

<b>Runyes</b> <sup>®</sup>	<b>Technical File</b>	File No.	TF-YY-02
		Rev. No.	2
	2. EC Declaration of Conformity	Rev. Date	Jan.18,2024
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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** Integral Dental Unit Chair

**Type Reference** Care-11, Care-22, Care-33

**Classification** Class IIa, Rule 9

**Conformity Assessment Route** Annex II excluding 4

**GMDNS Code** 47144

**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. Xu Buguang

**Place and date** Ningbo 2024-01-18

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

徐步光