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

Digitally signed by Matei Vasile
Date: 2022.05.19 14:19:33 EEST
Reason: MoldSign Signature
Location: Moldova

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
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

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

CE

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.

Compliance of the Medical Supply Units with the Directive 93/42/EEC have been assessed following the procedure relating to het 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

CE 0197

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: 2018-10-24

Signature: _____
Name: Zhiqiang Wang
Position: General Manager
Revision Date: 2020-12-21

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Company Name: Lotus NL B.V.
Company Address: Koningin Julianaplein 10, le Verd, 2595AA,The Hague, Netherlands.

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO14971:2019 EN 62366-1:2015
EN ISO15223-1:2016
ISO10993-1:2018
EN ISO10993-5:2009
EN ISO10993-10:2013
EN 1041:2008+A1:2013
IEC 60601-2-46:2016
EN 60601-1-2:2015
EN 60601-1:2006+A12:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-VG01.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: VG Medical Technology Co., Ltd.
Address: No.35-201 Changjiang South Road, XinWu District, Wuxi, China

Product Information

Name：Electric Operating table
Model：COMFORT 300 Series
GMDN：35379
Basic UDI-DI: 697462584COMFORT300TH
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:2021.05.31

Position:GM Place: Jiangsu , China

VG MEDICAL TECHNOLOGY CO., LTD 320211001156

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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

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
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Canada