

	Technical File	File No.	TF-XRG-02
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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
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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.
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