

CE Technical Documentation Review Report

(According to MDD Directive 93/42/EEC)

Report No. TFR_SHA_54487201601

The Manufacturer

SHANGHAI FUHONG SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD
Building 4, No. 6788 Songze Avenue, Qingpu District, Shanghai, P.R.China

Has Established CE Technical Documentation for the Following Products

Surgery Shadowless lamp (TOPLED Series)

This report is issued on a voluntary basis. It confirms that the CE technical documentation (no. FH/QRCE-xx-TOPLED, Rev 1.0, Date 2016-04-26) of the listed products is complete with regard to the requirements of Annex VII section 3 of Directive 93/42/EEC. Detail products covered under the technical documentation are described in this report. This report would be re-assessed before 2019-05-02

Issue Place:

Medical, Health Service Dept.
TÜV SÜD China, Shanghai Branch

Issue Date:

2016-05-05



Any significant changes in design or construction of the product or amendments to the directive or standards applied may render this report invalid. Also, this report is only valid in combination with ISO13485 certificate issued by TÜV SÜD.

1. Information about the company, scope, general

The company SHANGHAI FUHONG SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD. located in Building 4, No. 6788 Songze Avenue, Qingpu District, Shanghai, P.R, China, provided the following CE technical documentation to TÜV SÜD China, Shanghai Branch in April, 26, 2016:

- CE technical documentation for Surgery Shadowless lamp (TOPLED Series), document no. FH/QRCE-xx-TOPLED, Rev 1.0, Date 2016-04-26

Following models are covered in the CE technical documentation:

TOPLED-8080, TOPLED-6060, TOPLED-8060, TOPLED-8000, TOPLED-6000

The Surgery Shadowless Lamp, mainly used in relevant medical operation lighting field, can partly eliminate the shadows of the surgeons to realize the shadowless effect. According to Directive 93/42/EEC, the classification is class I.

According to the manufacturer's application, TÜV SÜD China, Shanghai Branch has reviewed the CE documentation and drafted this report on a voluntary basis. This report is only valid in combination with a valid ISO13485 certificate issued by TÜV SÜD.

The EC Representative is Shanghai International Holding Corp. GmbH (Europe), located in Eiffestrasse 80, 20537 Hamburg, Germany

2. Purpose of the review

Review for completeness of Technical Documentation on a voluntary basis based on Annex VII, section 3 of the Council Directive 93/42/EEC on Medical Devices.

3. Content of the review

The CE technical documentation has been reviewed by Yanan Liu who is authorized by the certification body of TÜV SÜD Product Service for Medical Device Lead Auditor.

The technical file review included the following parts:

- Section 1, Declaration of conformity

Declaration of conformity #FH/QRCE-7-TOPLED was issued by General Manager in 2016-04-26

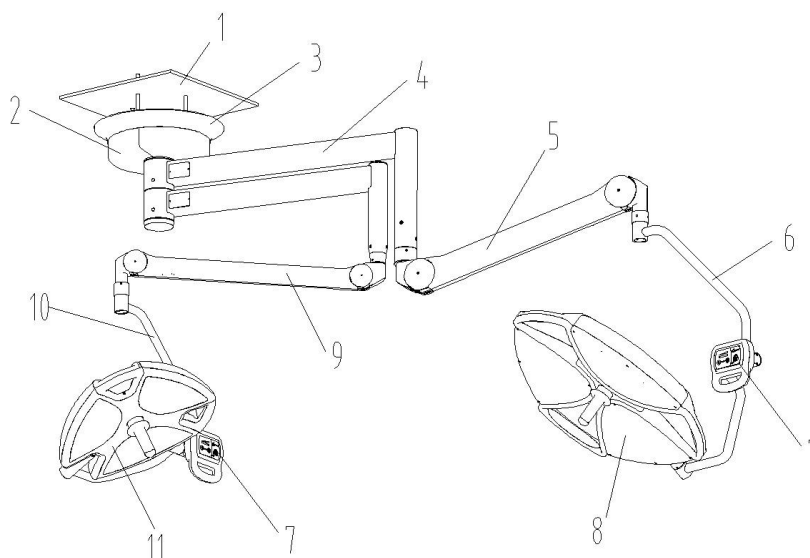
- Section 2, Intended use

The Surgery Shadowless Lamp, mainly used in relevant medical operation lighting field, can partly eliminate the shadows of the surgeons to realize the shadowless effect.

