

CE Documentation Review



No. 3J191029.SMTCN45

Holder:

Specore Med-Tech Co., Limited

6F# Building, No.1 HuaFu North Road,
ChanCheng District, Foshan, China.

Review goal:

Verification of the presence of the
Technical File in regards of the Medical
Devices Directive 93/42/EEC Annex VII

Product:

LED Dental Lamp

Model(s):

KY-P113, KY-P103, KY-P106, KY-P102, KY-
P138, KY-P136, KY-P105, KY-P108, KY-P111,
KY-P112, KY-P115, KY-P116, KY-P118, KY-
P132, KY-P133, KY-P135, KY-P139

Classification:

Class I

(accordingly to the Manufacturer's declaration)

Review output:

We attest that a Technical File in reference to the
Directive 93/42/EEC is in place for the CE Marking
process. Test report identified with the no. BCTC-
FY190906277E, BCTC-FY190906278S. This document has
been issued on voluntary basis and not as NB.
Whereas the Manufacturer is responsible and not
exempted to carry out all the necessary activities, as
required by the Directive, before placing the CE Mark
on the product.

Date of issue 30 October 2019

Expiry date 29 October 2024

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Marco Morina



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Ente Certificazione Macchine

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