



VF 8-2-6-1

EU-Konformitätserklärung für Medizinprodukte

Gültig ab 17.05.2023

|                                  |                                                                                                                                                                   |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer                     | Akrus GmbH & Co. KG<br>Otto-Hahn-Str. 3<br>25337 Elmshorn<br>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                     | 426064794ak480J6                                                                                                                                                  |
| ID of Technical Documentation    | TD01                                                                                                                                                              |
| Intended Use                     | The surgeon's chair is a chair for supporting medical activities carried out in a seated position. Exceptions are surgical procedures in the field of cardiology. |
| EMDN-Code                        | V08020101 – generic use electric medical chairs                                                                                                                   |
| GMDN-Code                        | 34833 – medical chair                                                                                                                                             |
| MDA/MDN-Code                     | MDA 0318 - Other active non-implantable devices                                                                                                                   |
| UMDNS-Code                       | 15-690 – chair, height adjustable                                                                                                                                 |
| FDA product code                 | GDC – Table, Operating-Room, Electrical                                                                                                                           |
| EU-Conformity regarding          | Medical Device Regulation (EU) 2017/745<br>RoHS 2011/65/EU                                                                                                        |
| Risk classification              | Class I<br>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 –<br>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 |



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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***Product List**

| Product / Trade name | Article number | UDI-DI         |
|----------------------|----------------|----------------|
| Surgeon chair ak 480 | 279.000000     | 04260647945928 |

| Product / Trade name | Catalogue number of fix configuration | UDI-DI         |
|----------------------|---------------------------------------|----------------|
| Surgeon chair ak 480 | 279.000013                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000012                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000011                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000010                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000018                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000017                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000016                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000015                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000023                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000022                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000021                            | 04260647945928 |
| Surgeon chair ak 480 | 279.000020                            | 04260647945928 |



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#### 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.

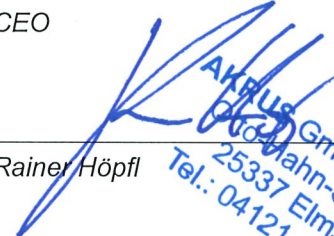
This declaration of conformity is valid until a new version is issued, but not longer than the 2028-11-17 and covers all in this time range produced medical devices in this declaration.

Elmshorn, 2026-06-19

Person responsible for regulatory  
compliance according to article 15 in  
MDR

  
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