



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	426064794CZMIT2020FX
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	Z12129001 - ELECTRIC OPHTHALMOLOGIC TABLES
GMDN-Code	36400 - Ophthalmic instrument table, line-powered
MDA-Code	MDA 0318 – other active non-implantable devices
UMDNS-Code	13-959 - Tables, instrument
FDA product code	HRJ – Table, instrument, powered, ophthalmic
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



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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**No particular standard for these medical devices existent***Product List**

Product / Trade name	Article number	UDI-DI
Instrument delivery table ak 106	444.000000	04260647946239
IT 1060.i	470.000000	04260647940015
IT 760.i	471.000000	04260647940008

Configuration parts

Configuration group / device model	Product / Trade name	Article number	UDI-DI
Tabletop	Tischplatte V-förmig Kabeldurchlass	444.050001	04260647946246
Tabletop	Tischplatte 600x1000x28 m.Kabeldurchlass	444.050002	04260647946246
Tabletop	Tischplatte 500x600x28	442.050001	04260647946246
Tabletop	Tischplatte V-förmig 500x1000x28	442.050002	04260647946246
Tabletop	Tischplatte 600x1000x28	442.050003	04260647946246

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 2028-11-19 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-10-07



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Person responsible for regulatory
compliance according to article 15 in
MDR

Roman Gartz

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