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	SE-MF-000014315
Product group	CuroCell active air plus mattresses
Basic UDI-DI	7331345PC010CE240FA
EMDN code	V080702
Classification	Class I, according to Annex VIII MDR (EU) 2017/745, rule 1
Common specifications	There are no common specifications.
Product(s)/Device name	• *CuroCell® CX 20 Plus*
Configuration	Any of the mattresses above must be combined with any of the control units below: • *Control unit CuroCell®A4 Plus* The combination of a mattress and a control unit constitutes a medical device that fulfills the intended purpose. The mattresses in different sizes are CE-marked together with a mattress cover.
Marks 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:	2025-01-02

Signatures:

PLM Document Approved:	I hereby approve this PLM document		
Name:	**Susanne Andersson** **careofsweden.se\susanne**	Title:	
	Susanne Andersson		2025-01-03 08:30:21 (UTC+00:00)
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