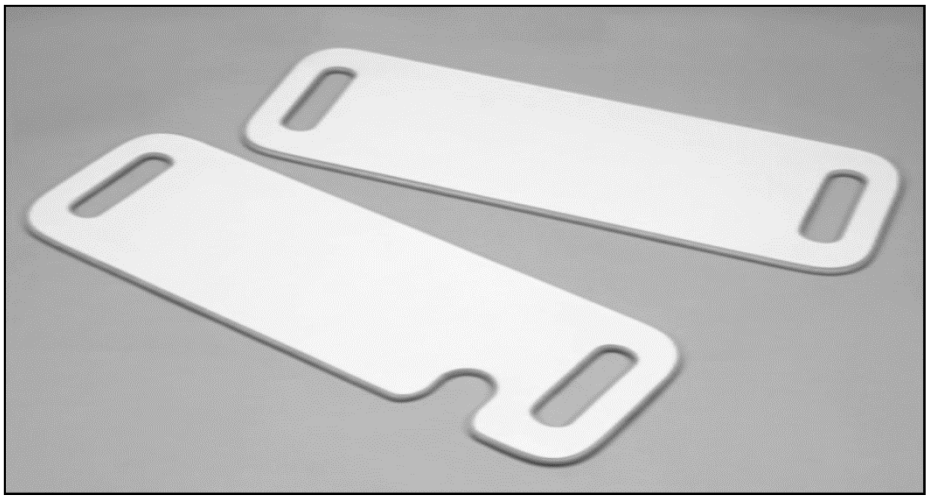
Sliding board



Instruction for use

Stand: 05/2022
(Rev. 2.0)

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1 Foreword

Dear customer!

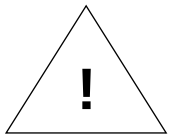
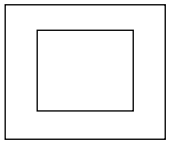
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.

Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

Not all conceivable uses of the device can be covered in these instructions for use. For further information or in the event of problems that are not described in sufficient detail in these instructions for use, please contact your specialist dealer or medical supply store.

2 General notes

2.1 Used symbols

	This warning sign indicates all instructions that are important for safety. Non-observance can lead to accidents or injuries.
	Manufacturer - Indicates the manufacturer of the medical device according to EU Directives 2017/745. The symbol must appear in close proximity to the symbol, together with the name and address of the manufacturer (i.e. the person who places the medical device on the market)
	Conformity symbol according to 2017/745 of the Medical Devices Directive
	Medical Device - Shows the medical device provided by the manufacturer in accordance with EU Directives 2017/745
	Device type B according to IEC 601-1 (Special protection against electric shock)
	Device of protection class II, protective insulation

	Dispose of electrical components in accordance with the legal requirements. Do not dispose of in household waste!
	Date of manufacture - indicates the date when the medical device was manufactured.
	Part number - displays the manufacturer's part number so that the medical device can be identified.
	Serial number - displays the manufacturer's serial number so that a specific medical device can be identified.
	Distributor - indicates the company that distributes the medical device at the location.
	Temperature Limit - indicates the temperature limits to which the medical device can be safely exposed.
	Humidity, Limit - indicates the humidity range to which the medical device can be safely exposed.
	Air Pressure, Limit - indicates the range of air pressure to which the medical device can be safely exposed.
	Observe instruction for use or electronic instruction for use - indicates to the user that it is necessary to observe the instruction for use.

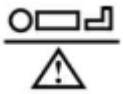
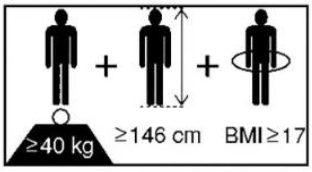
UDI	Unique identifier of a medical device - displays a carrier containing information about a unique identifier of a medical device.
	Safe working load
	Max. patient weight
	Minimum body dimensions/weights of the patient

Table 1: Used symbols

2.2 Type plate

The type plate is attached to the head of the trolley frame. The nameplate allows the product to be clearly identified.

