OVERENSSTEMMELSESERKLÆRING

EU Declaration of Conformity
MDR (2017/745/EU)

Concerns organization:	
Manufacturer	**Spring Produkties B.V.**
Address	Gaffel 19
Zip, City	3891 KC, Zeewolde
SRN#	NL-MF-000037908
Chamber of commerce#	39067888
PRRC	C. Heida

Intended purpose:	
ORHD 110220	Adjustable bed for positioning and mobilization of heavy persons with disabilities.

Related Regulation and Standards:	
REGULATION (EU) 2017/745/EU (MDR)	EU Medical Device Regulation
NEN-EN-IEC 60601-2-52	Medical electrical equipment – Part 2-52: Particular requirements for basic safety and essential performance of medical beds
ISO EN 14971	Medical Devices - Application of risk management to medical devices
NEN-EN-IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
NEN-EN-ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
REGULATION (EU) 2017/745/EU (MDR) Annex 1	The device is according to the requirements of the MDR, Annex 1

Medical device identification:		
Product	GMDN	Basic UDI-DI
ORHD 110220	30032	87193268915OrbitZC
Classification	Risk class I, according to MDR 2017/745/EU Annex VIII rule 13	

We, Spring Produkties B.V., hereby declare under sole responsibility as manufacturer that this product complies with the provisions of REGULATION (EU) 2017/745 (MDR) and the General Safety and Performance Requirements, defined in Annex I of the Regulation (EU) 2017/745.

The Conformity Assessment Procedure has been performed under our sole responsibility according to Art. 52, paragraph 7 and Art. 19 of the Regulation (EU) 2017/745. We confirm that we have established and maintain a technical documentation according to Annex II and III of the Regulation (EU) 2017/745.

City/Date of issue: Zeewolde, 12 December 2025

C. Heida
Director/Major-Shareholder (DMS) Spring Produkties B.V.