

EU Declaration of Conformity

- **Reference No.** : **DOC-S3**
- **Manufacturer** : **DENTIS Co., Ltd.**
99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea
- **SRN(Single Registration Number)** : **KR-MF-000012523**
- **Product** : **Minor Surgical Luminaire**
- **Basic Model** : **S300**
- **Classification** : **Class I (Rule 13)**
- **Basic UDI-DI** : **88000530S300F5**
- **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:

A handwritten signature in black ink, appearing to read 'Sim Gi-Bong', written over a horizontal line.

- Model Reference

Models	Separator	HEAD ARM Axis	NONE	NONE	BATTERY	SMPS
S300	—	A=2Axis	0=None	0=None	0=None 1=installed	0=GCS150PS24

- Attribute of Model designation

ARM Type		Spring ARM	Central Axis or Mobile	Drop tube or Mobile
FA=Fixed ARM, MA=Mobile ARM	—	[S-Model] 0=TENSION SPRING ARM	[S-Model] 0=MOBILE VERTICAL ARM 1=CHAIR SECOND ARM 2=WALL SECOND ARM (applicable to both WALL Type and DUAL CEILING Type) 3=CEILING SECOND ARM	[S-Model] 0= MOBILE BASE 1=DUAL CONNECTOR 2=WALL BRACKET 3=CEILING VERTICAL ARM 4= DUAL CEILING VERTICAL ARM & DUAL BRACKET

**U.S. FOOD & DRUG**
ADMINISTRATION[Follow FDA](#) | [En Español](#)[SEARCH](#)[Home](#)[Food](#)[Drugs](#)[Medical Devices](#)[Radiation-Emitting Products](#)[Vaccines, Blood & Biologics](#)[Animal & Veterinary](#)[Cosmetics](#)[Tobacco Products](#)

Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)[New Search](#)[Back To Search Results](#)

Proprietary Name:	L200 Series (Ceiling, Mobile); L400 Series (Ceiling, Mobile); M200 Series (Ceiling, Mobile); M210 Series(Ceiling, Mobile); M300 Series(Ceiling, Mobile); M310 Series(Ceiling, Mobile); M400 Series (Ceiling, Mobile); S300 series
Classification Name:	LAMP, SURGICAL
Product Code:	FTD
Device Class:	2
Regulation Number:	878.4580
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	DENTIS MEDICAL DIVISION
Registered Establishment Number:	3010373494
Owner/Operator:	Dentis Co., Ltd.
Owner/Operator Number:	10025697
Establishment Operations:	Manufacturer



CERTIFICATE OF REGISTRATION

This certificate has been awarded to the company

DENTIS CO.,LTD.

**99,Seongseoseo-ro,Dalseo-gu,Daegu,Korea
(Head Office)**

**6,Yuram-ro,Dong-gu,Daegu,Korea
(DENTIS MEDICAL DIVISION)**

To certify that the implemented medical devices quality management system complies with

ISO 13485:2016

For the activities described below

**Design & Development, Production, Installation
and Service of Medical Lights and Materials(Resin)
For Dental 3D Printing**

Kalitest Certification and Training Services Ltd. Şti.



Figen BİGÜN
Vice General Manager

Certificate No	K-MD-1093
Date of Registration	17.02.2016
Period of Registration	3 yıl / years
Certificate Date	11.02.2022
Expiry Date	17.02.2025

Please verify the validity of this certificate with the serial number of 5575528 from the web site of www.kalitest.com.tr or with TÜRKAK BDS NO from the web site of tbds.turkak.org.tr

KALİTEST BELGELENDİRME VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ
Yazgölü Sokak, Aydın Sitesi 1.Kısım, C-4 1/D Blok, D:33, Levazım-Beşiktaş/İSTANBUL
www.kalitest.com.tr info@kalitest.com.tr

The validity of this certificate depends on the company's conformity with KALİTEST Certificate Regulations and the result of the surveillance audits which will be carried out at least once in a year.