

Declaration of Conformity

Manufacturer: VG Medical Technology Co., Ltd.
 No. 35-201, Changjiang South Road, Xinwu District, Wuxi, Jiangsu, China.
European Representative: Lotus NL B.V.
 Koningin Julianaplein 10, Le Verd, 2595AA, The Hague, Netherlands.

We herewith declare that the following mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Product Name	Model	UMDNS Code
Medical Ceiling Supply Units	i-PORT、TT-PORT	16001
Operating Table	YS-3	13961
	YS-100	
	COMFORT 200	
	COMFORT 300-207; COMFORT 300-207D; COMFORT 300-307; COMFORT 300-307D; COMFORT 300-317; COMFORT 300-317D; COMFORT 300-308; COMFORT 300-308D; COMFORT 300-318; COMFORT 300-318D; COMFORT 300-407; COMFORT 300-407D; COMFORT 300-417; COMFORT 300-417D; COMFORT 300-408; COMFORT 300-408D; COMFORT 300-418; COMFORT 300-418D; COMFORT 300-509; COMFORT 300-509D; COMFORT 300-519; COMFORT 300-519D	
	YF-5; YF-6; YJ-6	13960



Confidential and Proprietary:

The information contained in this document is legally privileged and confidential information intended only for the use by employees of VG Medical Technology Co., Ltd.

Surgical Light	LUCKYSTAR LE528; LUCKYSTAR LE628; LUCKYSTAR LS628; LUCKYSTAR E528; LUCKYSTAR E628; LUCKYSTAR S628; LUCKYSTAR S628 C; LUCKYSTAR S628 D; LUCKYSTAR S628 CD; LUCKYSTAR E528/E528; LUCKYSTAR E628/E528; LUCKYSTAR E628/E628; LUCKYSTAR S628/E528; LUCKYSTAR S628/E528 C LUCKYSTAR S628/E528 D; LUCKYSTAR S628/E528 CD LUCKYSTAR S628/E628; LUCKYSTAR S628/E628 C LUCKYSTAR S628/E628 D; LUCKYSTAR S628/E628 CD LUCKYSTAR S628/S628; LUCKYSTAR S628/S628 C LUCKYSTAR S628/S628 D; LUCKYSTAR S628/S628 CD	12347
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Examination Light	EXLED15 CLED 328 CD;CLED 328 CS;CLED 328 WD CLED 328 WS;CLED 328 M; CLED 328 MB CLED 388 CD; CLED 388 CS; CLED 388 WD CLED 388 WS; CLED 388 M; CLED 388 MB	12276
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The Examination Light, Surgical Light and Operating Table have been assessed following the procedure relating to the EC Declaration of Conformity set out in ANNEX VII of the Directive 93/42/EEC.

The Examination Light, Surgical Light and Operating Table have been assigned to Class I by Rule 12 according to ANNEX IX of the Directive 93/42/EEC, and these products bear the mark22



The above declaration about the Medical Supply Units is based on the certification of full quality assurance system according to ANNEX II, Article 3 of the Directive 93/42/EEC.

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Compliance of the Medical Supply Units with the Directive 93/42/EEC have been assessed following the procedure relating to the EC Declaration of Conformity set out in ANNEX II, Article 3 of the Directive 93/42/EEC and has been certified by the Notified Body

TÜV Rheinland LGA Products GmbH

The Medical Supply Units have been assigned to Class IIb by Rule 11 according to ANNEX IX of the Directive 93/42/EEC, and these products bear the mark



General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Standard Applied:

ISO 15223-1:2016	EN1041:2016	EN ISO 13485:2016
EN ISO 14971:2012	EN 60601-1:2006/A1:2012	EN 60601-2-41:2009
EN ISO 11197:2009	IEC60601-2-46:2016	EN 60601-1-2:2015

Notified Body: TÜV Rheinland (Shanghai) Co., Ltd.

NB Identification number: 0197

EC Certificate(s): HD 60131348 0001

Expire date of the Certificate: 2023-10-23

Date of Issue: 2018-10-26

Signature: 

Name: Zhiqiang Wang

Position: General Manager

Revision Date: 2020-12-21



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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

VG Medical Technology Co., Ltd.

