CERTIFIED BY MIDES

- MDR conformity
- Sustainability
- Top service
- Multilingual support
- Technology and quality leadership

MDR – Certificate

Repair and Refurbishment of Medical Devices

1. Introduction

For more than 20 years, MIDES Healthcare Technology GmbH (hereinafter referred to as MIDES) has been offering the highest quality in the repair and refurbishment of a wide range of medical devices.

In order to guarantee its customers the highest quality and compliance with rigorous safety standards, MIDES repairs each device in accordance with certified process flows and in accordance with the MDR regulations, which came into force as part of the European Medical Device Regulation (EU2017/745) in 2021.

2. Extracts from the MDR regulations on repairs and refurbishments

The regulations of the MDR generally refer to new medical devices.

With regard to the repair or refurbishment of a medical device, Article 23, paragraph 1, of the MDR regulations clearly states that any component ("spare part") used in the course of a repair must not impair the safety features or the performance of the device:

> *(1) Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.*

3. Conclusion

The regulations of the European Medical Device Regulation (MDR) define the safety and performance requirements for medical devices.
For components ("spare parts") that are used in the course of the repair or reprocessing of a medical device, the MDR requires that these components must not impair the safety features or the performance of the repaired product.

For over ten years MIDES Healthcare Technology GmbH has been certified according ISO 9001 and ISO 13485, which is the comprehensive quality management system for medical devices. In accordance with these quality processes, MIDES warrants that all components and all so-called spare parts, which are used in the course of a repair or refurbishment, ensure the full functionality and operational safety of the medical device within the scope of its product specification.

This guarantee can be provided in particular through the use of original components as well as the implementation and documentation of a comprehensive spare parts qualification process (i.e. SLP-process flow for safety and performance-relevant products), which ensures that all spare parts used have equivalent performance and safety characteristics to the original components, and which is regularly internally and externally audited.

Thus, it can be confirmed that repairs and refurbishments of medical devices carried out by MIDES Healthcare Technology GmbH ensure the full functionality and operational safety of the medical devices concerned in accordance with the European Medical Device Regulation (MDR).

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