

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	Automatic active airflow controlled mattress systems
Basic UDI-DI	7331345A0010B0010FC
EMDN code	V080701 - ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES
Classification	Class I, according to Annex VIII (MDR (EU) 2017/745, rule 13
Product/Device name	CuroCell® A4 CX10
Article/Part number	List of Sales configuration CuroCell® A4 CX10 (A4CX10-CE-010)
Common Specifications	There are no applicable Common Specifications.

Mark of compliance**Declaration**

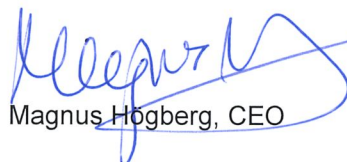
We declare under our sole responsibility as Manufacturer that the product(s) listed above conform to the requirements of the MDR (EU) 2017/745. The product(s) meet(s) the relevant General Safety and Performance Requirements of Annex I.

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: 2020-07-01

Updated: 2021-09-29

Manufacturer's signature

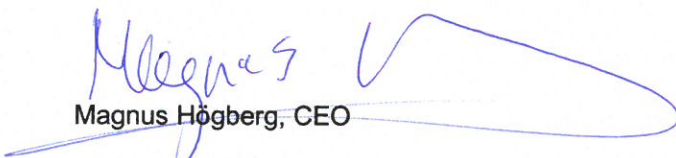


Magnus Högberg, CEO

Date 2021-09-29



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Equipment description	Mattress pump for alternating mattress system
Classification	Class I, according to Annex IX (MDD 93/42/EEC), rule 12
Brand name/trademark	Care of Sweden
Type designation/model	Mattress Pump CuroCell A4
Type, article number	List of sales configuration Mattress Pump CuroCell A4 (A4-CE-010)
European standards	The European standards which applicable requirements are met are listed below. EN ISO 10993-1 EN 62366 EN ISO 12182 IEC 62304 EN ISO 14971 EN ISO 15223-1 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11
Mark of compliance	CE
Declaration	We declare compliance of this medical device with the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2003:11. Thus, the medical device complies with the requirements of the corresponding Medical Device Directive 93/42/EEC. The conformity assessment was made according to Appendix 7 of this directive. Any modification to the device, not authorized by us, will invalidate this declaration.
Valid from:	2018-10-25
Updated:	2018-10-25
Manufacturer's signature	 Magnus Högberg, CEO
Date	2018-10-25

