

 S GR11.1 DOC 68 REV07 OF 21/03/2022	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 22-CRT04558
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CODE	LOT.N°	DEVICE NAME	EXP. DATE
608CS01R	221560000	Enat	30/09/2023

DEVICE DESCRIPTION:	1 ML PRESERVATION MEDIUM FOR NUCLEIC ACIDS
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Goods have been manufactured according to EN ISO13485:2016 and UNI EN ISO 9001:2015 compliant Quality Systems.

QC REPORT:

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

Final Visual 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.

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

All reported results were obtained at time of Lot release.

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

15/09/2022

Certificate Date of Issue



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