

## DECLARATION OF CONFORMITY

**Manufacturer:** Enthermics Medical Systems, Inc.

**Manufacturer's Address:** W164 N9221 Water Street, Menomonee Falls, WI 53052 USA  
Tel: +1 800-862-9276

**EU Representative:** MDSS GmbH

**EU Rep's. Address:** Schiffgraben 41, 30175 Hannover, Germany  
Tel.: +49 511 6262 8630

**Devices:** Warming Units – Multipurpose

**Description:** The Enthermics Warming Units – Multipurpose are designed in multiple configurations and including a wide variety of accessories according the intended devices, materials, or solutions to be heated. These units typically consist of a cabinet with appropriate racks, a heating system, temperature controls, and overheat alarms. Multipurpose warming units may be used to warm solutions (e.g., peritoneal dialysate, irrigation solutions), and blankets.

**Device model# schematic:** Per the equation: X#Z, where, as defined within the Technical File:

- X represents the product family and includes any alpha sequence
- # represents the unit capacity code and includes any numeric sequence
- Z represents further delineation between units and includes any alpha-numeric sequence

### List of Devices:

#### Blanket Warmers

- DC150
- DC250
- DC350
- DC400
- DC750
- EC230
- EC250
- EC340
- EC350
- EC750
- EC770
- EC1540
- EC2060

#### Fluid Warmers

- DC250L
- DC400L
- EC230L
- EC340L
- EC390L
- EC770L
- ivNOW-1
- ivNOW-2
- ivNOW-3
- ivNOW-4
- ivNOW-5
- ivNOW-6

#### Combination Warmers

- EC1260BL
- EC1540BL
- EC1730BL

**ENTHERMICS MEDICAL SYSTEMS**

An ISO 13485:2003 certified company

PO Box 443, Menomonee Falls WI 53052-0443  
W164 N9221 Water St, Menomonee Falls WI 53051  
Phone 262-251-8356 | 800-862-9276 | Fax 262-251-7067  
generalinfo@enthermics.com  
www.enthermics.com

Made in the USA

**EC Product Class:** Class I per Annex IX, Rule 12

**Applied Directive:** Annex VII to the Medical Devices Directive 93/42/EEC  
Low Voltage Directive (LVD) of the European Union  
EMC Test and Measurement

**Applied Standards:** ISO 13485:2003, EN 60601-1-2 (2007) [All Devices]  
IEC/EN 60601-1: 1988 + A1:1991 + A2:1995 [EC Series Fluid Warmers]  
IEC/EN 60601-1: 1990 + A1:1993 + A2:1995 [DC Series Fluid and ivNow Series]  
IEC 61010-1:2010, 3<sup>rd</sup> Edition, 2012-05-11 [Blanket Warmers]

*We the undersigned, hereby declare that the equipment specified above conforms to the Directives and Standards referenced in this Declaration of Conformity.*

 03/03/2015  
Christa Pieper, Certifications Manager [date (dd/mm/yyyy)]



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