MDD – Change Assessment

Letter No: 41311047-01-001
Certificate No: 41311047-01
Date: 08 September 2022
Handled by: [redacted]
E-mail: [redacted]

SunTech Medical Inc.
Attn: [redacted]
5827 S. Miami Boulevard, Suite 100
Durham, North Carolina, 27560
USA

Purpose	Assessment, according to Regulation 2017/745 (MDR) article 120, of the notification dated 16 July 2022 for changes of company address for your quality system certified to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).
Scope of assessment	Blood pressure and patient monitoring products, Class IIa, Annex II
Details of change	The manufacturer is relocating their registered place of business due to need for additional space of growth. New Address: 5827 S. Miami Boulevard, Suite 100, Durham, North Carolina, 27560, United States
Conclusions/Decisions	The planned change has been assessed and concluded to not represent a significant change in design or intended purpose under MDR Article 120(3). The MDD certificate 41311047-01 remains valid also for the new address.
Follow-up assessments	At the next audit your auditor may follow-up on the implementation of the change(s) in the Quality system.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB

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Peter Nermander
Certification Authority MDD