

DECLARATION OF CONFORMITY

THERMOSAVER

Medical Device Regulation 745/2017/EU

Thermosaver AS located at Ramstadløkka 1, 1850 Mysen, hereby declare in exclusive responsibility that the Thermosaver products listed adhere to the essential health and safety requirements of the above-mentioned directive. The Quality management system of Thermosaver AS conforms to the requirements of Article 10 and is self-validated, as per requirements for Medical Devices Class 1.

To ensure conformity, the products have been assessed for compliance with the following directives and standards either in full or in parts.

| Directive | Standards Applied |
|--|-------------------|
| Medical Device Regulation 745/2017/EU | ISO13485 |
| | ISO15223 |
| | ISO14971 |
| | ISO10993 |
| | EN1041 |

EUDAMED SRN: NO-MF-000018350

Name: Ketil Thorsen

Title: Chief Executive Officer

Date: 2021 – 12 – 22

Signature: 

Manufacturer: Thermosaver AS

Name: Ketil Thorsen 

Title: Chief Executive Officer

Date: 2021 – 12 – 22

Signature:

| Code | Basic UDI-DI | Product Name | Risk Classification |
|-------------|---------------------|-----------------------|----------------------------|
| TSR5 | 709005795TSRNZ | Thermosaver Edition 5 | 1 |