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	426064794ak446J6
ID of Technical Documentation	TD01
Intended Use	The doctor's stools are chairs for supporting medical activities carried out in a seated position. Surgical procedures in the fields of neurology and cardiology are excluded. The doctor's stools (ak445, ak446, ak447) and surgeon's chairs (ak480) are ergonomically designed chairs for seated medical activities. The product is suitable for use in the immediate patient environment. The chairs are not approved for transporting people. Any use other than the intended use is not permitted. - The ak445, ak446 and ak447 surgeon's stool is designed for a maximum load of 135 kg.
EMDN-Code	V080202 – manual, medical chairs
GMDN-Code	34833 – medical chair
MDA/MDN-Code	MDN 1214 - General non-active non-implantable devices used in health care and other nonactive non-implantable devices
UMDNS-Code	15-690 – chair, height adjustable
FDA product code	FZM – stool, operating-room
EU-Conformity regarding	Medical Device Regulation (EU) 2017/745 RoHS 2011/65/EU
Risk classification	Class I according to annex VIII, rule 1 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 Deklaration of conformity

Common Standards

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	
-	-

Product List

Product / Trade name	Article number	UDI-DI
Doctor stool ak 446	281.000000	04260647946116

Product / Trade name	Catalogue number of fix configuration	UDI-DI
Doctor stool ak 446	281.000002	04260647946116
Doctor stool ak 446	281.000004	04260647946116
Doctor stool ak 446	281.000003	04260647946116
Doctor stool ak 446	281.000005	04260647946116
Doctor stool ak 446	281.000006	04260647946116
Doctor stool ak 446	281.000007	04260647946116
Doctor stool ak 446	281.000001	04260647946116
Doctor stool ak 446	281.000000	04260647946116
Doctor stool ak 446	281.000008	04260647946116

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, 2026-06-22

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

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