EC Declaration of Conformity

In accordance with EC Medical Directive
(93/42/EEC as amended by Directive 2007/47/EC)

Manufacturer	Ningbo Runyes Medical Instrument Co., Ltd. 032 Building, No. 456,Tonghui Road, Jiangbei Investment & Pioneering Park C, 315033 Ningbo, PEOPLE'S REPUBLIC OF CHINA
EC REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product	Diagnostic X-ray Equipment
Type Reference	RAY98(M), RAY98(W)
Classification	Class IIb, Rule 10
Conformity Assessment Route	Annex II excluding 4
GMDNS Code	41000
Applied Directive	Medical Device Directive (93/42/EEC as amended by Directive 2007/47/EC)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by Directive 2007/47/EC and the REGULATION (EU) 2023/607. All Supporting documents are retained under the premises of the manufactures. We are exclusively responsible for the DOC.

Notified Body	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65,D-80339 MÜNCHEN, GERMANY
NB NO.	0123
EC certificate No.	G1 088627 0002 Rev.01
Extension certificate No.	CL 088627 0004 Rev. 00
Validity from	2024-01-08
Validity date	2028-12-31
CEO Signature	**Mr. Buguang Xu**
Place and date	**Ningbo** 2024-03-03

宁波蓝野医疗器械有限公司
NINGBO RUNYES MEDICAL INSTRUMENT CO.,LTD.