



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	426064794ak445/ak4473T
ID of Technical Documentation	TD01
Intended Use	<p>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.</p> <p>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.</p> <p>The chairs are not approved for transporting people. Any use other than the intended use is not permitted.</p> <ul style="list-style-type: none">- The ak445, ak446 and ak447 surgeon's stool is designed for a maximum load of 135 kg.- The ak480 surgeon's chair is designed for a maximum load of 135 kg.
EMDN-Code	V080202
GMDN-Code	34833
MDA/MDN-Code	MDN 1214
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 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 declaration of conformity

Common Standards



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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

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Product List

Product / Trade name	Article number	UDI-DI
Doctor stool ak 445	280.001002	04260647945515
Doctor stool ak 445	280.002002	04260647945560
Doctor stool ak 445	280.001005	04260647945539
Doctor stool ak 445	280.002008	04260647945591
Doctor stool ak 447	278.001002	04260647945744
Doctor stool ak 447	278.002002	04260647945799
Doctor stool ak 445	280.001003	04260647945522
Doctor stool ak 445	280.002003	04260647945577
Doctor stool ak 445	280.001006	04260647945669
Doctor stool ak 445	280.202003	04260647945676
Doctor stool ak 447	278.001003	04260647945751
Doctor stool ak 447	278.002003	04260647945805
Doctor stool ak 445	280.001007	04260647945683
Doctor stool ak 445	280.002007	04260647945584
Doctor stool ak 445	280.001008	04260647945812
Doctor stool ak 445	280.002009	04260647945607
Doctor stool ak 447	278.001005	04260647945768
Doctor stool ak 447	278.002005	04260647945829
Doctor stool ak 445	280.001001	04260647945508
Doctor stool ak 445	280.001000	04260647945492
Doctor stool ak 445	280.002001	04260647945553
Doctor stool ak 445	280.002000	04260647945546
Doctor stool ak 445	280.001009	04260647945836
Doctor stool ak 445	280.002010	04260647945652



Doctor stool ak 447	278.001001	04260647945737
Doctor stool ak 447	278.001000	04260647945720
Doctor stool ak 447	278.002001	04260647945782
Doctor stool ak 447	278.002000	04260647945775

Additional Information


This declaration of conformity is valid until a new version is issued, but not longer than the 2024-11-20 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

CEO


Roman Gartz


Rainer Höpfl