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	Patient Support System LSCneo
Article number	636.000004
UDI-DI	04260647943573
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
MDA-Code	0313
UMDNS-Code	13-961
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	
DIN EN 60601-2-46:2020-04	*Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables*
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, 2023-10-26

Person responsible for regulatory compliance according to article 15 in MDR

Roman Gartz

CEO

Rainer Höpfl