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:

EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019 – Medical devices – Application of risk management to medical devices
EN 12183:2014 – Manual wheelchairs – Requirements and test methods
DIN EN 10993-1:2018 – Biological evaluation of medical devices - **DIN EN 10993-5:2009** – In vitro Cytotoxicity

This EU Declaration of Conformity is
valid until **25.05.2023**

Armin Janusch

Altusried, the 26th of May 2022

Armin Janusch
CEO A2J GmbH

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