

CE Documentation Review



No. 3J190729.SHMTN80

Holder: Shanghai Huifeng Medical Instrument Co., Ltd.

2 Buildings, No. 885, Qixing Road, Nicheng Town, Pudong New Area, Shanghai, China

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

Product: Operating Table, Shadowless Operating Lamp

Model(s): (see the following annex I)

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. 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 29 July 2019

Expiry date 28 July 2024

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Annex I

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Name	Model/ Type
Operating Table	HFOT99C, HFOT99, HFOT99D, HFEPB99A, HFEPB99B, HFEPB99C, HFEPB99, HFOT99S, HFOT99X, HFOOT99A
Shadowless Operating Lamp	SY02-LED3+5, SY02-LED3, SY02-LED5, SY02-LED5+5, SY02-LED3+5-TV, SY02-LED5+5-TV, SY02-LED3+3, HF-L3+4CLED, HF-L4+4CLED, HF-L3+3CLED, HF-L4CLED, HF-L3CLED, HF-L4WLED, HF-L3WLED, HF-L4SLED, HF-L3SLED, HF-L4ELED, HF-L3ELED, 700/500LED, 700LED, 500LED



Ente Certificazione Macchine

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