

## 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 **01.01.2025**

Altusried, 25.05.2024

*Armin Janusch*

Armin Janusch  
CEO A2J GmbH

**Manufacturers SRN: DE-MF-000008341**

Version 1.1	Erstellt von: TC	Freigegeben von: AJ – 25.05.24	Qualitätsmanagementsystem nach EN ISO 13485		
Datei: A2J CE KE-EN CHActive 05-24.docx			Anlage: 11.03.2021	Stand: 25.05.2024	Seite 1 von 1
Firma A2J GmbH – Am Fuchsberg 13 – D 87452 Altusried			© Castner Consulting – Medizinische Systemberatung		