

 <b>Guangzhou Sunray Medical Apparatus Co.,Ltd.</b> 广州三瑞医疗器械有限公司	
Subject: Declaration of Conformity	Document No: CE-SRF-X9-01
	Ver: 09
	Date: 2024.03.18

### Declaration of Conformity

<b>Legal Manufacturer</b>	<b>Name</b>	Guangzhou Sunray Medical Apparatus Co., Ltd.
	<b>Address</b>	38 Gaoke Road, Gaotang Industry District, GuangShanEr Road,510520,Guangzhou, PEOPLE'S REPUBLIC OF CHINA
<b>Signal registration number (SRN)</b>		CN-MF-00001980
<b>European Representative:</b>		Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80,20537 Hamburg Germany
<b>Medical device(s)</b>	<b>Product Name</b>	<b>Maternal and Fetal Monitor</b>
	<b>Model/s</b>	SRF618K9, SRF618X9
	<b>Classification</b>	<b>IIb, rule 10</b> The medical device has been assigned to class IIb according to rule 10 of Annex IX of the directive 93/42/EEC.
	<b>Basic UDI-DI</b>	69346679SRK10013M
	<b>GMDN Code</b>	<b>60260</b>
<b>Conformity Assessment by</b>	<b>Annex II without the section 4</b> We here declare that above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.	
<b>Directives</b>	<b>General applicable directives</b> Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amendment by 2007/47/EC.	
<b>Standards Applied</b>	Refer to "Standards Applied for Maternal and Fetal Monitors CE-SRF-K9-03" and "Standards Applied for Maternal and Fetal Monitors CE-SRF-X9-03" for applicable standards	
<b>Notified Body</b>	<b>TÜV SÜD Product Service GmbH (NB # 0123)</b> Ridlerstr. 65, 80339 , München, Germany	
<b>(EC) Certificate(s)</b>	<b>EC Certificate number</b>	G1 048151 0005 Rev.00
	<b>Expire date</b>	2028-12-31
<b>Start of CE marking</b>	2015-05 for SRF618K9 2017-07 for SRF618X9	

**We are exclusively responsible for the Declaration of Conformity.**

Guangzhou, PEOPLE'S REPUBLIC OF CHINA 2024-03-18

(Place and date of issue)

Signature Liu Lijun

Name: Mr. Liu Lijun

Position: Management Representative

(name and signature or equivalent marking of authorized person)

