

## 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 <b>PEL VI.LOC®</b> System includes the following products						
<b>pelvi.loc</b> Basic UDI-DI: <b>426072548 01650120229 D2</b>			<b>torso.loc</b> Basic UDI-DI: <b>426072548 20015018019015 Z5</b>		<b>foot.loc</b> Basic UDI-DI: <b>426072548 6015015020 AX</b>	
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	RT-2DS	TL-W			

The intended use of 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 I medical devices and the applicable essential safety and performance requirements according to Annex I MDR are fulfilled. Technical documentation in accordance with Annex II & III MDR is maintained.

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 – 8.5

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

**DIN EN ISO 10993-1** – Biological evaluation of medical devices - **DIN EN ISO 10993-5** – In vitro Cytotoxicity

This EU Declaration of Conformity applies in conjunction with the delivered product

Altusried, the **27.04.2025**

  
Armin Janusch  
CEO A2J GmbH

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