EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to 93/42/EEC Medical devices.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Foshan Roson Medical Instruments Co.,Ltd.**
No.9 Henggui Mid-Road,Lianhe Industrial Zone,Luocun, Shishan Town,Nanhai District,Foshan City,Guangdong, Province,China,528226

We declare under our sole responsibility that the medical device:

Model： Dental Unit
KLT-6210,KLT-6220

of class:/ IIa,rule 5and rule 9
according to 93/42/EEC Medical devices Annex IX.

meets the provisions of the 93/42/EEC Medical devices and its transpositions in national laws which apply to it.All supporting documentations are retained under the premises of the manufacturer.

Conformity assessment procedure:/ **93/42/EEC Medical devices Annex V**
合格评定程序：/

Registration No.: **FI16/07015-1**

Notified Body: **SGS Fimko OY**
Takomotie 8
00380 HELSINKI
Country:Finland

IDENTIFICATION NUMBER: 0598

EUROPEAN REPRESENTATIVE: Wellkang Ltd,
Enterprise Hub,NW Business Complex,1 Beraghmore Road,Derry, BT488SE,Northern Ireland

STANDARDS APPLIED: See Annex 1

Foshan/23 Feb.2024
Place/date

Management Representative/wangdaiping

2024.2.23

Annexl Standards Applied

Item	Standard	Description
1	EN 1041:2008+A1:2013	Terminology, symbols and information provided with medical devices-Information supplied by the manufacturer with medical devices
2	EN ISO 14971:2020	Medical Devices -Application of Risk Management to Medical Devices
3	IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment;Part 1:General requirements for basic safety and essential performance
4	IEC60601-1-2:2014/A1:2020	Medical electrical equipment -Part 1-2:General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances-Requirements and tests
5	IEC 60601-1-6:2010 +A1:2013+AMD2:2020 CSV	Medical electrical equipment -Part 1-6:General requirements for basic safety and essential performance -Collateral standard: Usability(IEC 60601-1-6:2010+A1:2013+AMD2:2020CSV);German version EN 60601-1-6:2010+A1:2013+AMD2:2020CSV.
6	IEC62366:2007+A1:2015	Medical devices -Application of usability engineering to medical devices
7	EN 62304:2006/A1:2015	Medical device software-Software life-cycle processes
8	EN ISO 10993-1:2020	Biological evaluation of medical devices -Part 1:Evaluation and testing within a risk management system
9	IEC80601-2-60:2019	Medical electrical equipment.Part 2-60.Particular requirements for basic safety and essential performance of dental equipmen
10	EN ISO 7494-1:2018	Dentistry -Dental units -Part 1:General requirements and test methods
11	EN ISO7494-2:2022	Dentistry -Dental units-Part 2:Water and air supply
12	EN 1640:2009	Dentistry -Medical devices for dentistry -Equipment
13	EN 62471:2008	Photobiological safety of lamps and lamp systems
14	EN ISO9680:2021	Dentistry -Operating lights