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:

Model:	**Lenus**
Basic-UDI-DI:	4047037270000T3

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.

To evaluate the conformity to the Directives set out in Annex IX, all applicable parts of the following standards were referred to:

Harmonised standards:

EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971: 2019	Risk analysis for medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied
EN 60601-1: 2006+Cor.:2010 +A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6: 2010+ A1:2015 EN 62366: 2010 +A1:2015	Medical electrical equipment: Usability
EN 60601-1-11: 2016	Medical electrical equipment.. Requirements for medical electrical equipment ... used in the home healthcare environment:
EN 60601-2-52:2010 + AC:2011 + A1:2015	Medical electrical equipment: Particular requirements for the basic safety and essential performance of medical beds

International standards:

IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012	Medical electrical equipment: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-52: 2009-12 +AMD 1: 2015-03	Medical electrical equipment: Particular requirements for the basic safety and essential performance of medical beds

Hiddenhausen, 2021-08-05

Georgios Kampisiulis Kemmler
(Management)

Reiner Rekemeier
(Management)