

CE Technical Documentation Review Report

Manufacturer:

Shanghai PAX Medical Instrument Co., Ltd.

No. 3 Building, No. 438 Fulian Two Road, Baoshan

District, Shanghai 201901, China

Report Number:

15095970 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):

Operating Lights

Type(s)/Model(s):

PANALEX series, ELD series

Classification:

Class I, rule 12

(according to manufacturer's declaration)

Review result:

During the examination of the provided Technical Documentation (No.: CE-43-00, Revision A, Date 2016-03-30), no Non-compliance according to the requirements of the Medical Devices Directive

93/42/EEC Annex VII was detected.

Shanghai, 2016-06-02

Allen CHEN

Lead Auditor, Product Ass

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