



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: For positioning and facilitating the care of frail adult persons in need of care in homes for the elderly, nursing homes and home care.

Model:	Regia
Basic-UDI-DI:	4047037Regia8W

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 concerning medical devices (MDR).

It is classified as a Class I active medical device in accordance with the classification criteria set out in Annex VIII. The relevant technical documentation is kept by the manufacturer's safety representative.

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 Regulation according to Annex IX:

Harmonised standards:

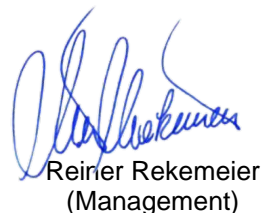
- EN ISO 10993-1 Biological evaluation of medical devices
- EN ISO 14971 Risk analysis for medical devices
- EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied
- EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety 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, 2023-01-02


Georgios Kampisiulis Kemmler
(Management)


Reiner Rekemeier
(Management)