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	426064794ak5010MBSEU
ID of Technical Documentation	TD05
Intended Use	Mammography chairs are intended for positioning and positioning patients for examinations before and during mammography and stereotactic breast biopsy.
EMDN-Code	Z12011201 - OPERATING CHAIRS
GMDN-Code	38447 - General examination/treatment chair, electric
MDA-Code	MDA 0313 - Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
UMDNS-Code	16-437 – Chairs EXAMINATION / TREATMENT
FDA product code	LGX – TABLE, EXAMINATION, MEDICAL POWERED
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	
Not applicable	*No particular standard for these medical devices existent*

Product List

Product / Trade name	Article number	UDI-DI
ak 5010 MBS	277.000000	04260647941524
ak 5010 MBS	277.000009	04260647941555
ak 5010 MBS	277.000004	04260647941524
ak 5010 MBS	277.000007	04260647941555
ak 5010 MBS	277.000005	04260647941524

Configuration parts

Configuration group / Device Model	Product / Trade name	Article number	UDI-DI
Headrest	Kopfstütze verschiebbar	277.030700	04260647942170
Headrest	Kopfstütze Standard	277.030600	04260647942170
Upholstery	Polsterteile (Standard)	277.900000	04260647942187
Upholstery	Polsterteile (viscoel.)	277.901000	04260647942187

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 2028-11-22 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-10-07

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

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