

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41311047-01

Initial Certification Date
September 24, 2002

Certificate Valid from
October 19, 2017

Certificate Expiry Date
September 24, 2022

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.

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Ackred. nr 1003
ISO/IEC 17021

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:

SunTech Medical, Inc

507 Airport Boulevard, Suite 117, Morrisville, NC 27560-8200, USA

Product Category:

Blood pressure and patient monitoring products

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

October 19, 2017

Signed date

Bob Andersson, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41311047-01
Issued to: **SunTech Medical, Inc.**
507 Airport Boulevard, Suite 117
Morrisville, NC 27560-8200
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Blood Pressure Monitor	Tango / Tango + / 2120	Ila	No	-	*
	Tango M2	Ila	No	16173	April 16, 2013
	Accutrack II / 104	Ila	No	-	*
	Accutrack DX / 105	Ila	No	-	*
	CT40, Model 260	Ila	No	57960	April 1, 2016
	Oscar 2 / 222	Ila	No	-	*
	Oscar 2, Model 250	Ila	No	-	June 11, 2015
	Oscar 2, Model 250D	Ila	No	36888	Aug 15, 2019
	Oscar 2B / 222B	Ila	No	-	*
	Oscar Express / 222E	Ila	No	-	*
	Cycle	Ila	No	-	*
	247	Ila	No	-	*
	CT50 (Model 270)	Ilb	No	57960	Nov 27, 2017

* Product added before 2010.

Date of Issue: August 15, 2019

Intertek Semko AB
Notified Body MDD



Pontus Gedda
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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Product List for Certificate No: 41311047-01
Date: August 15, 2019
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