

	Technical File	File No.	TF-S-02
		Rev. No.	3.0
	2. EC Declaration of Conformity	Rev. Date	Jan.23,2024
		Page	1 / 1

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, Ningbo, China
EC REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product	Small Steam Sterilizers
Type Reference	SEA45, SEA29, SEA23, SEA18, SEA16, SEA12, SEA8, STE23, STE18, STE16, STE12, STE8
Classification	Class IIb, Rule 15
Conformity Assessment Route	Annex II excluding 4
GMDNS Code	38671
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 2024-01-23

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