Declaration of Conformity

Manufacturer	AKRUS GmbH & Co. KG Otto-Hahn-Str. 3 25337 Elmshorn Germany
Single Registration Number (SRN)	DE-MF-000005262
D-U-N-S number	324099522

Product / Trade name	See product list
Article number	See product list
UDI-DI	See product list
Basic UDI-DI	426064794SCSB5010surgeS8
ID of Technical Documentation	TD04
Intended Use	The mobile, electrically operated operating tables are designed for placement and positioning of patients in the required posture during diagnostic and therapeutic procedures as well as during surgical interventions on humans. The product enables optimal access to the patient's head in its various positions and is intended for use in the following medical fields: • Ophthalmology • ENT (ear, nose and throat) • Oral and maxillofacial surgery • Plastic, reconstructive and aesthetic surgery, primarily in the head area • Dentistry • Dermatology • Nerve stimulation • Blood donation Due to its design, functionality and accessories, the surgical chair only allows the following positioning of patients: • Supine position • Sitting position • Beach chair position • Prone position • Shock position: Zero position and Trendelenburg position. The surgical chair is designed for patients weighing a maximum of 200 kg or 300 kg, depending on the variant. The headrest is designed to support a maximum weight of 20 kg. The operating tables are only intended for positioning patients immediately before, during and after a procedure/surgical intervention and for short-distance transportation for transfer purposes along with a safety rail or patient fixation belt.

	Positioning may only be carried out by appropriately trained specialist personnel. The product is suitable for use in the immediate controlled patient environment. The essential performance of the product is given by no movement during first error situations.
EMDN-Code	Z12011201
GMDN-Code	38447 - General examination/treatment chair, electric
MDA-Code	0313 - Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
UMDNS-Code	13-961 – table, operating
FDA product code	GDC – Table, Operating-Room, Electrical
EU-Conformity regarding	Medical Device Regulation (EU) 2017/745 RoHS 2011/65/EU
Risk classification	Class I according to annex VIII, rule 13 of regulation (EU) 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, that the medical device in regard of this declaration is conform to Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Common Standards

DIN EN 60601-1:2022-11	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
DIN EN ISO 14971:2022-04	Medical devices - Application of risk management to medical devices
DIN EN ISO 15223-1:2022-02	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
RoHS	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances
Regulation (EU) 2023/1230	Regulation (EU) on machinery

Common Specification

DIN EN 60601-2-46:2025-04	*Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables*

Product List

Device model	Product / Trade name	Article number	UDI-DI
mobile operating chair	SC 5010 ES	242.000000	04260647941494
mobile operating chair	SC 5010 HS	275.000000	04260647941500

Configuration Parts

Configuration group / Device model	Product / Trade name	Article number	UDI-DI
lifting unit	standard incl. control unit	242.012233	04260647942200
lifting unit	heavy duty incl. control unit	242.012234	04260647942200
lifting unit	standard incl. control unit	275.012233	04260647942200
lifting unit	heavy duty incl. control unit	275.012234	04260647942200
head rest	holding bracket	241.030651	04260647942217
head rest	additional tilt	275.030650	04260647942217
head rest	headrest (horseshoe shaped)	241.030690	04260647942217
head rest	headrest flat (width=250mm)	241.030660	04260647942217
head rest	headrest flat (width=350mm)	275.030800	04260647942217
head rest	headrest flat (width=450mm)	275.030700	04260647942217
head rest	multi-joint headrest	241.030648	04260647942217
safety support for patient transport	safety rail	240.020200	04260647942262
anesthesia bow without air passage	anesthesia bow without air passage	240.030500	04260647941678
instrument tray	instrument tray	275.020400	04260647942071
table for x-ray	arm rest table	276.032800	04260647942279
table for x-ray	arm rest table (viscoelastic)	276.032850	04260647942279
arm rest	multi-joint armrest	241.030250	04260647942224
arm rest	armrest without adjustment options	241.030260	04260647942224
arm rest	arm support for side and prone positions	276.032300	04260647942224
arm rest	multi-joint armrest (seated application)	275.030250	04260647942224
arm rest	wrist rest for surgeons	240.030400	04260647942224

control unit	remote control (with cord)	101-151	04260647942248
control unit	foot switch 2 axes	275.012800	04260647942248
control unit	6 Foot joystick panel function (M1+M2 available)	275.012900	04260647942248
upholstery	standard SC 5010 ES	242.900000	04260647942255
upholstery	viscoelastic SC 5010 ES	242.901000	04260647942255
upholstery	standard SC 5010 HS	275.900000	04260647942255
upholstery	viscoelastic SC 5010 HS	275.901000	04260647942255

Additional information

The conformity assessment procedure for the products have been conducted in accordance with article 10, article 15 and article 52(7) by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III of the Medical Device Regulation (EU) 2017/745. This conformity assessment is the basis for the issued EU declaration of conformity.

This declaration of conformity is valid until a new version is issued, but not longer than the 2031-04-01 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-03-25

Person responsible for regulatory compliance according to article 15 in MDR

2026-03-25

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