



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	426064794ak4802Y
ID of Technical Documentation	TD01
Intended Use	The surgeon's chair is a chair for supporting medical activities carried out in a seated position. Exceptions are surgical procedures in the field of cardiology.
EMDN-Code	V08020101
GMDN-Code	34833
MDA/MDN-Code	MDA 0318
UMDNS-Code	15-690
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
Surgeon chair ak 480	279.000013	04260647946352
Surgeon chair ak 480	279.000012	04260647946345
Surgeon chair ak 480	279.000011	04260647946338
Surgeon chair ak 480	279.000010	04260647946321
Surgeon chair ak 480	279.000018	04260647946406
Surgeon chair ak 480	279.000017	04260647946390
Surgeon chair ak 480	279.000016	04260647946383
Surgeon chair ak 480	279.000015	04260647946376
Surgeon chair ak 480	279.000023	04260647946451
Surgeon chair ak 480	279.000022	04260647946444
Surgeon chair ak 480	279.000021	04260647946437
Surgeon chair ak 480	279.000020	04260647946420

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, 2023-12-05

Person responsible for regulatory
compliance according to article 15 in
MDR

Roman Gartz

CEO

Rainer Höpfl