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
Product / Trade name	See product list
Article number	See product list
UDI-DI	See product list
Basic UDI-DI	426064794Zubehoer/ITQQ
ID of Technical Documentation	TD03
Intended Use	The instrument tables are height-adjustable equipment tables. They are used to hold and supply power to ophthalmic devices and accessories for the treatment of seated patients. The IT 1060.i instrument table is suitable for wheelchair users. For treatment, push the wheelchair with the front castors onto the base plate of the instrument table. The castors are secured against rolling away by the grooves in the base plate.
EMDN-Code	Z121290001
GMDN-Code	36400
MDA-Code	MDN 1214
UMDNS-Code	13-959
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
Directive 2006/42/EC	Machinery directive

Common Specification

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Product List

Product / Trade name	Article number	UDI-DI
Sliding keyboard shelf	470.032000	04260647940022
Footrest extension	472.010003	04260647940039

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, 2023-11-21

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

CEO

Rainer Höpfl