Manufacturer's declaration of conformity

Name and address	Care of Sweden AB Visit: Fabriksgatan 5A, SE-514 33 Tranemo, Mail: Box 146, SE-514 23 Tranemo Phone: +46 (0)771 106 600, Fax +46 (0)325 128 40 info@careofsweden.se
SRN	Not available yet.
Product group	Optimal preventative mattresses
Basic UDI-DI	7331345A0030B0030GL
EMDN code	Y033306 – Pressure alleviation mattress and underpads
Classification	Class I, according to Annex VIII (MDR (EU) 2017/745, rule 1
Product/Device name	CuroCell AREA Zone
Article/Part number	List of Sales configuration CuroCell AREA Zone (AREA-CE-010)

European standards

The European standards and Common Specifications which applicable requirements are met are listed below.

EN ISO 14971	EN 597-2	EN 14126
EN 62366-1	SS 876 00 04	EN ISO 15496
EN 12182	SS 876 00 13	EN ISO 15223-1
EN ISO 10993-1	EN ISO 20342-1	EN 1041
SS 876 00 01	ISO 16603	
EN 597-1	ISO 16604	

Mark of compliance CE

Declaration

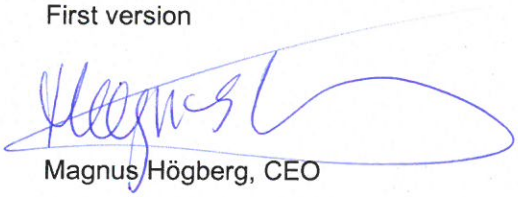
We declare under our sole responsibility as Manufacturer that the product(s) listed above conform to the requirements of the MDR (EU) 2017/745. The product(s) meet(s) the relevant General Safety and Performance Requirements of Annex I.

The conformity assessment procedure was performed following Annex II to III of MDR (EU) 2017/745. Any modification to the device, not authorized by us, will invalidate this declaration.

Valid from: 2020-09-25

Updated: First version

Manufacturer's signature



Magnus Högberg, CEO

Date 2020-09-25