

## **Certificate of Conformity – Nalgene**

Date: 11 Aug 2025

Effective Date: 26 Oct 22

Product: Nalgene 650ml PET Square Bottle Capped

29 Jul 2030

 Item Number:
 842040-0650

 Lot Number:
 M571200

 Resin Number:
 8-0003-32

 Closure Number
 430118-0320

Date of Expiry:

Thermo Fisher Scientific confirms that the product supplied has been manufactured in a controlled environment, inspected and tested in accordance to relevant specifications.

Test Description	Requirements	Result
Visual	According to specification	Complies
Test of function	According to specification	Complies
USP<85> Bacterial Endotoxins Test	<0.5 endotoxins unit/ml	Complies
USP Class VI	According to specification	Complies

Sterility is obtained through irradiation according to ISO 11137 "Sterilization of health care products - Radiation" with SAL 10<sup>-6</sup>.

	Min	Max	Certificate of	Date of
	(kGy)	(kGy)	Irradiation Ref	Irradiation
Calculated Dose	24.5	35.5	46,303 x 825	08 Aug 25
Specification	20.0	45.0		

Quality assurance of the product is performed in accordance with the requirements of Quality management System ISO 9001:2015 "Quality management system - Requirements".

Signed on behalf of the Quality Department:

Harvey Mayers

Interim Batch Release-Document Controller

Laboratory Products Division Parkway Newport +44(0) 1495 242200 <u>www.thermofisher.com</u>

Rev: 04.00

Pen y Fan Industrial Estate NP11 3EF +44(0) 1495 242242 fax Page 1 of 1

FRM0034360 (Legacy Ref: QF509)