

A4-CE-090 Rev. 1.0

Manufacturer's declaration of conformity

Name and address

Care of Sweden AB

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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