



EC CERTIFICATE

Belmont Medical Technologies

780 Boston Road
Billerica, Massachusetts 01821 UNITED STATES

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of fluid management systems and fluid warmers

Device Classifications:

Class IIa

Class IIb

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number A18173
Certificate Number 693.181127
Initial Issue Date June 1, 2013

Cycle Start Date July 9, 2016
Effective Date November 27, 2018
Expiry Date July 8, 2019

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



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Status: [here](#)

Notified Body
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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Fluid warmers	The Belmont® buddy™	The Belmont® buddy lite™ Blood/Fluid Warmer	Class IIb	47616
		The Belmont® buddy lite AC™ Blood/Fluid Warmer	Class IIb	47616
		The Belmont® buddy™2 Blood/Fluid Warmer.	Class IIb	47616
	The Belmont® Hyperthermia Pump	The buddy™family Disposable Set and Accessories	Class IIa	47618
		The Belmont® Hyperthermia Pump	Class IIb	40784
		Hyperthermia Pump Disposable Set and Accessories	Class IIa	40796
Fluid management systems	The Belmont® Rapid Infuser	The Belmont® Rapid Infuser RI-2	Class IIb	17907
		The Belmont® Rapid Infuser FMS2000	Class IIb	17907
		Rapid Infuser Disposable Set and Accessories	Class IIa	41609

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