



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 13-Jan-2021

FR01S12520765-1-1

This is to certify that Synergy Health Marseille, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

PROMEPLA
Le Copori
9 avenue Albert II
MONACO
98000
MONACO

Order Information

Account Number:	104501
Synergy Health Sales Part Reference:	1127465
Customer Reference Number:	396/PLANER PLC - 23/12/2020
Product Description:	496618P - PRODUITS CULTURE CELLULAIRE
Validation Reference:	S12029202
Quantity Received:	10
Customer Minimum Specification KGy:	25.0
Customer Maximum Specification KGy:	45.0
Customer Unit Lot/Batch Number:	G005109

Irradiation Data

Date and Time of Irradiation:	12-JAN-2021 11:44
Calculated Minimum Dose KGy:	26.4
Calculated Maximum Dose KGy:	40.5

01568-1	Qty: 4,800 Each
P Ref:	
Q5/BOTTLE	GRN: 363
CN 101568-1	Purchase Order #PN182
	MTMS PO # PND045466

Irradiation Release Authorised By Synergy Health Marseille SAS, a STERIS Company

Processing Site: M.I.N. 712 - Arnavaux, Marseille Cedex 14, 13323 Phone No: +33 (0) 4 91 214 214

Registered Office: M.I.N. 712 - Arnavaux, 13323 Marseille Cedex 14, FRANCE
N° TVA: FR59 343 092 540



TEST INSTRUCTIONS

XT104117 Rev 2

Goods Inwards Inspection_bottle assy

Test Results Status

Step	Details	Result	Notes/Pass value
#1	<ul style="list-style-type: none"> To ensure bottle assemblies have received appropriate level of Irradiation. To create electronic record of Irradiation Certificate. To visually inspect packaging. 		
#2	Record GRN number (goods received number) for shipment under inspection.	✓	Enter the value here : GRN number GR363
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT G005109
#4	Perform visual inspection upon entire shipment. Confirm all packaging free from external damage.		Enter the value here : DR
#5	In the event of damage being discovered, raise defect report and record its number here.		If not applicable, goto #5
#6	Referring to QA procedure PRO-Sd011 (Inspection Sampling Plan) perform detailed inspection in accordance with batch size.		Done ? <input type="checkbox"/>
#7	Confirm Certificate of Irradiation supplied with bottle shipment. NB: In some cases, certificates may be sent in advance, these are located in Box File # BX0141. Use Lot number as search phrase within Box File data base to facilitate retrieval, as required.		Done ? <input type="checkbox"/>
#8	Record Certificate Number	✓	Enter the value here : Cert of Irradiation number FR01812520765-1-1
#9	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : 12-1-21
#10	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose.	✓	Enter the value here : 26.4 KGy > 24.999 KGy
#11	Confirm Minimum Calculated Dose not less than 25 KGy.		Done ? <input checked="" type="checkbox"/>
#12	If completing this test instruction on paper, attach copy of the Irradiation Certificate to this test instruction.		If not applicable, goto #11
#13	If completing this instruction electronically, photograph the first page of Certificate of Irradiation (Ensure photograph legible before attaching)	W/A	If not applicable, goto #12
#14	From Part Number Generator, print current revision of Bottle Assembly Label (# 1A101713) (Ensure photograph legible before attaching)	N/A	If not applicable, goto #13
#15	From Part Number Generator, print current revision of Bottle Assembly Label (# 1A101713)		Done ? <input checked="" type="checkbox"/>
#16	Confirm all boxes within shipment are labelled with current issue of Bottle Assembly Label.		Enter the value here : 2020-04-28
#17	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.		Done ? <input checked="" type="checkbox"/>
#18	Confirm all boxes within shipment are marked with correct USE BY date. This must be 2 years + 5 months from date of manufacture. (Refer to date of manufacture recorded in previous step as required)		Reference results at #13
#19	Approvals: Signature & Date stamp		
<p>ASSEMBLER/TESTER: PLANER PIC APPROVER (Test auditor): Name of Approver: APPROVER (Test auditor) Name of Tester: SIGNED: C. P. Valle Name of Approver: APPROVER (Test auditor)</p>			
<p>19 FEB 2021</p> <p>PRODUCTION</p>			
<p>END OF TEST RESULTS</p>			

