

 S GR11.1 DOC 68 REV08 OF 10/11/2023	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 25-CRT03239
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CODE	LOT.N°	DEVICE NAME	EXP. DATE
608CS01R	251054300	Enat	31/07/2026

DEVICE DESCRIPTION:	1 ML PRESERVATION MEDIUM FOR NUCLEIC ACIDS
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Manufacturing process is supported by the Quality System certification based on the standard UNI EN ISO 9001:2015 and on the EN ISO13485:2016.

Quality Controls: tests are performed following internal SOPs on defined monitoring plan.

AET Test: medium was inoculated with the following test organisms according to internal SOP. The following results must be obtained after 30 minutes of contact in order to pass the test:

TEST ORGANISMS	ATCC	RESULT
<i>E. coli</i>	25922	No growth on plate
<i>S. aureus</i>	6538	No growth on plate
<i>C. albicans</i>	10231	No growth on plate

pH of medium at 25°C: passed according to internal SOP.

pH at 20°C - 25°C (Bulk solution)	Specification	Actual Value
	6.60 – 7.80	Pass

Visual and mechanical Inspection: within acceptability limits according to internal SOP

Goods have been irradiated by gamma radiation.

The applied dose range is validated to guarantee the Sterility Assurance Level SAL 10⁻⁶.

Sterilization procedure is validated in conformity with BS EN ISO 11137-1:2015 and BS EN ISO 11137-2:2015.

Copan Italia SpA certifies that all product quality requirements have been met and that all information stated above is correct.

17/07/2025

Certificate Date of Issue



Quality Representative
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