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

PELVI.LOC® Positioning and Retraction System

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

The ***PELVI.LOC*®** System includes the following products				
pelvi.loc Basic UDI-DI: **426072548 01650120229 D2**			**torso.loc** Basic UDI-DI: **426072548 20015018019015 Z5**	**foot.loc** Basic UDI-DI: **426072548 6015015020 AX**
PL-2DB	PL-3DSR	PL-CSS	PL-W	PL-KG-KS
PL-2DS	PL-3DSRR	PL-UG	PL-WR	PL-KG-ZR
PL-2DA	PL-3DA	PL-UGR	PL-OPS	PL-KG-GO
PL-2DAS	PL-3DAS	PL-GF	PL-OPG-FLEX	PL-RR
PL-3DB	PL-3DASR	PL-3DWP	TL-3DSR	PL-RR-GO
PL-3DS	PL-ASY		TL-W	

The intended use oft the ***PELVI.LOC*®** System is: Positioning and retraction for persons with limited mobility e.g. wheelchair, seating shell, therapy chair, rehab buggy, sports equipment, standing device.

According to Annex VIII, Rule 1 MDR, all devices of the ***PELVI.LOC*®** System 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 – 8.5

DIN EN 12184:2014 – Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods - 9.5

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**