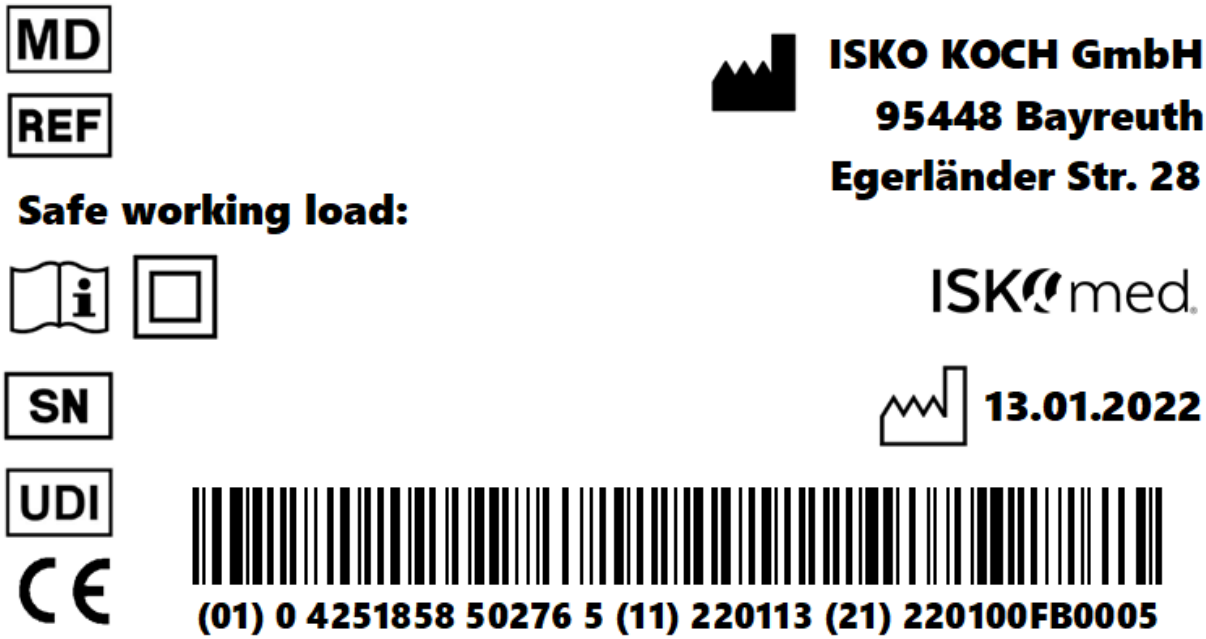


Figure 1: Exemplary type plate

Figure 1 shows an exemplary type plate. For the exact specifications of your product, please refer to the attached type plate.

2.3 Standards verification

The following national and international norms (standards) are used in the design and verification of the product, labeling and instructions for use.

Standard	Title	Edition
DIN EN 60601-1-6	*Serviceability specification*	2010
DIN EN ISO 10993	*Biological evaluation of medical devices - Part 1:* *Assessment and testing*	2010
DIN EN 1041	*Provision of information by the manufacturer of a medical device*	2008
DIN EN ISO 14971	*Medical devices - Application of risk management to medical devices*	2020

Table 2: Standards verification

3 Safety instructions

- Before operating the sliding board, you should read this instruction for use carefully (see Medical Devices Operator Ordinance under your national law). It contains important information for the safe and reliable use of the device. Keep the instruction for use for future reference.
- Safety, reliability and performance are guaranteed if the following instructions are observed and the device is used in an expert manner. As the operator, you must comply with the Medical Devices Operator Ordinance under your national law.

4 General product description

4.1 Intended purpose / Indication

MD

The slide board enables patients/disabled persons who still have sufficiently strong arm muscles and trunk stability to change position without the use of an assistant. The sliding board is a board with a very smooth surface in order to minimize frictional resistance and thus enable the patient to slide over it without any problems. It is used to transfer the patient e.g. to the wheelchair or the nursing bed. The patient can change position independently or, if necessary, with assistance. In general, instruction and a check of the user's physical condition by qualified therapeutic personnel are necessary for use.

4.2 Contraindication

The following patients are not eligible for use of the slide board:

- Decubitus in the buttock area
- Temporary or permanent vertigo
- Impaired cognitive perception

5 Transfer process

Figure 2: Transfer process as an example from wheelchair to care bed

1. Push the slide board under the buttocks.
2. Then grab the end with one hand
3. Now pull your body over the slide board

6 Ambient conditions

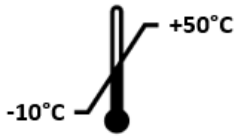
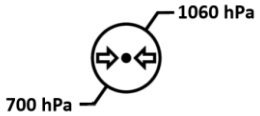
Operating conditions	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Operating conditions

7 Technical data

Designation	Sliding board
Width	**230 mm**
Thickness	**8 mm or 16 mm**
Weight	**0,8 - 1,0 kg**