Main Site: No. 35-201, South Changjiang Road, Xinwu District, Wuxi City,
Jiangsu Province, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

The design, manufacture, installation and after-sales service of surgical
light, operation table and medical ceiling supply unit.

Certificate Number:

0109240

Initial Certification Date:

7 January 2021

Date of Certification Decision:

7 January 2021

Issuing Date:

7 January 2021

Valid Until:

6 January 2024



Intertek



A handwritten signature in black ink, appearing to read "Calin Moldovean", is written over a horizontal line.

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada



Surgical Light

User Manual



LUCKYSTAR E528	LUCKYSTAR E628	LUCKYSTAR S628
LUCKYSTAR S628 C	LUCKYSTAR S628 D	LUCKYSTAR S628 CD
LUCKYSTAR E528/E528	LUCKYSTAR E628/E528	LUCKYSTAR E628/E628
LUCKYSTAR S628/E528	LUCKYSTAR S628/E528 C	LUCKYSTAR S628/E528 D
LUCKYSTAR S628/E528 CD	LUCKYSTAR S628/E628	LUCKYSTAR S628/E628 C
LUCKYSTAR S628/E628 D	LUCKYSTAR S628/E628 CD	LUCKYSTAR S628/S628
LUCKYSTAR S628/S628 C	LUCKYSTAR S628/S628 D	
LUCKYSTAR S628/S628 CD		

E528/E528 means no electric focusing function, double lamp head, the outer diameter of the lamp head are $\varnothing 528\text{mm}$ and $\varnothing 528\text{mm}$

E628/E528 means no electric focusing function, double lamp head, the outer diameter of the lamp head are $\varnothing 628\text{mm}$ and $\varnothing 528\text{mm}$

E628/E628 means no electric focusing function, double lamp head, the outer diameter of the lamp head are $\varnothing 628\text{mm}$ and $\varnothing 628\text{mm}$

S628/E528 S628 means electric focusing function, E528 means no electric focusing function, ceiling type with double lamp head, the outer diameter of the lamp head are $\varnothing 628\text{mm}$ and $\varnothing 528\text{mm}$

S628/E628 S628 means electric focusing function, E628 means no electric focusing function, ceiling type with double lamp head, the outer diameter of the lamp head are $\varnothing 628\text{mm}$ and $\varnothing 628\text{mm}$

S628/S628 means electric focusing function, ceiling type with double lamp head, the outer diameter of the lamp head are $\varnothing 628\text{mm}$ and $\varnothing 628\text{mm}$

※ Camera system: it means equipped with the camera system. C is the first letter of camera.

※ Display: it means equipped with display, D is the first letter of display.

Type listing:

LUCKYSTAR E528	LUCKYSTAR E628	LUCKYSTAR S628
LUCKYSTAR S628 C	LUCKYSTAR S628 D	LUCKYSTAR S628 CD
LUCKYSTAR E528/E528	LUCKYSTAR E628/E528	LUCKYSTAR E628/E628
LUCKYSTAR S628/E528	LUCKYSTAR S628/E528 C	LUCKYSTAR S628/E528 D
LUCKYSTAR S628/E528 CD	LUCKYSTAR S628/E628	LUCKYSTAR S628/E628 C
LUCKYSTAR S628/E628 D	LUCKYSTAR S628/E628 CD	LUCKYSTAR S628/S628
LUCKYSTAR S628/S628 C	LUCKYSTAR S628/S628 D	LUCKYSTAR S628/S628 CD

2.6 Technical parameters

Parameters specification		$\varnothing 528\text{mm}$ lamp cap	$\varnothing 628\text{mm}$ lamp cap
Center luminance (E_c)	Step I	$40\text{klx} \leq E_c \leq 140\text{klx}$	$40\text{klx} \leq E_c \leq 160\text{klx}$
	Step II		
	Step III		
	Step IV		
	Step V		
Light spot	Diameter (d_{10})	$200\text{mm} \pm 15\% \leq d_{10} \leq 280\text{mm} \pm 15\%$	
	d_{50}/d_{10}	$\geq 60\%$	$\geq 60\%$
	focusing	/	$200\text{mm} \pm 50\%$
Note: $\varnothing 628\text{mm}$ light spot focusing is optical			
Sha do wle ss	Remaining illumination with one baffle	40%	50%
	Remaining illumination with two baffle	45%	45%
	Remaining illumination with tube	$\geq 90\%$	$\geq 88\%$
	Remaining illumination with one tube and baffle	$\geq 28\%$	$\geq 40\%$

