



## 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

Article Number:

Basic UDI-DI:

Product Classification:

Sterility Status:

Measuring Function:

Conformity Assessment Procedure:

#### AMS

A-000001

PP 12312 AMS01 41

I Medical Device

non-sterile

no

Annex VIII

(Trade name and product name)

Classification rule(s) 1 & 13

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

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

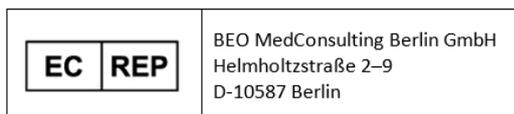
Furthermore, the products comply with the following standards and recommendations

- 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:



SRN: DE-AR-000006764

compliant concept AG, Wettingen, 19.06.2023

  
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