- Section 3, Product description

The product is mainly consisted of the lamp holder, the balance arm, the rotation arm, the electric control unit and the spare parts, etc.

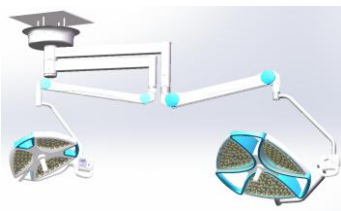
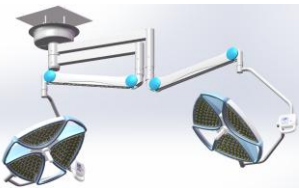

Structure (TOPLED-8060)



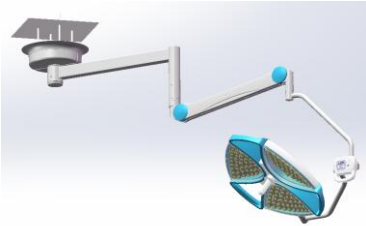
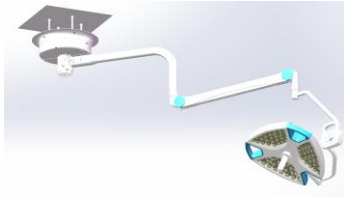
1) Embedded part	2) Chassis dust cover	3) Ornamental ring
4) Rotating arm	5) 3000N spring arm	6) Long bend assembly
7) Electric control handle	8) 80 lamp holder	9) 2000N spring arm
10) Short bend assembly	11) 60 lamp holder	

The lifetime of the device is 10 years.

Specification:

model Specification	TOPLED-8060	TOPLED-8080	TOPLED-6060
Photo			
Lamp holder external diameter	80cm lamp holder + 60cm lamp holder	80cm lamp holder + 80cm lamp holder	60cm lamp holder + 60cm lamp holder
Structural composition	Composed of rotating arm, spring arm, lamp holder, electrical control part and power automatic switch device.		
Structure classification	Hanging type, double-lamp type and automatic fault prevention type of surgery shadowless lamp.		
Lamp holder power	150 1W high-power LEDs + 90 1W high-power LEDs	150 1W high-power LEDs + 150 1W high-power LEDs	90 1W high-power LEDs + 90 1W high-power LEDs
Electrical	Composed of main power supply input terminal, T2AL250VAC main power		

control	supply fuse, B2KL-6A type power supply filter, power supply automatic switch device (MY4N-J type relay), auxiliary power supply input terminal, switching power supply, T5AL250VAC output fuse and control circuit board. See details in: Double-Lamp Type Wiring Diagram (P4).		
Input power	150VA + 90VA	150VA + 150VA	90VA + 90VA
Color temperature Tc	4500K±500K		
Center illuminance Ec	80cm lamp holder: ≥130000lx, 60cm lamp holder: ≥120000lx, the center illuminance of lamp holder shall not exceed 160000lx.		
Color rendering index Ra	95±5		
Ultraviolet irradiance	Ultraviolet irradiance under 400nm wavelength ≤10W/m ²		

model	Specification	
	TOPLED-8000	TOPLED-6000
Photo		
Lamp holder external diameter *	80cm lamp holder	60cm lamp holder
Structural composition *	Composed of rotating arm, spring arm, lamp holder and electrical control part.	
Structure classification *	Hanging type, single-lamp type and non fault prevention type of surgery shadowless lamp.	
Lamp holder power *	150 1W high-power LEDs	90 1W high-power LEDs
Electrical control *	Composed of main power supply input terminal, T2AL250VAC main power supply fuse, B2KL-6A type power supply filter, switching power supply, T5AL250VAC output fuse and control circuit board. See details in: Single-lamp Type Wiring Diagram (P5).	
Input power *	150VA	90VA
Color temperature Tc	4500K±500K	
Center illuminance Ec	80cm lamp holder: ≥130000lx, 60cm lamp holder: ≥120000lx, the center illuminance of lamp holder shall not exceed 160000lx.	
Color rendering index Ra	95±5	
Ultraviolet irradiance	Ultraviolet irradiance under 400nm wavelength ≤10W/m ²	

Power supply voltage	AC 230V 50Hz
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Use ambient temperature	+10~+30°C
Range of relative humidity	≤75%
Range of atmospheric pressure	860~1060hpa
Safety classification	Class I equipment
Mode of operation	Continuous
Supply connection	Permanently installed
This device can't be used in the flammable anesthetic gas and air mixture atmosphere or flammable anesthetic gas and oxygen or nitrous oxide mixture atmosphere.	
Transportation and storage conditions: ambient temperature: -40~+55°C; relative humidity: ≤93%; atmospheric pressure: 500~1060hpa. Upward, Fragile, Keep Away from Moisture.	
No applied parts.	

