

EU Declaration of Conformity

- **Reference No.** : **DOC-L4**
- **Manufacturer** : **DENTIS Co., Ltd.**
99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea
- **SRN(Single Registration Number)** : **KR-MF-000012523**
- **Product** : **Major Surgical Luminaire**
- **Basic Model** : **L400, M400**
- **Classification** : **Class I (Rule 13)**
- **Basic UDI-DI** : **88000530LM400B7**
- **Authorised representative** : **CALMED INVEST Kft.**
Hegyalja ut 21., Nadap, 8097, Hungary
- **Harmonized Standards** : **EN ISO 13485:2016**
Medical devices – Quality management systems – Requirements for regulatory purpose
EN ISO 14971:2019
Medical devices – Application of risk management to medical devices
EN 60601-1:2006 /A1:2013
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-6:2010
Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 60601-2-41:2009 /A1:2015
Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
EN 62471:2008
Photo biological safety of lamps and lamps systems



This declaration of conformity is issued under the sole responsibility of DENTIS CO., LTD.. We hereby declare that the medical device specified above meets the provision of the Regulation (EU) MDR 2017/745 for medical device. If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Date of issue of the declaration: January 21, 2022
Place of issue of the declaration: DENTIS Co., Ltd.
99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea
Function of the person who signed: CEO
Name of the person who signed: Sim Gi-Bong

Signature: 

- Model Reference

Models	Separator	HEAD ARM Axis	CAMERA	WALL CONTROLLER	BATTERY	SMPS
L400, M400	-	A=3Axis B=2Axis	0=None 1=installed 2= Camera installable status 3=Wireless installed 4= Wireless Camera installable status	0=None	0=None 1=installed	0=GCS180PS28- C

Note 1) While Fixed Type covers 2 and 3Axis of HEAD ARM, Mobile Type covers only 2Axis.
Mobile Types are used for 2Axis of HEAD ARM only.
Example) L400-B0010 (o), M400-A1010 (x)

- Attribute of Model designation

ARM Type	Spring ARM	Central Axis or Mobile	Drop tube or Mobile
FA=Fixed ARM, MA=Mobile ARM	[ACROBAT] A=AC2000 STD 13.5-21kg B=AC2000 LCH C=AC2000 STD 9-15kg D=AC77 LCH E=AC2000 W/S Monitor F=AC2000 W/S External camera G=AC2000 W/S Internal Camera H=AC2000 Mobile [VALIA] I=L21 3P J=L21 HDC5 K=L21 HDC11 L=L21 HDC5S M=MD21 W/S N=LCH19 3P O=LCH19 HDC5 P=LCH19 HDC11 Q=LCH19 HDC5S	[ACROBAT] 0=Mobile 1=1 Fold 2=2 Fold 3=3 Fold [VALIA] 4=1 Fold 5=2 Fold 6=3 Fold	0=Mobile 1=ACROBAT type 2=Dentis type 3=VALIA type

Note 1) Available for combination use of ACROBAT and VALIA individual parts
Example) FA-A11 (o), FA-A53 (x), FA-A51 (x)
Note 2) MA-H00 applied only for the Mobile type