	Remaining illumination with one tube and two baffles	≥40%	≥40%
Depth of illumination		≥1000mm	≥1000mm
Color rendering index (R _a)	3500K±250K	96±3	96±3
	4000K±250K	96±3	96±3
	4500K±250K	≥92	≥92
	5000K±250K	≥86	≥86
Color temperature (T _k)	I (x≈0.41±0.1; y≈0.39±0.1)	3500K±250K	3500K±250K
	II (x≈0.38±0.1; y≈0.38±0.1)	4000K±250K	4000K±250K
	III (x≈0.36±0.1; y≈0.37±0.1)	4500K±250K	4500K±250K
	IV (x≈0.35±0.1; y≈0.35±0.1)	5000K±250K	5000K±250K
Note: color temper is adjustable with four steps, the standard color temp is 4000K.			
The total irradiance (E _e)		≤500W/m ²	≤600W/m ²
The ratio of irradiance vs illumination		≤3.8mW/(m ² .lx)	≤3.8mW/(m ² .lx)
Head light power consumption		75W	100W
Input power consumption		200VA	200VA
Fuse wire		T1AL250V	T2AL250V

2.7 Electricity specification

Power supply voltage: AC220V±22V

Frequency: 50Hz±1Hz

Lamp head power consumption: 75W (Ø528mm lamp cap); 100W (Ø628mm lamp cap)

Input power consumption: 200VA

Fuse:T1AL 250V (Ø528mm lamp cap); T2AL 250V (Ø628mm lamp cap)

2.8 Package, Transportation and Storage conditions

a) Package

There should be a using manual, testing report and packing list in the packing case. The surgical light should be fixed firmly in the box. Using the soft upholstery of suitable thickness, avoid the movement or any friction during the transportation.

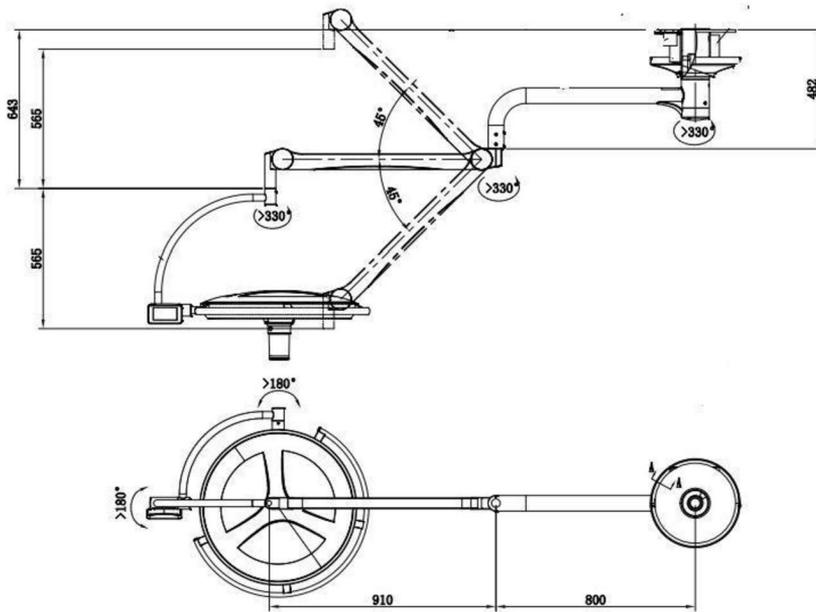
b) Transportation

Use normal transportation methods. Prevent the goods from violently hitting, shock, crashing. Keep away from rain/ snow. .

