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	Control unit CuroCell® IQ
Article/Part number	List of Sales configuration Control unit CuroCell® IQ (IQ-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

Manufacturer's declaration of conformity

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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® IQ CX15
Article/Part number	List of Sales configuration CuroCell® IQ CX15 (IQCX15-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
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