


## Manufacturer's declaration of conformity

<b>Name and address</b>	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
<b>SRN</b>	Not available yet.
<b>Product group</b>	Automatic active airflow controlled mattress systems
<b>Basic UDI-DI</b>	7331345A0010B0010FC
<b>EMDN code</b>	V080701 - ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES
<b>Classification</b>	Class I, according to Annex VIII (MDR (EU) 2017/745, rule 13
<b>Product/Device name</b>	Control unit CuroCell UNO®
<b>Article/Part number</b>	List of Sales configuration Control unit CuroCell UNO® (UNO-CE-011)
<b>Common Specifications</b>	There are no applicable Common Specifications.
<b>Mark of compliance</b>	
<b>Declaration</b>	<p>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.</p> <p>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.</p>
<b>Valid from:</b>	2020-07-01
<b>Updated:</b>	2021-09-29
<b>Manufacturer's signature</b>	 Magnus Högborg, CEO
<b>Date</b>	2021-09-29



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<b>SRN</b>	Not available yet.
<b>Product group</b>	CuroCell active air mattresses
<b>Basic UDI-DI</b>	7331345A0010B0013FJ
<b>EMDN code</b>	V080702 – NON ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES
<b>Classification</b>	Class I, according to Annex VIII (MDR (EU) 2017/745, rule 1
<b>Product/Device name</b>	CuroCell UNO® mattress
<b>Article/Part number</b>	List of Sales configuration CuroCell UNO® mattress (UNOMDR-CE-010)
<b>Common Specifications</b>	There are no applicable Common Specifications.
<b>Mark of compliance</b>	<b>CE</b>
<b>Declaration</b>	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.
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<b>SRN</b>	Not available yet.
<b>Product group</b>	Automatic active airflow controlled mattress systems
<b>Basic UDI-DI</b>	7331345A0010B0010FC
<b>EMDN code</b>	V080701 - ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES
<b>Classification</b>	Class I, according to Annex VIII (MDR (EU) 2017/745, rule 13
<b>Product/Device name</b>	CuroCell UNO®
<b>Article/Part number</b>	List of Sales configuration CuroCell UNO® (UNO-CE-010)
<b>Common Specifications</b>	There are no applicable Common Specifications.
<b>Mark of compliance</b>	<b>CE</b>
<b>Declaration</b>	<p>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.</p> <p>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.</p>
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