can lead to injuries to the patient.

7 Ambient conditions

7.1 Storage conditions

Storage temperature	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Storage conditions

7.2 Operating conditions

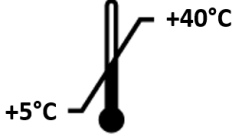


Operating temperature	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 5: Operating conditions

8 Technical data



Designation	KR-214-B/S
Rated voltage	~230 V/50Hz
Rated power	690 VA
Device type B according to IEC 601-1	
Protection class	
Sound power level	63 dB(A)
IP protection class hand control, control box, motor	IPX4
IP protection class standing device lifting mechanism	IPX1
Duty cycle ED 10%	maximum 6 minutes/hour
Max. patient weight	120 kg
Patient height	140 - 200 cm
Empty weight	approx. 65 kg
width	78 cm
length	100 cm
Table height	100-132 cm
Height of knee pads / depth of knee pads	45 - 65 cm / max. 45 cm
Height of the back cushion	86 - 140 cm / max. 45 cm
Angle of inclination	15°
Swivel diameter	200 cm

Table 6: Technical data



Repairs may only be carried out by ISKO specialist personnel or by persons authorized and trained by ISKO with comprehensive product knowledge. Any warranty and liability claims will be rejected if this provision is not complied with.

9 Materials used

The standing device is manufactured as a welded tubular steel construction. The surfaces are powder-coated. All wooden parts are either laminated or lacquered. The surfaces of this product are harmless to the skin from a health point of view.

10 Service and care

All household cleaners without ammonia and abrasives are permitted for cleaning the tubular parts, the lying surface and the wooden parts with a damp cloth. Solvents (e.g. nitro) destroy the coating of the tubes and the lying surface!

Mechanical cleaning (e.g. scraping, sanding) or jet cleaning of the standing device is not permitted. All pivot points of the moving parts are fitted with maintenance-free plain bearings and must not be oiled or greased.

11 Service life of the product

With an expected average degree of use in home care, the service life of the standing device is 10 years. Lack of maintenance and excessive strain on the product can significantly reduce the service life of the standing device. The expected service life in professional nursing home use is 7 years.

12 Disinfection

- To ensure that the standing device functions properly, it should be cleaned, disinfected and checked after each use so that it can be used again immediately.
- Improper cleaning/disinfection of the standing device can be dangerous.
- Depending on the degree of soiling, we recommend cleaning the standing device with a damp cloth or similar.
- For wipe and spray disinfection, disinfectants can be used in their intended concentration. (see manufacturer's instructions)
- The dilution ratio recommended by the manufacturer in the respective instructions for use must be used.



Solvents are not permitted.

Abrasives or scouring pads must not be used.

12.1 Specifications of cleaning agents and disinfectants:

- The working solutions are normally to be used freshly prepared.
- Do not exceed or fall below the specified concentrations.
- They must not contain any corrosive or caustic components.
- They must not contain any substances that change the surface structure or the adhesion properties of the materials.
- Lubricants must not be attacked by the cleaning agent and disinfectant.



Under no circumstances may soap or detergent substances be added to the disinfectant. There is a risk of explosion and fire if alcohol-based agents are used over large areas.



The use of unsuitable detergents and disinfectants can cause damage to the surface coating, for which ISKO KOCH GmbH cannot be held liable.

13 Malfunctions and their rectification

	Fault	Action
1	None of the motors react to the hand control actuations.	Check the plug connection of the mains connection cable. Check the plug connection between the hand control and motor cables with the control unit.
2	One motor does not react to the control actuation	Check plug connection between motor cable and control unit.

Table 7: Malfunctions and their rectification



Modifications, readjustments and repairs to the standing device that cannot be rectified in accordance with the above instructions may only be carried out by the manufacturer directly or by a workshop authorized by the manufacturer.

14 Reporting incidents

All serious incidents occurring in connection with the medical device must be reported to ISKO Koch GmbH and the competent authority of the Member State in which the user and/or patient is established.

15 Recommended accessories

Article name	Order number
Support bar with hip supports	KR-620-X
Upper body support with head and arm support	KR-631-X
Chest support 15 cm, attached to table with screw clamps	KR-744-X
Chest support 25 cm, attaches to table with screw clamps	KR-745-X
Table top horizontally adjustable	KR-710-X
Table edge	KR-602-X
Patient support belt, size S, with base	KR-608-X
Patient support belt, size M, with base	KR-607-X
Patient support belt, size L, with base	KR-606-X
Patient support belt, size XL, with base	KR-609-X

Table 8: Recommended accessories

16 Maintenance

16.1 Legal basis

The Medical Device Regulation (EU) 2017/745 (MDR) and national laws and regulations require operators of medical devices to ensure that the medical device is in a safe operating condition throughout its entire service life.

16.2 Maintenance intervals

As a requirement of the Medical Device Operator Ordinance, a safety inspection must be carried out every two years at the latest. This includes a thorough visual inspection (1), a functional test (2) and a current leakage test (3) in accordance with EN 62353.

(1) Particular attention must be paid to the following points during the visual inspection:

- Tight fit of all screw connections
- Mobility of the pivot points
- Check the power supply cable for crushing or shearing points

(2) Pay particular attention to the following points during the functional check:

- Function of all electrically operated movements
- Fully extend and retract all motors on the standing device (without patients) until they switch off automatically. (Limit switches in the motors must switch off with an audible click)
- Functionality of the brakes
- Movement of the triggers
- Checking the hand control

Functional tests and current leakage tests may only be carried out by ISKO specialist personnel or by persons authorized and trained by ISKO with comprehensive product knowledge.

16.3 Spare parts

All spare parts for this medical device are available from ISKO KOCH GmbH, stating the serial number, order number and article number (these can be found on the type plate attached to the medical device).

To ensure that functional safety and any warranty claims remain valid, only original ISKO KOCH GmbH spare parts should be used.

17 Re-use

Before each reuse of the standing device, a thorough visual and functional check of all electrically operated functions and a current leakage test in accordance with EN 62353 must be carried out as described in the maintenance intervals section. The points on service and care & maintenance specified in the operating instructions must be observed when cleaning the standing device.

18 Disposal

18.1 Disposal of the appliance

The appliance and accessories must be disposed of in accordance with national legal regulations. Please comply with the applicable waste separation regulations! If you are still unsure about this, please contact your local authority or waste disposal company.

18.2 Disposal of electrical components

In accordance with the WEEE Directive 2012/19/EU, this medical device is classified as electrical equipment. All electrical components are free from unauthorized substances classified as hazardous in accordance with RoHS II Directive 2011/65/EU. Replaced electrical components must be disposed of in accordance with the WEEE Directive 2012/19/EU and national regulations.

18.3 Disposal of the packaging

The Waste Framework Directive 2008/98/EU applies in the EU for handling the disposal of packaging. Reusable materials must be recycled in accordance with national regulations.



ISKO KOCH GmbH

Egerländer Str. 28

95448 Bayreuth

Germany

