

## EC Declaration of Conformity

### Manufacturer

**Name:** Guangzhou Fengdan Medical Equipment Co., Ltd

**Address:** No.286, Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province 511480, P. R. China

### Medical Device

**Name:** Galaxy Standard sciatica lamp

**Model:** 12 LEDs

**Intended use:** The Galaxy Standard sciatica lamp is intended for use to illuminate the treatment area during dental treatment by trained and qualified personnel. It is permanently installed on dental chair and not equipped with a setting intended for use while handling light-activated restorative materials.

**We confirm our product can meet requirement of Medical Device Regulation and the following harmonized standards:**

EN ISO 9680:2021

EN 60601-1-2:2015+A1:2021

EN 60601-1: 2006+A1:2013+A12:2014+A2:2021

We, the manufacturer, here with declare that the stated medical devices meet the transposition into national law, the provisions of the European Union Medical Device Regulation: directive 93/42/EEC All supporting documentation is retained at the premises of the manufacturer.

WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS doc.

PLACE, DATE OF DECLARATION:|

SIGNATURE:

Calvin Chen

NAME: Calvin Chen

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)

PLACE: No.286, Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province 511480, P. R. China

DATE: 02/20 2025