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| **Manufacturer** | Akrus GmbH & Co. KG<br>Otto-Hahn-Str. 3<br>25337 Elmshorn<br>Germany |
| Single Registration Number (SRN) | DE-MF-000005262 |
| Product / Trade name | Additive Back support MBS |
| Article number | 277.032010 |
| UDI-DI | 04260647942040 |
| Basic UDI-DI | 426064794Zubehoer/MBSE6 |
| 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<br>RoHS 2011/65/EU |
| Risk classification | Class I<br>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**

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| DIN EN 60601-1:2022-11 | Medical electrical equipment –<br>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<br>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*