



EC CERTIFICATE

Biometric Cables

A 28, Phase 3
Sidco Industrial Estate
Guindy, Chennai, Tamilnadu, 600032 India

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 Breathing Circuits for Anesthesia and Ventilator Circuits

Device Classification:

Ila

G/UMDN Code:

Device Descriptions:

See Attachments

Model Type:

See Attachments

We hereby declare that an examination of the full quality assurance system has been carried out per report 11876167, 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 6 attachments listing model numbers covered by this certificate.

File Number A28454
Certificate No. 876.170913

Cycle Start Date 13 September 2017
Effective Date 13 September 2017
Expiry Date 12 March 2018

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body

0843



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Attachment 1 of 6

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Anesthesia Circuits – Single Use	Adult	910113001	IIa	
	Adult with limb	910113002		
	Adult with Catheter Mount	910113003		
	Adult with Catheter Mount & limb	910113004		
	Pediatric	910133001		
	Pediatric with limb	910133002		
	Pediatric with Catheter Mount	910133003		
	Pediatric with Catheter Mount & limb	910133004		
Anesthesia Circuits - Reusable	Adult	910213006		
	Adult with limb	910213007		
	Adult with Catheter Mount	910213008		
	Adult with Catheter Mount & limb	910213009		
	Pediatric	910233006		
	Pediatric with limb	910233007		
	Pediatric with Catheter Mount	910233008		
	Pediatric with Catheter Mount & limb	910233009		

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Attachment 2 of 6

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Anesthesia Circuits - Reusable	Neonatal	910243006	Ila	
	Neonatal with limb	910243007		
	Neonatal with Catheter Mount	910243008		
	Neonatal with Catheter Mount & limb	910243009		

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Attachment 3 of 6

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Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Ventilator Circuits – Single use	Adult – SWT	910111001	IIa	
	Adult – SWT with limb	910111002		
	Adult – SWT with Catheter Mount	910111003		
	Adult – SWT with Catheter Mount & limb	910111004		
	Adult – DWT	910112001		
	Adult – DWT with limb	910112002		
	Adult – DWT with Catheter Mount	910112003		
	Adult – DWT with Catheter Mount & limb	910112004		
	Pediatric – SWT	910131001		
	Pediatric – SWT with limb	910131002		
	Pediatric – SWT with Catheter Mount	910131003		
	Pediatric – SWT with Catheter Mount & limb	910131004		
	Pediatric – DWT	910132001		
	Pediatric – DWT with limb	910132002		
	Pediatric – DWT with Catheter Mount	910132003		
	Pediatric – DWT with Catheter Mount & limb	910132004		

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Attachment 4 of 6

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Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Ventilator Circuits – Reusable	Adult	910213001	IIa	
	Adult with limb	910213002		
	Adult with Catheter Mount	910213003		
	Adult with Catheter Mount & limb	910213004		
	Adult – SWT	910211001		
	Adult – SWT with limb	910211002		
	Adult – SWT with Catheter Mount	910211003		
	Adult – SWT with Catheter Mount & limb	910211004		
	Adult – SWT with Inspiratory heated wire with limb	910211005		
	Adult – DWT	910212001		
	Adult – DWT with limb	910212002		
	Adult – DWT with Catheter Mount	910212003		
	Adult – DWT with Catheter Mount & limb	910212004		
	Pediatric	910233001		
	Pediatric with limb	910233002		
	Pediatric with Catheter Mount	910233003		
	Pediatric with Catheter Mount & limb	910233004		

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Attachment 5 of 6

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Ventilator Circuits – Reusable	Pediatric – SWT	910231001	IIa	
	Pediatric – SWT with limb	910231002		
	Pediatric – SWT with Catheter Mount	910231003		
	Pediatric – SWT with Catheter Mount & limb	910231004		
	Pediatric – SWT with Inspiratory heated wire with limb	910231005		
	Pediatric – DWT	910232001		
	Pediatric – DWT with limb	910232002		
	Pediatric – DWT with Catheter Mount	910232003		
	Pediatric – DWT with Catheter Mount & limb	910232004		
	Neonatal	910243001		
	Neonatal with limb	910243002		
	Neonatal with Catheter Mount	910243003		
	Neonatal with Catheter Mount & limb	910243004		

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Attachment 6 of 6

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Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Ventilator Circuits – Reusable	Neonatal – SWT	910241001	IIa	
	Neonatal – SWT with limb	910241002		
	Neonatal – SWT with Catheter Mount	910241003		
	Neonatal – SWT with Catheter Mount & limb	910241004		
	Neonatal – SWT with Inspiratory heated wire with limb	910241005		
	Neonatal – DWT	910242001		
	Neonatal – DWT with limb	910242002		
	Neonatal – DWT with Catheter Mount	910242003		
	Neonatal – DWT with Catheter Mount & limb	910242004		

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