AKRUS	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	Additive Back support (viscoel.) MBS
Article number	277.032020
UDI-DI	04260647942057
Basic UDI-DI	426064794Zubehoer/MBSE7
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	MDN 1214
UMDNS-Code	MDA 0204
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

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*

Additional Information

This declaration of conformity is valid until a new version is issued, but not longer than the 2024-11-22 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2023-11-23

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

CEO

Rainer Höpfl