

	<b>Technical File</b>	File No.	TF-S-02
		Rev. No.	4.0
	<b>2. EC Declaration of Conformity</b>	Rev. Date	Sep.4,2024
		Page	1 / 1

# EC Declaration of Conformity

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

<b>Manufacturer</b>	Ningbo Runyes Medical Instrument Co.,Ltd. 032 Building, No. 456, Tonghui Road, Jiangbei Investment & Pioneering Park C, Ningbo, China
<b>EC REP</b>	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
<b>Product</b>	Small Steam Sterilizers
<b>Type Reference</b>	SEA45L,SEA29L,SEA23L,SEA18L,STE16L,STE12L
<b>Classification</b>	Class IIb, Rule 15
<b>Conformity Assessment Route</b>	Annex II excluding 4
<b>GMDNS Code</b>	38671
<b>Applied Directive</b>	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.

<b>Notified Body</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65,D-80339 MÜNCHEN, GERMANY
<b>NB NO.</b>	0123
<b>EC certificate No.</b>	G1 088627 0002 Rev.01
<b>Extension certificate No.</b>	CL 088627 0004 Rev.01
<b>Validity from</b>	2024-01-08
<b>Validity date</b>	2028-12-31
<b>CEO Signature</b>	Mr. Xu Buguang
<b>Place and date</b>	Ningbo 2024-09-04

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

徐步光