



CERTIFICATE

Certificate Number

AI-MDD-0003/09/2019

Manufacturer

: Hefei Health Science and Technology Development Co., Ltd.

Address

: No. 77, Fushan Road, High-tech Zone, Hefei 230088 Anhui, China

Product(s)

: Surgical Lights, Operating Tables, Medical Pendants

Model(s)

: Please see 2nd page for details of product

Product Classification

: Class I

Related Directive

: 93/42/EEC Medical Device Directive

Technical File Document Number

: TCF-001, TCF-002, TCF-003

First Issue Date and Place

: 20.09.2019 & Istanbul

Revision Number and Date

: 00 / --

Validity Date

: 26.05.2024

This certificate has been issued according to the voluntary application of the manufacturer. NOTICE confirms that a technical file exists for the above mentioned product(s) and Declaration of Conformity prepared by the manufacturer is available. This certificate is valid only for the product(s) described in above mentioned technical file. It is manufacturer's sole responsibility to fulfill all necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards for the mentioned product(s) before placing them on the market. It is the manufacturer's responsibility to compile a full Technical File according to Annex VII of 93/42/EEC in order to comply with the requirements of 93/42/EEC and to appoint a European Representative before placing the products on the European Market. Additionally, the manufacturer is responsible to take necessary actions, such as internal production controls to fulfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

Özgür Vjcdan
General Manager

**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM**

HİZMETLERİ A.Ş.

AI-MDD-0003/09/2019

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
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Product Name	Series	Type	Model
Medical Pendants	T series	Single-arm	TD-100; TD-D-100; TD-Q-100; TD-DQ-100
		Double-arm	TS-100; TS-D-100; TS-Q-100; TS-DQ-100; QF-JX-300
Operating Tables	T series	Mechanical multifunction	TS; TF; TY; TG
	TD series	Electric multifunction	TDG-1; TDY-1; TDY-G-1; TDY-Y-1
	FD series	Gynaecological multifunctional	FD-G-1; FD-G-2
Surgical Lights	D series: Halogen lamp	D: hanging type	DD700/700, DD700, DD620/620, DD500/500, DD500, DD700/500, DD620
		B: wall type	DB700, DB620, DB500, DB215
		L: standing type	DL700, DL620, DL500, DL215
	LED series	D: hanging type	LEDD700/700, LEDD700, LEDD500/500, LEDD500, LEDD700/500, LEDD730/730, LEDD740/740, LEDD730/740, LEDD730, LEDD740
		B: wall type	LEDB730, LEDB740, LEDB260, LEDB700, LEDB500
		L: standing type	LEDL700, LEDL500, LEDL730, LEDL740, LEDL260, LEDL215

