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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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.

Organization:

Ivy BioMedical Systems, Inc.

Main Site: 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.

Certificate Number:
41312188-02

Initial Certification Date:
20 August 1998

Certificate Valid from:
21 August 2018

Certificate Expiry Date:
20 August 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

17 August 2018
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
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medtechsweden@intertek.com

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.

MDD – Product List

Products included in the Certificate No: 41312188-02

Issued to: **Ivy BioMedical Systems, Inc.**
11 Business Park Drive
Branford, CT 06405
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	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 7700	IIb	No		November 6, 2015
	Model 7800	IIb	No	-	Feb 3, 2012
	Model 7810	IIb	No		November 6, 2015

* Product added before September 1, 2009.

Issue Date: 17 August 2018
Valid Date: 21 August 2018

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority 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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