

CE Documentation Review



No. 3J191105.SHMSU05

Holder: Shanghai Huifeng Medical Instrument Co., Ltd.

2 Buildings, No. 885, Qiuxing 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: 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 05 November 2019

Expiry date 04 November 2024

Chief Manager
Marco Morina

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Annex I

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Model(s): 700/700LED, 500/500LED, 700W LED, 700S LED, 700E LED, 500WLED, 500S LED, 500E LED, YD02-LED5+5, YD02-LED3+4, YD02-LED4+4, YD02-LED3+3, YD02-LED3, YD02-LED3W, YD02-LED3S, YD02-LED3E, YD02-LED4, YD02-LED4W, YD02-LED4S, YD02-LED4E, YD02-LED3+5, YD02-LED5, YD02-LED5W, YD02-LED5S, YD02-LED5E, YD200C LED, YD200W LED, YD200S LED, YD200E LED, YD02-5LED, YD02-5W LED, YD02-5+5 LED, HF-L25LED, HF-L25C LED, HF-L25C+L25C LED, HF-L25W LED, HF-L25E LED, HF-280LED, HF-280CLED, HF-280WLED, HF-280ELED, HF-FS LED, YD01-4E LED, YD01-4 LED, YD01-5E LED, YD01-5 LED, YD01-4, YD01-4E, YD01-5, YD01-5E, YD01A, YD01AE, YD01W, YD01W LED, YD01A LED, YD01AE LED, YD01-1SA, YD01-SE, YD150LED, YD01-I, YD01-II, YD01-1LED, YD01-1E LED, ZF700/700, ZF700/500, ZF500/500, ZF600/600, ZF600, ZF700, ZF500, ZF700S, ZF700E, ZF600E, ZF600S, ZF500S, ZF500E, ZF500W, ZF600W, ZF700W, YD50(LED), YD300(LED), YD01-LED3, YD01-LED4, YD01-LED5, SY01-LED3, SY01-LED3A, SY02-LED3+5D, SY02-LED3+5D-TV, SY02-LED5+5D, SY02-LED3+3D, SY02-LED3D, SY02-LED5D, YD300 LED, YD300+300LED, YD300E LED, YD300CLED, YD300WLED, 760/760 LED, 760 LED, 760/300LED, YD02-4LED, YD02-4W LED, YD02-4+4 LED