

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 HorseE –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 HorseE - 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 HorseE - 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 HorseE - 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**

Altusried, the 20th of May 2023

Armin Janusch

Armin Janusch
CEO A2J GmbH

Manufacturers SRN: DE-MF-000008341

Version 1.1	Erstellt von: TC	Freigegeben von: AJ – 20.05.2023	Qualitätsmanagementsystem nach EN ISO 13485		
Datei: A2J CE KE ENol CHEPow 05-23	Anlage: 11.03.2021		Stand: 20.05.2023	Seite 1 von 1	
Firma A2J GmbH – Am Fuchsberg 13 – D 87452 Altusried			© Castner Consulting – Medizinische Systemberatung		