

Manufacturer's declaration of conformity

Name and address

Care of Sweden AB

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SRN

Not available yet.

Product group

*Optimal preventative mattresses

Basic UDI-DI

7331345A0030B0030GL

EMDN code

V080702 - NON ACTIVE ANTI-DECUBITUS MEDICAL

MATTRESSES

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)

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:

2020-09-25

Updated:

2021-09-29

Manufacturer's signature

Magnus Högberg, CEO

Date

2021-09-29