EC Declaration of Conformity

We,

Stiegelmeyer GmbH & CO. KG
Ackerstraße 42
D - 32051 Herford,

SRN: DE-MF-000005878

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

Hospital 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:	**Evario one**
REF:	288288
Basic-UDI-DI:	4046936Evario_oneU6

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 (LVD).

All applicable parts of the following standards, each with the 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	Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 20417	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 60601-2-52	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

Herford, 2024-01-02

Georgios Kampisiulis Kemmler
(Management)

Gunter Röper
(Management)