

Poweam Medical Co., Ltd	Technical File	File No.	PM-001-2
		Rev. No.	0
	2. EC Declaration of Conformity	Rev. Date	2015-04-08
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Declaration of Conformity

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive.

If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Description of Equipment: Anesthesia machine(Veterinary use and Human use)

Model Name: PAS-200, PAS-200A, PAS-200B, PAS-200C, PAS-200D, PAS-200E

Classification: Class IIb

According to the Rule 11 of Classification Criteria, annex IX, 93/42/EEC as amended by 2007/47/EC

Applied Standards:

EN 60601-1: 2006	EN 60601-1-2:2007	EN 60601-1-4:1996
EN 60601-2-13: 2006	EN 980:2008	EN 1040:2008
ISO 14971:2007	ISO 8835-2:2009	ISO 8835-4:2009
ISO 8835-5:2009	93/42 EEC	MDDEV 2.12-1 rev 6: 2009
EN ISO 13485: 2003		

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Representative:

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Date: 2015-04-08