

Declaration of Conformity

Manufacturer: VG Medical Technology Co., Ltd.
No. 35-201, Changjiang South Road, Xinwu District, Wuxi, Jiangsu, China.
European Lotus NL B.V.
Representative: 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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