EC Declaration of Conformity

We,

Burmeier GmbH & Co. KG
Industriestraße 53
D - 32120 Hiddenhausen,

SRN: DE-MF-000010563

hereby declare under sole responsibility as the manufacturer that the product model named below:

Care bed

Intended purpose: Bed used for medical purposes for positioning and optionally securing patients against accidentally falling out. Aid to assist in the diagnosis, monitoring, prevention, treatment, alleviation of illness or to compensate for an injury or impairment.

Model:	**Dali**
REF:	300000
Basic-UDI-DI:	4047037Dali4Y

in the version submitted complies with the essential safety and performance requirements set out in Annex I to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 last amended on 5.April 2023, concerning medical devices (MDR).

It is classified as a Class I active medical device in accordance with the classification criteria set out in MDR- Annex VIII rule 1+13.

Furthermore, this product complies with the following EU directives: 2006/42/EC (machinery); 2011/65/EU (RoHS); 2014/30/EU (EMC); 2014/35/EU (Low Voltage Directive); 2014/53/EU (RED).

All applicable parts of the following standards, each with the current status at the time of placing on the market, were used to assess the conformity with the mentioned EU-Directives and MDR-Regulation according to Annex IX, chapter I+III:

Harmonised standards:	
EN ISO 10993-1 EN ISO 10993-5	Biological evaluation of medical devices: Part 1: Evaluation and testing within a risk management process; Part 5: Tests for in vitro cytotoxicity
EN ISO 14971	Risk analysis for medical devices
EN ISO 15223-1 EN ISO 20417	Symbols to be used with medical device labels, labelling and information to be supplied Medical devices - Information to be supplied by the manufacturer
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6; EN 62366	Medical electrical equipment: Usability
EN 60601-1-11	Medical electrical equipment.. Requirements for medical electrical equipment ... used in the home healthcare environment:
EN 60601-2-52	Medical electrical equipment: Particular requirements for the basic safety and essential performance of medical beds
International standards:	
IEC 60601-1	Medical electrical equipment: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-52	Medical electrical equipment: Particular requirements for the basic safety and essential performance of medical beds

Hiddenhausen, 2024-01-02

Georgios Kampisiulis Kemmler
(Management)

Reiner Bekemeier
(Management)