

CE Technical Documentation Review Report

Manufacturer: **Suzhou Kangjie Medical Inc.**
Bldg 15, No. 2 Shuangma Str., Weiting Town,
Suzhou Industrial Park, 215121 Jiangsu, China

Report Number: 15096261 001

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s): Portable Slit Lamp Microscope
Streak Retinoscope
Direct Ophthalmoscope
Slit Lamp Microscope

Type(s)/Model(s): - Portable Slit Lamp Microscope, model name: KJ5S1, KJ5S2, KJ5S3, KJ5S4
- Streak Retinoscope, model name: KJ6B, KJ6A
- Direct Ophthalmoscope, model name: KJ8B, KJ8A, KJ8C
- Slit Lamp Microscope, model name: KJ5D, KJ5E, KJ5P, KJ5P-A, KJ5X, KJ5F, KJ5DI, KJ5DII

Classification: Class I, rule 12
(according to manufacturer's declaration)

Review result: During the examination of the provided Technical Documentation (No.: KJ/CE01, Version A/0, Date: 2017-07-28), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

Shanghai, 2018-01-22

TÜV Rheinland (Shanghai) Co., Ltd.



Allen CHEN
Lead Auditor, Product Assessor
Medical Device Services