# 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 –Power wheelchair pulling aid*

Basic UDI-DI: **426072548 50160150235018 6D**

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 - Power wheelchair pulling aid** includes the following products | |
|---|---|
| Crazy HorsE-Power 400R | Crazy HorsE-Power 600R |
| Crazy HorsE-Power 500R | |

The intended use of the **Crazy HorsE - Power wheelchair pulling aid** is:
Electrical motorized wheelchair pulling aid for outdoor activities

According to Annex VIII, Rule 13 MDR, all devices of the **Crazy HorsE - 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**

Armin Janusch

Altusried, 25.05.2024

Armin Janusch
CEO A2J GmbH

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