

## Declaration of Conformity

Manufacturer: **CAREVISION OY**

SRN: **FI-MF-000032554**

Products:

- CVN Arctic Pallas Hypothermia Bag MIL | H5000-5016P | 06429810144133
- CVN Arctic Pallas Hypothermia Bag EMS | H5000-5016E | 06429810144218

Product identification: **See above for tradenames, product numbers and UDI-numbers.**

Risk class: **Class 1 Medical Device, based on rule 5 of Annex VIII.**

***We, Carevision Oy, hereby declare and confirm that the products; mentioned above, that are covered by this declaration are in conformity with EU regulation 2017/745.***

***This declaration of conformity is issued under the sole responsibility of Carevision Oy and supported by the Quality System certification based on ISO 13485:2016, quality system certificate with reference number GSC 22-TH-001.***

***This declaration is no longer valid if any change on the products will be made without our written confirmation.***

Oulu 30.4.2023



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**Mervi Karjalainen, CEO**  
**Carevision Oy**

**CAREVISION**  
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