care of sweden

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
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 ISO 12182
EN ISO 14971
IEC 60601-1
IEC 60601-1-2
IEC 60601-1-11
EN 62366
IEC 62304
EN ISO 15223-1

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

care of sweden

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 Cirrus
Article/Part number	List of Sales configuration CuroCell® A4 Cirrus (A4CIR-CE-010)
Common Specifications	There are no applicable Common Specifications.
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:	2020-07-01
Updated:	2021-09-29
Manufacturer's signature	Magnus Högberg, CEO
Date	2021-09-29