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
D-U-N-S number	324099522
Product / Trade name	See product list
Article number	See product list
UDI-DI	See product list
Basic UDI-DI	426064794ak480J6
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 – generic use electric medical chairs
GMDN-Code	34833 – medical chair
MDA/MDN-Code	MDA 0318 - Other active non-implantable devices
UMDNS-Code	15-690 – chair, height adjustable
FDA product code	GDC – Table, Operating-Room, Electrical
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

Regulation (EU) 2023/1230 Regulation (EU) on machinery

Common Specification

Not applicable

Product List

Product / Trade name	Article number	UDI-DI
Surgeon chair ak 480	279.000000	04260647945928

Product / Trade name	Catalogue number of fix configuration	UDI-DI
Surgeon chair ak 480	279.000013	04260647945928
Surgeon chair ak 480	279.000012	04260647945928
Surgeon chair ak 480	279.000011	04260647945928
Surgeon chair ak 480	279.000010	04260647945928
Surgeon chair ak 480	279.000018	04260647945928
Surgeon chair ak 480	279.000017	04260647945928
Surgeon chair ak 480	279.000016	04260647945928
Surgeon chair ak 480	279.000015	04260647945928
Surgeon chair ak 480	279.000023	04260647945928
Surgeon chair ak 480	279.000022	04260647945928
Surgeon chair ak 480	279.000021	04260647945928
Surgeon chair ak 480	279.000020	04260647945928

Additional Information

The conformity assessment procedure for the products have been conducted in accordance with article 10, article 15 and article 52(7) by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III of the Medical Device Regulation (EU) 2017/745. This conformity assessment is the basis for the issued EU declaration of conformity.

This declaration of conformity is valid until a new version is issued, but not longer than the 2028-11-17 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-06-19

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

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