CE EC Declaration of Conformity

Manufacturer:

compliant concept AG
Jurastrasse 58 • 5430 Wettingen • Switzerland SRN: CH-MF-000018990

We declare under our sole responsibility that the product

Product:

Active Mobilisation System	**AMS**	(Trade name and product name)
Article Number:	A-000001	
Basic UDI-DI:	PP 12312 AMS01 41	
Product Classification:	I Medical Device	Classification rule(s) 1 & 13
Sterility Status:	non-sterile	
Measuring Function:	no	
Conformity Assessment Procedure:	Annex VIII	

to which this declaration relates, are in conformity with the requirements of the following regulations

- **Medical Devices Regulation (EU) 2017/745 and MepV**

Furthermore, the products comply with the following standards and recommendations

- **EN 60601-1**
- **EN 60601-1-2**
- **EN 62353 VDE 0751-1**
- **EN 12182**
- **EN 597-1**
- **EN 597-2**

Intended Use of the Product:

The AMS is a hybrid, dynamic mattress that combines continuous lateral positioning with additional intermittent pressure relief to support the prevention and treatment of pressure ulcers.

European Representative:

EC REP
BEO MedConsulting Berlin GmbH
Helmholtzstraße 2–9
D-10587 Berlin

SRN: DE-AR-000006764

compliant concept AG, Wettingen, 19.06.2023

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