- Section 4, essential requirements checklist

Following harmonized standards are listed in the ER checklist FH/QRCE-2-TOPLED and listed in the applied standards form: EN ISO 14971:2012, IEC 60601-1:2005/A1:2012, IEC 60601-1-2:2007, IEC60601-2-41:2011, IEC 60601-1-6:2010.

Test reports for TOPLED 8060 #70.198.14.323.01-11-0(Rev.00) according to IEC 60601-1:2005/A1:2012, #701981432301-12-0 according to EN 60601-1-2:2007 by TÜV SÜD, #CW2015-013 according to IEC60601-2-41:2009 by CMTCC, # FH/QRCE-15-TOPLED according to IEC60601-1-6:2010 by the manufacturer.

- Section 5, risk management report

Risk management report #FH/QRCE-3-TOPLED, include risk management plan, the product description, responsibility of analysis stuff, risk acceptance criteria, risk analysis summary, conclusion, etc. After taken risk reduction activity, all risk is acceptable level.

- Section 6, clinical data

Route without clinic data is selected and justification is given in clinical data compilation FH/QRCE-6-TOPLED;

Base safety and essential requirement for the device is defined in IEC standards, IEC60601-1, IEC60601-2-41.

- Section 7, information supplied by the manufacturer

Nameplate as below

 Heal Force®		Surgery Shadowless Lamp 手术无影灯	
Model No. (型号):	TOPLED-8060		
Serial No. (机身号):	SN		
Date of production (生产日期):			
Standard No. (注册号):			
Production License No. (生产许可证编号):	沪食药监械生产许20000305号		
Product Technical Requirement No. (产品技术要求编号):			
 Shanghai International Holding Corp. GmbH Eiffeistrasse. 80. 20537 Hamburg. Germany Shanghai Fuhong Scientific & Technology Development CO., Ltd. (上海复弘科技发展有限公司) MF Addr. (制造厂地址): Building 4th, No. 6788 Songze Ave., QingPu Shanghai, PRC (上海市青浦区崧泽大道6788号4号楼) Web Site(网址): http://www.healforce.com Registered Addr. (住所地址): No. 8 Zhanchuan Store-house, Duimian St., Huaxia(E) Rd, Shanghai, PRC (上海市浦东新区华夏东路对面街振川仓储站8号) Tel(电话): 0086-21-58374808 Dimdi No.: DE/0000040627 E-mail: shholding@hotmail.com  Before using this surgery shadowless lamp, please carefully read technical specification (在使用本手术无影灯之前, 请仔细阅读技术使用说明书)			
Rated Voltage(额定电压): AC 230V 50Hz/60Hz		In Voltage(输入电压): DC 30V	
Max Power (最大功率): 150VA+90VA		Rated Current(标称电流): 0.68A+0.41A	
LED Life(LED寿命): 15000h		Period of Validity(有效期): 10年 (ten years)	
European Authorized Representative(欧盟代表):		Shanghai International Holding Corp. GmbH (Europe)	
上海国际(欧洲)集团公司		Add(地址): Eiffeistrasse 80, 20537 Hamburg, Germany	
德国汉堡艾佛路80号		Tel(电话): +49-40-2513175 Fax(传真): +49-40-255726	

Surgery Shadowless Lamp Technical instruction for TOPLED series #FH/QS-01-LED V201601-040-1.0 is submitted and reviewed.

■ Section 8, biocompatibility


No applied parts, so the biocompatibility requirement is not applicable.

The CE technical file is in English.

4. Summary of Review

With regard to the reviewed documents, TÜV SÜD China, Shanghai Branch was able to verify that the CE technical documentation is complete according to the requirements of Directive 93/42/EEC Annex VII. The objectives of this review are met:

- SHANGHAI FUHONG SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD. located in Building 4, No. 6788 Songze Avenue, Qingpu District, Shanghai, P.R, China has established a CE technical documentation for Operating Table.
- The content of CE technical documentation is complete with respect of the requirements of Annex VII section 3 of the Council Directive 93/42/EEC on Medical Devices

	Name	Signature	Date
Reviewed by	Yanan Liu		2016-05-05
Approved by	Irene Chen	_____	2016-05-05