



VF 8-2-6-1

EU-Konformitätserklärung für Medizinprodukte

Gültig ab 17.05.2023

Manufacturer	Akrus GmbH & 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 0204
UMDNS-Code	16-437
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



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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	277.30700	04260647942170
Kopfstütze Standard	277.30600	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 2024-10-25 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2023-11-21

Person responsible for regulatory
compliance according to article 15 in
MDR


Roman Gartz

CEO


Rainer Höpfl