

**Guangzhou Sunray Medical Apparatus Co.,Ltd.**

广州三瑞医疗器械有限公司

Subject:

Declaration of Conformity

Document No: RED-Maternal and Fetal Monitor-01

Ver: 01

Date: 2019.01.08

EC Declaration of Conformity

Manufacturer Name:	Guangzhou Sunray Medical Apparatus Co.,Ltd
Address:	38 Gaoke Road, Gaotang Industry District, GuangShanEr Road, 510520,Guangzhou, PEOPLE'S REPUBLIC OF CHINA
EU Representative Name:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestrasse 80, 20537 Hamburg Germany
Radio Equipment Name:	Maternal and Fetal Monitor
Model :	SRF618K9,SRF618X9
Radio Equipment Description:	The radio equipment is equipped with capability for wireless monitoring using wireless Ultrasound transducer, TOCO transducer and fetal movement marker.
We declare under our sole responsibility that the radio equipment described above is in conformity with the Radio Equipment Directive 2014/53/EU. The following harmonized standards are those which the product applies.	
EN 300 440-2,V3.1.1	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1,V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-3,V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10MHz~ 300GHz)
Signed by:	
Name:Liu Lijun <i>Liu Li Jun</i>	
Position:Management Representative	
Date: <i>2019-01-08</i>	