

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41312188

Initial Certification Date
August 20, 1998

Certificate Valid from
August 21, 2013

Certificate Expiry Date
August 20, 2018

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation, LVFS 2003:11, to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the 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 the result entitles the organization to use the CE 0413 marking on those products listed below.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

*Intertek Semko AB
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Organization:

Ivy BioMedical Systems, Inc.

11 Business Park Drive, Branford, CT 06405, USA

Product Category:

- Physiological monitors

For further identification of the products covered, see the MDD product list/product schedule.

August 7, 2013

Signed date



Mats Premfors, Certification Manager MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41312188

Issued to:

Ivy BioMedical Systems, Inc.
 11 Business Park Drive
 Branford, CT 06405
 USA

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Physiological monitors					
	Type CF Model 101 (Series)	IIb	No	-	*
	Type CF Model 3000 (Series)	IIb	No	-	*
	Type CF Model 450C (Series)	IIb	No	-	*
	Model 6000	IIb	No	-	Sept 1, 2009
	Model 7600	IIb	No	-	June 7, 2011
	Model 7800	IIb	No	-	Feb 3, 2012
Cardiac Trigger Module					
	Type CF Model CTM300	IIa	No	-	*
	Model CTM400	IIa	No	-	March 7, 2013
	Universal Physiological Measurement Module – Model UPMM	IIa	No	-	*
	PAM 100 Module	IIa	No	-	June 7, 2011
	PAM 200 Module	IIa	No	-	June 7, 2011

* Product added before September 1, 2009.

Date of Issue: August 7, 2013

Intertek Semko AB
 Notified Body MDD



Mats Premfors
 Certification Manager MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Product List for Certificate No: 41312188

Date: August 7, 2013

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Intertek Semko AB

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