

EU – Declaration of Conformity



We, A2J GmbH, Am Fuchsberg 13 - D 87452 Altusried, represented by Armin Janusch, CEO, declare under our sole responsibility that the medical device group

Crazy Horse Active Power wheelchair pulling aid

Basic UDI-DI: **426072548 1302090225 8N**

complies with the relevant provisions of Regulation (EU) 2017/745 (MDR) on medical devices and, where applicable, other relevant Union legislation

The product group **Crazy Horse Active Power wheelchair pulling aid** includes the following products

Crazy Horse Active Power

various model versions

The intended use of the **Crazy Horse Active Power wheelchair pulling aid** is:
Manual wheelchair pulling aid for outdoor activities

According to Annex VIII, Rule 1 MDR, all devices of the **Crazy Horse Active Power wheelchair pulling aid** product group are class 1 medical devices and the applicable essential safety and performance requirements according to Annex I MDR are fulfilled. A conformity assessment procedure according to Annex II & III MDR has been carried out.

Applicable harmonized standards, national standards, or other regulatory documents:

DIN EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes

DIN EN ISO 14971 – Medical devices – Application of risk management to medical devices

DIN EN 12183 – Manual wheelchairs – Requirements and test methods

DIN EN ISO 10993-1 – Biological evaluation of medical devices - **DIN EN ISO 10993-5** – In vitro Cytotoxicity

This EU Declaration of Conformity is
valid until **25.05.2024**

Armin Janusch

Altusried, the 20th of May 2023

Armin Janusch
CEO A2J GmbH

Manufacturers SRN: DE-MF-000008341

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