

TEST INSTRUCTIONS

XT104117 Rev 2

Goods Inwards inspection_bottle assy

Test Results Status

Step	Details	Result	Notes/Pass value
#1	Purpose of test: <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 GR2619
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT 6005726
#4	Perform visual inspection upon entire shipment. Confirm all packaging free from external damage. In the event of damage being discovered, raise defect report and record its number here.	✓	Enter the value here : DR
#5	Referring to QA procedure PRO-Sdo11 (Inspection Sampling Plan) perform detailed inspection in accordance with batch size.	✓	If not applicable, goto #5 <input checked="" type="checkbox"/> Done?
#6	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.	✓	Enter the value here : Cert of Irradiation number <input checked="" type="checkbox"/> Done? Reference results at #3
#7	Record Certificate Number FR01512602508-1-1	✓	Enter the value here : Cert of Irradiation number
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : 8-9-21
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	25 kGy > 24.999 kGy
#10	If completing this test instruction on paper, attach copy of the Irradiation Certificate to this test instruction.	✓	<input checked="" type="checkbox"/> Done? If not applicable, goto #11
#11	If completing this instruction electronically, photograph the first page of Certificate of Irradiation (Ensure photograph legible before attaching)	NA	If not applicable, goto #12
#12	If completing this instruction electronically, photograph the second page of Certificate of Irradiation (Ensure photograph legible before attaching)	NA	If not applicable, goto #13
#13	From Part Number Generator, print current revision of Bottle Assembly Label (# LA101713) Confirm all boxes within shipment are labelled with current issue of Bottle Assembly Label.	✓	<input checked="" type="checkbox"/> Done?
#14	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.	✓	Enter the value here : 2021-08-28
#15	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)	✓	<input checked="" type="checkbox"/> Done? Reference results at #13
#16	End of test.		

Approvals:
Signature & Date stamp

ASSEMBLER/TESTER

Name of tester

J. Adams

PLANER PLC

13 OCT 2021

APPROVER (Test auditor)

PRODUCTION

Name of Approver

SIGNED: *Adams*

END OF TEST RESULTS



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

Certificate of Irradiation

Date Issued: 14-Sep-2021

FR01S12604499-1-1

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:	446/PLANNER PLC - 09/09/2021
Product Description:	496618P - PRODUITS CULTURE CELLULAIRE
Validation Reference:	S12029202
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT G005726 QTE 2400

Irradiation Data

Date and Time of Irradiation:	12-SEP-2021 22:43
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	40.2

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

Détail de la commande: 446

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
<i>CLIENT: PLANER PLC</i>					
OOG00199SR148		480	10	G005726	R210117
OOG00199SR148		480	10	G005726	R210118
OOG00199SR148		480	10	G005726	R210119
OOG00199SR148		480	10	G005726	R210120
OOG00199SR148		480	10	G005726	R210121
		2400	50		



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

Certificate of Irradiation

Date Issued: 08-Sep-2021

FR01S12602508-1-1

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:	444/PLANER PLC - 01/09/2021
Product Description:	496618P - PRODUITS CULTURE CELLULAIRE
Validation Reference:	S12029202
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT G005726 QTE 960

Irradiation Data

Date and Time of Irradiation:	08-SEP-2021 05:50
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	39.0

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

Détail de la commande: 444

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
CLIENT: PLANER PLC					
OOG00199SR148		480	10	G005726	R210114
OOG00199SR148		480	10	G005726	R210115
		960	20		

PLANER

PLANER Ltd, 110 Windmill Road, Sunbury-on-Thames
Middlesex, TW16 7HD, United Kingdom
Tel : +44(0)1932 755000

E-mail : sales@planer.com Web : www.planer.com

DESCRIPTION : STERILIZED BOTTLE ASSEMBLY

REF CN101568-1 **RX ONLY** **CE** 1639 **LOT** G005726

BATCH CODE

STERILE R

STERILIZED USING IRRADIATION DO NOT REUSE



DO NOT USE IF THE PACKAGE IS DAMAGED



MANUFACTURE

DATE OF

MM 2021-08-28



STORE IN A DARK PLACE AT ROOM TEMPERATURE

USE BY

MM 2024-01-28

Do not use if package is damaged.
Nepoužívejte, je-li balení poškozeno.
Mà ikke anvendes, hvis emballagen er beskadiget.
Niet gebruiken indien de verpakking beschadigd is.
Ei saa käyttää, jos pakkaus on vahingoittunut.
Ne pas utiliser si l'emballage est endommagé.
Inhalt bei beschädigter Verpackung nicht verwenden.

Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιώ.

Non utilizzare se la confezione è danneggiata.
Nie stosować, jeżeli opakowanie zostało uszkodzone.
Não utilizar se a embalagem estiver danificada.
No utilizar si el envase está dañado.
Får inte användas om förpackningen är skadad.
Nepoužívat, ak je balenie poškodené.



EC REP Advena Ltd. Tower Business centre, 2nd Flr.,
Tower Street, Swindon, BKR 4013 Malta

GRN: GR2619

Supplier	PA169 Promepia Sa	Receipt date	11/10/2021	Created From	Purchase #PN238	Order
Supplier advice note	CPLANER	Department				

PO line#	Count items ?	Location	Part#	Store	Bin	Serial/Lot#	Expiration	Qty
1	No	Production	CN101568-1	QS	QS/BOTTLE	BC202635	28/01/2024	3,360

PROMEPLA SAM

9, Avenue Albert II
98000 Monaco

TEL : 00 377 97 98 42 32
FAX : 00 377 92 05 61 50
E-mail : sales@promepia.com
Site : www.promepia.com

Monaco le 29/09/21

Packing List N° BL212074

PLANER LTD
110 WINDMILL ROAD
MIDDLESEX
TW16 7HD SUNBURY-ON-THAMES
ANGLETERRE (UK)

Delivery address

PLANER PLC
110 WINDMILL ROAD
UNIT F, DOLPHIN IND ESTATE
TW16 7HD SUNBURY-ON-THAMES
ANGLETERRE (UK)

Your Ref : PNO46271 SEPT

Code : CPLANER

Shipment : MONACO LOGISTIQUE
N° Tracking : 80cmx1m20x1m95

Number of Cases : 70
Handling Unit : 7
Total Weight : 700

Part N°	Y/ Part N°	Description	Batch N° Compl.	Batch N°	Qty	Still to deliver
00G00199SR148	CN101568-1	ASSEMBLED BOTTLE AND CAP - DISPOSABLE HUMIDIFICATION ASSY		G005726	960	
00G00199SR148	CN101568-1	ASSEMBLED BOTTLE AND CAP - DISPOSABLE HUMIDIFICATION ASSY CUSTOMS 9018390000/ EORI NUMBER: FR00 00 0905900010/ FRANCE ORIGIN		G005726	2400	

CERTIFICATE OF COMPLIANCE

Bearing all circumstances beyond our control, we here by certify that all the above-mentioned products bearing a batch number are in conformity with the technical specifications and have not undergone any modifications
whats ever with respect to raw materials, processing or technical characteristics and are in accordance with our NF EN ISO13485 : 2016 Quality System.
EXTRACT OF GENERAL TERMS OF SALES
All our goods travel at the address's own risks.

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PROMEPLA S.A.M.

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Immeuble Le Copori
98000 MONACO
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Mail : contact@promepia.com