

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This declaration is no longer valid if any change on the products will be made without our written confirmation.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



Mervi Karjalainen, CEO
Carevision Oy

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