5827 South Miami Blvd, Ste 100
Morrisville, NC 27560-8394 USA

Subject: Extension to MDD certificates
Ref: Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746

22 March 2023

To whom it may concern,

Intertek Semko AB ("**Intertek**") is the notified body for SunTech Medical, Inc. ("**SunTech**") with respect to the medical devices listed in the Annex to this letter (the "**SunTech Devices**").

SunTech hereby confirms that certificates Intertek issued with respect to the SunTech devices under Directive 93/42/EEC ("**MDD**"), through the operation of Regulation 2023/607amending Regulation (EU) 2017/745 and (EU) 2017/746, have been extended until the date stated in the attached Annex. Therefore, the SunTech devices may continue to be lawfully placed on the market in the EU, the EEA and Turkey until the end of the extension if the following conditions are/continue to be met:

- before the MDD certificate expired, SunTech and Intertek signed a written agreement for the conformity assessment in accordance with Section 4.3. second subparagraph of Annex VII, this is demonstrated by the signed agreement between Intertek and SunTech dated 18JUL2022 (see attached);
- the MDD certificate for the SunTech devices has not been withdrawn;
- the SunTech devices continue to comply with the MDD, this is demonstrated by Intertek MDD surveillance audit report of SunTech dated 31DEC2021 (see attached audit report excerpt);
- there are no significant changes in design or intended purpose (Intertek has not been notified of any such significant changes);
- the SunTech devices do not present an unacceptable risk to the health or safety or patients, users or other persons, or to other aspects of the protection of public health;
- By 26 May 2024 the manufacturer must have:
    - a QMS compliant with the MDR (we confirm Stage 1 and Stage 2 of the QMS conformity assessment was completed in 2022); and
    - applied to a notified body for a conformity assessment (see attached conformity assessment agreement between Intertek and SunTech).

If you have any questions, please do not hesitate to contact SunTech Medical, Inc. at regulatoryrequests@suntechmed.com.

Yours faithfully,

Digitally signed by Prodan Sveatoslav
Date: 2023.07.28 08:19:18 EEST
Reason: MoldSign Signature
Location: Moldova

Michael Williams
Vice President, OPS/QA/RA

5827 South Miami Blvd, Ste 100
Morrisville, NC 27560-8394 USA

SunTech Medical, Inc.

5827 South Miami Blvd, Ste 100
Morrisville, NC 27560-8394 USA

Annex

Manufacturer Name	Names of devices benefitting from an extension to their certificates issued under Directive 93/42/EEC to	Class	MDD Certificate Number	GMDN/ Device Category	Extension Date
SunTech Medical, Inc.	Tango / Tango+ / 2120	IIa	41311047-01	-	31 December 2028
	Tango M2	IIa		16173	
	Accutracker II / 104	IIa		-	
	Accutracker DX / 105	IIa		-	
	CT40, Model 260	IIa		57960	
	Oscar 2 / 222	IIa		-	
	Oscar 2, Model 250	IIa		-	
	Oscar 2, Model 250D	IIa		36888	
	Oscar 2B / 222B	IIa		-	
	Oscar Express / 222E	IIa		-	
	Cycle	IIa		-	
	247	IIa		-	
	CT50 (Model 270)	IIb		57960	