



VF 8-2-6-1

EU-Konformitätserklärung für Medizinprodukte

Gültig ab 17.05.2023

Declaration of Conformity

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	426064794LSCLASER_OPEG
ID of Technical Documentation	TD02
Intended Use	The medical device is intended for use as a medical device for examinations and surgical procedures in ophthalmology on the human body. Any other use of the product is not permitted. The medical device is intended as external patient support for supine position in ophthalmic applications.
EMDN-Code	Z12011202 Operating Tables
GMDN-Code	43383 - Ophthalmic operating table, electromechanical
MDA-Code	0313 - Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
UMDNS-Code	13-961 - table, operating
FDA Product code	FQO - Table, Operating-Room, Ac-Powered
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

DIN EN 60601-2-46:2025-04

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

Product List

Product / Trade name	Article number	UDI-DI
Patient Support System LSCneo	636.000004	04260647943573

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 2028-11-23 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-06-02

Person responsible for regulatory compliance according to article 15 in MDR


Roman Gartz

AKRUS GmbH & Co. KG
Otto-Hahn-Strasse 3
25337 Elmshorn
Tel.: 04121 - 79 19 30

CEO


Rainer Höpfl
AKRUS GmbH & Co. KG
Otto-Hahn-Strasse 3
25337 Elmshorn
Tel.: 04121 - 79 19 30