



VF 8-2-6-1

EU-Konformitätserklärung für Medizinprodukte

Gültig ab 17.05.2023

**Manufacturer**

Akrus GmbH &amp; Co. KG

Otto-Hahn-Str. 3

25337 Elmshorn

Germany

Single Registration Number (SRN)

DE-MF-000005262

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

GMDN-Code 38447

MDA-Code MDA 0313

UMDNS-Code 16-437

EU-Conformity regarding Medical Device Regulation (EU) 2017/745  
RoHS 2011/65/EURisk 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



Directive 2006/42/EC

Machinery directive

### Common Specification

DIN EN 60601-2-46:2020-04

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

### 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
Kopfstütze verschiebbar	277.030700	04260647942170
Kopfstütze Standard	277.030600	04260647942170
Polsterteile (Standard)	277.900000	04260647942187
Polsterteile (viscoel.)	277.901000	04260647942187

### Additional Information

This declaration of conformity is valid until a new version is issued, but not longer than the 2025-06-06 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2024-06-06

Person responsible for regulatory  
compliance according to article 15 in  
MDR

  
Roman Gartz

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