



EU Quality Management System Certificate

Certificate no.:
10000517272-PA-NoMA-USA

Initial certification date:
28 September 2023

Valid Until:
28 September 2028

This is to certify that the quality system of

Augustine Temperature Management LLC

6581 City West Parkway, Eden Prairie, MN 55344 USA
SRN: US-MF-000020611

For design, production, and final product inspection/testing of:
HotDog® Temperature Management System

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX,
(Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:
Høvik, 28 September 2023

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway



Sholeh Gheissar
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

MCR-CO-078-A V0.5

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2643613	28 September 2023

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
HotDog® Temperature Management System monitors the temperature of the warming device and modulates power to maintain a temperature setpoint.	Lower Body Warming Blanket (Catalog number B103)	IIb
	Full Body Warming Blanket (Catalog number B104)	
	Multi Position Warming Blanket (Catalog number B105)	
	Head Warming Wrap (Catalog number B107)	
	Torso Warming Blanket (Catalog number B110)	
	Pediatric Lower Body Warming Blanket (Catalog number B203)	
	Small Pediatric Head Warming Wrap (Catalog number B270)	
	Large Pediatric Head Warming Wrap (Catalog number B271)	
	Universal Warming Blanket (Catalog number B500)	
	Under Body Warming Mattress, 82 cm (32") (Catalog number U101)	
	Under Body Warming Mattress, 127 cm (50") (Catalog number U102)	
	Pediatric Underbody Warming Mattress (Catalog number U220)	
	Trendelenburg Warming Mattress, 89 cm (35") (Catalog number U300)	
	HotDog Temperature Management Controller – Single Port (Catalog number WC71)	
HotDog Temperature Management Controller - Multiport (Catalog number WC77)		

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: NA



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The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Augustine Temperature Management LLC	1. Corporate: 6581 City West Parkway Eden Prairie, MN, 55344, USA 2. Manufacturing: 7656 West 78th St. Minneapolis, MN, 55439, USA

EU Representative
Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.