



Technical File Review Report

This is to state that Technical Documentation (KL2018CE4,rev.A/0) for Product(s)

Shadowless Operation Lamp

(Model: KL500-III, KL500/500-III, KL600-I, KL600-II, KL600/600-I, KL600/600-II, KL700/700-III, KL700/500-III, KL700/700-III, KL-LED·MD61, KL-LED·MDT61, KL-LED·DT61, KL-LED·DT61/DT61, KL-LED·D61, KL-LED·D61/D61, KL-LED·D78/D61, KL-LED·D78/D78, KL-LED·DTR78, KL-LED·DTR78/DT61, KL-LED·DTR78/DT78, KL-LED·SZ4, KL-LED·SZ4/SZ4, KL-LED·MSZ4, KL-LED·STZ4, KL-LED·STZ4/STZ4, KL-LED·MSTZ4, KL-LED·SZ5, KL-LED·SZ5/SZ5, KL-LED·MSZ5, KL-LED·STZ5, KL-LED·STZ5/STZ5, KL-LED·MSTZ5, KL-LED·SZ4/SZ5, KL-LED·STZ4/STZ5, KL-LED·SZ4/STZ4, KL-LED·SZ5/STZ5, KL01L·IP, KL01L·IL, KL01L·IIL, KL01L·IILED -I, KL01L·IIL (AC/DC) , KL01L·II LED (AC/DC) , KL01L·IILED-I (AC/DC), KL01L·IIIL, KL01L·IIILED, KL04L·I, KL04L·II, KL04L·III, KL05L, KL05L·I, KL05L·III, KL09L, KL12L, KL1205L)

(Class I not sterile or measuring via Annex IX Rule X)

Manufactured by

Jiangsu Keling Medical Appliances Co., Ltd.

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Has been assessed as meeting the Essential Requirements (Annex I) of EC Directive 93/42/EEC as amended by 2007/47 for Medical Devices

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