



EC CERTIFICATE

Monica Healthcare Limited

Biocity, Pennyfoot Street
Nottingham NG1 1GF, United Kingdom

Full Quality Assurance System Approval Certificate

Annex II, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:
Design and Manufacture of Fetal Monitoring Devices

Device Classification:
Class IIb

Device Descriptions:
Portable, battery-powered device designed to monitor a pregnant mother and unborn baby in the antenatal period and during labour and delivery

Model Type:
Please refer to Attachment 1

File Number	A16669	Cycle Start Date	23 November 2013
Certificate No.	543.131123	Effective Date	23 November 2013
		Expiry Date	22 November 2016

Authorised by

Anwen E. Evans
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 13CA38200, 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 model numbers.

Notified Body
0843

00-NB-F0413 1.0

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom



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Attachment 1 of 1

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

Product Family	Model/Type	Classification
Fetal Monitors	Monica AN24 including uterine activity monitoring and accessories; <ul style="list-style-type: none">• ECG lead assy & connector• AN24 Holster & belt clip• Battery Charger• Monitor connector/computer USB cable• Monica VS s/ware and manual• Electrodes• Abrasive skin tape• Bluetooth Dongle	IIB
	Monica VS Series consisting of the above and the following optional accessories; <ul style="list-style-type: none">• VS10/VS15 Monitors (including Monica Decision Support)	IIB

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