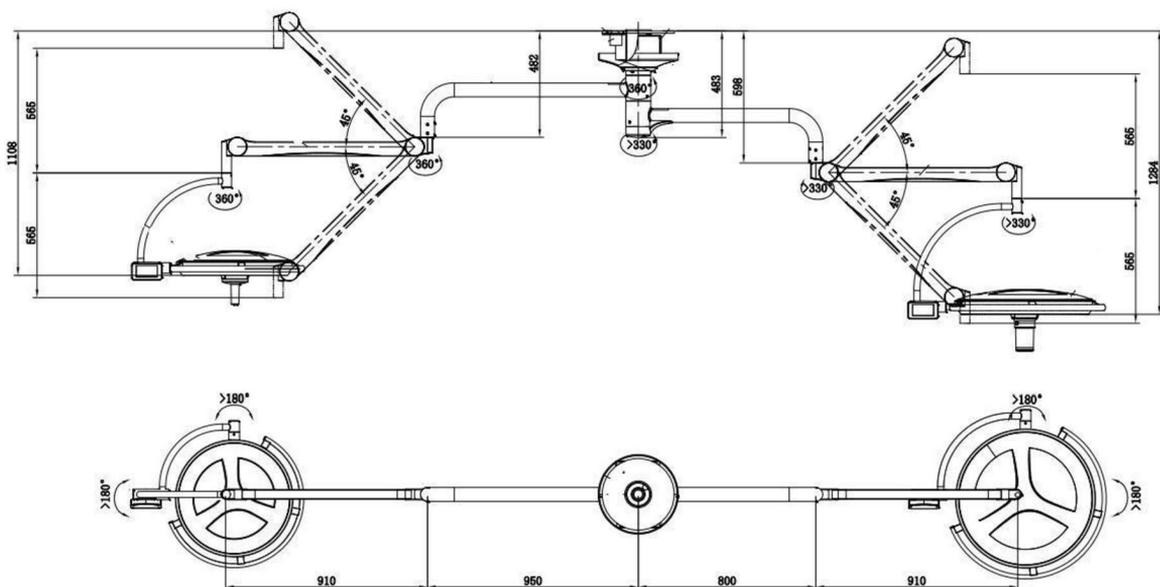
8. Technical instruction

8.1 Product standard – Examples of available configurations

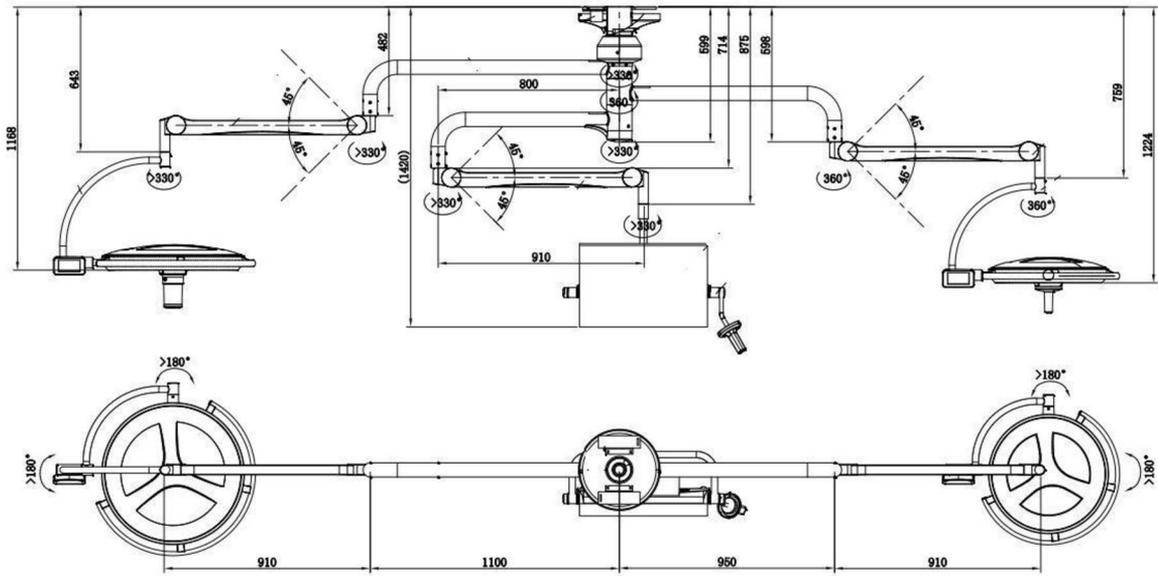
Configuration I



Configuration II



Configuration III



You can ask the distributor or our company if you need other dimensions, we will endeavor to provide you with quality service and help.