TSC LIFE

Innovation with purpose

Dear Valued Customer,

Our Mistral-Air® warming units are designed, approved, and validated exclusively for use with Mistral-Air® Warming Blankets.

In accordance with MDR requirements, Mistral-Air® Warming Blankets are classified as medical devices (Class I(s)) to be used in combination with the Mistral-Air® warming units (Class IIb), ensuring that compatibility between them has been properly validated. System validation is conducted specifically on the combination of these two products rather than each individually and rather than merely on generic compatibility specifications.*

The use of blankets which do not bear the Mistral-Air® logo may lead to undesired patient outcomes, including **hypothermia, hyperthermia or thermal injury.** The alarm system of the warming unit may not function correctly with non-compatible blankets, which lead to a risk of compromising patient safety. To ensure you are using Mistral-Air® blankets with the intended warming unit look for the Mistral-Air® logo on the blanket's label.

The hospital is responsible for patient safety when Mistral-Air® warming units are used with any blankets other than Mistral-Air®, as the warming units have not been validated for use with other blankets.

In summary:

- Use of blankets of which compatibility has not been validated with our warming unit may pose risks to patient safety.
- TSC Life holds no liability for patient-related issues where non-compatible blankets are used in place of Mistral-Air® Blankets.
- This usage is off-label and may lead to a loss of CE mark status for the Mistral-Air® warming unit, making it the hospital's responsibility to obtain its own CE mark or validate the Mistral-Air® warming unit as an in-house produced device for the combination with other blankets.
- The Mistral-Air® warming unit warranty will be voided when non-compatible blankets are used in place of Mistral-Air® Blankets.

We trust this provides you with sufficient information. Please reach out to your sales representative if you have any questions.

Regards,

Daphne Zwartjes, VP RAQA

Electronically signed by: Daphne Zwartjes
Reason: I am approving this document
Date: 07-Nov-2025 11:45:51 GMT+1

**We comply with MDR requirements, Annex I and II, and IEC 60601-2-35:2021.*