Bestellnummer	Ausführung	Skizze	Länge
RB-050-1	ohne Griffloch, ohne Radausschnitt		500mm
RB-060-1	ohne Griffloch, ohne Radausschnitt		600mm
RB-070-1	ohne Griffloch, ohne Radausschnitt		700mm
RB-050-2	mit 1 Griffloch, ohne Radausschnitt		500mm
RB-060-2	mit 1 Griffloch, ohne Radausschnitt		600mm
RB-070-2	mit 1 Griffloch, ohne Radausschnitt		700mm
RB-050-3	mit 1 Griffloch, 1 Radausschnitt		500mm
RB-060-3	mit 1 Griffloch, 1 Radausschnitt		600mm
RB-070-3	mit 1 Griffloch, 1 Radausschnitt		700mm
RB-050-4	mit 2 Grifflöcher, 1 Radausschnitt		500mm
RB-060-4	mit 2 Grifflöcher, 1 Radausschnitt		600mm
RB-070-4	mit 2 Grifflöcher, 1 Radausschnitt		700mm
RB-050-5	mit 2 Grifflöcher, ohne Radausschnitt		500mm
RB-060-5	mit 2 Grifflöcher, ohne Radausschnitt		600mm
RB-070-5	mit 2 Grifflöcher, ohne Radausschnitt		700mm

Table 4: Technical data

A "D" is added after the order number when the thickness changes from 8 mm to 16 mm.

Without this "D", the order number designates the 8 mm variant.

8 Used materials

The surface of the sliding board is made of melamine Eurodecor. The surfaces of this product are unthinkable for the skin from the point of view of health.

9 Service and care

For cleaning the sliding board with a damp cloth, all household cleaners without ammonia and scouring agents are permissible.

Please note: Solvents (e.g. nitro) destroy the coating, mechanical cleaning (e.g. sanding, scraping) is not permitted. Do not use sharp-edged tools (e.g. knives, metal scrapers) for cleaning.

The sliding board is intended for use in domestic or protected outdoor areas.

10 Service life of the product

At an expected average level of use in home care, the service life of the sliding board is 10 years. Lack of maintenance and excessive stress on the product can significantly reduce the service life of the sliding board. The expected service life in professional nursing home use is 7 years.

11 Maintenance

11.1 Legal basis

The Medical Device Regulation (EU) 2017/745 (MDR) as well as national laws and regulations require operators of medical devices to ensure a safe operating condition of the medical device during the entire period of use.

11.2 Maintenance intervals

As a requirement of the Medical Device Operator Ordinance §4 (Maintenance), a thorough visual must be performed after the medical device has been in operation for at least two years.

(1) During the visual inspection, particular attention must be paid to the following points:
- Cracks
- Surface injuries
- Fractures

11.3 Spare parts

All spare parts for this medical device must be ordered 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 the functional safety and any warranty claims remain valid, only original ISKO KOCH GmbH parts are to be used for the spare parts.

ISKO KOCH GmbH

Egerländer Straße 28

95448 Bayreuth

Tel.: +49(0)921/150845-0 (Monday – Thursday 8:00 – 17:00 pm & Friday 8:00 – 16:00 pm)

Fax: +49(0)921/150845-45

E-Mail: info@isko-koch.de

11.4 Notes on documentation

According to the Medical Device Operator Regulation and Medical Device Regulation (EU) 2017/745 (MDR), there is a documentation obligation for:

- Maintenance
- Incidents / near misses

12 Reuse

The service and care & maintenance points mentioned in the instruction for use must be observed when cleaning the sliding board.

13 Disposal

13.1 Disposal of the device

Disposal of the device and accessories, if any, should be carried out in an environmentally friendly manner and in accordance with the legal regulations. Please adhere to the valid waste separation regulations! If there are any uncertainties in this matter, please contact your local municipality or waste disposal company.

13.2 Disposal of the electrical components

*if electrical components are included in the medical device

According to Directive 2012/19/EU - WEEE2, this medical device is classified as an electrical device. All electrical components are free of unauthorized ingredients classified as harmful according to RoHS II Directive 2011/65/EU. In addition, replaced electrical components must be disposed of in accordance with European directives (see Directive 2012/19/EU - WEEE2).

13.3 Disposal of the packaging

The EU Waste Framework Directive 2008/98/EC is decisive for the handling during the disposal of the packaging. Reusable materials must be fed into a recycling cycle in accordance with national regulations.

14 Declaration of Conformity

As the manufacturer, we declare under our sole responsibility that our sliding boards complies with the basic requirements of the EC Directive for

Medical devices 2017/745, Annex II

ISKO KOCH GmbH

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95448 Bayreuth

CE