



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

Certificate of Irradiation

Date Issued: 22-Nov-2021

FR01S12623995-1-1

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:	456/PLANER PLC - 15/11/2021
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:	G005728

Irradiation Data

Date and Time of Irradiation:	21-NOV-2021 03:29
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	40.1

CN101568-1

Qty: ~~3260~~ Each
960

Supp Ref:

Bin:QS/BOTTLE

GRN:GR3202

Purchase Order
#PN238

LOT:G005728

EXP:28/10/2025

MTMS PO #
PN046271

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: 456

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
CLIENT: PLANER PLC					
OOG00199SR148		480	10	G005728	R210143
OOG00199SR148		480	10	G005728	R210144
		960	20		



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

Certificate of Irradiation

Date Issued: 27-Oct-2021

FR01S12616803-1-1

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:	455/PLANER PLC - 29/09/2021
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:	G005728

Irradiation Data

Date and Time of Irradiation:	25-OCT-2021 14:06
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	38.6

CN101568-1		Qty: 3,300 Each 2,400
Supp Ref:		
Bin: QS/BOTTLE	GRN: GR3202	Purchase Order #PN238
LOT: G005728	EXP: 28/10/2025	MTMS PO # PN046271

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

Page 1 of 1

Détail de la commande: 455

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
<i>CLIENT: PLANER PLC</i>					
OOG00199SR148		480	10	G005728	R210138
OOG00199SR148		480	10	G005728	R210139
OOG00199SR148		480	10	G005728	R210140
OOG00199SR148		480	10	G005728	R210141
OOG00199SR148		480	10	G005728	R210142
		2400	50		

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: <u>DAB.</u> GRN number GR3202
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT <u>6005728</u>
#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 If not applicable, goto #5
#5	Referring to QA procedure PRO-Sdo11 (Inspection Sampling Plan) perform detailed inspection in accordance with batch size.	✓	Done? <input checked="" type="checkbox"/>
#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.	✓	Done? <input checked="" type="checkbox"/> Reference results at #3
#7	Record Certificate Number	✓	Enter the value here : Cert of Irradiation number <u>FR01S12623995-1-1</u>
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : <u>22-11-21</u>
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	<u>25</u> kGy > 24.999 kGy
#10	If completing this test instruction on paper, attach copy of the Irradiation Certificate to this test instruction.	✓	Done? <input checked="" type="checkbox"/> 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)	N/A	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.	✓	Done? <input checked="" type="checkbox"/>
#14	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.	✓	Enter the value here : <u>2021-10-28</u>
#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)	✓	Done? <input checked="" type="checkbox"/> Reference results at #13 <u>Dr 20051.4yrs.</u>
#16	End of test.		

Approvals:

Signature & Date stamp

PLANER PLC

ASSEMBLER/TESTER

09 DEC 2021

APPROVER (Test auditor)

Name of tester

J Adams

Name of Approver

SIGNED: J Adams

END OF TEST RESULTS

Planer Limited Quality Assurance Defect Report

No:DR20051-U Status:(Open) Subject: Inspection instruction XT 104117 needs to be amended on step 15 to say the use by date is 4 yrs which has been extended from the original 2yrs 5 months.

<p>Person Responsible : Richard Clarke/Planer</p> <p>Fault Discovery (Where?) <input type="radio"/> Pre Despatch <input type="radio"/> Post Despatch <input checked="" type="radio"/> Observation <input type="radio"/> Product Under Development</p>	<p align="center">Complete By: 18-Dec-21</p> <p align="center">Does a Job/PO No. Apply?: <input checked="" type="radio"/> No <input type="radio"/> Yes</p>
<p>Select Which Fault Category: Design Improvements Design Name: BT37 (only for parts sold by Planer)</p> <p>Brief Fault Summary : Inspection instruction XT104117 needs to be amended on step 15 to say the use by date is 4 yrs which has been extended from the original 2yrs 5 months.</p> <p>Detail of Problem: Inspection instruction XT104117 needs to be amended on step 15 to say the use by date is 4 yrs which has been extended from the original 2yrs 5 months.</p>	<p align="center">Does a Serial No. Apply?: <input checked="" type="radio"/> No <input type="radio"/> Yes</p>
<p>Action Required : Amend step 15 of XT104117 as requiredThe responsibility was passed to Richard Clarke/Planer by Dave Barber</p> <p>Final Resolution : (must include comments on preventative action , i.e. how this problem is prevented from recurring)</p>	<p align="center">Is the Part in Quarantine ?: <input checked="" type="radio"/> No <input type="radio"/> Yes</p>
<p>Call Logs associated with this DR:</p>	
<p>Link to PMS ticket :</p>	

Original Part Number

Part No:	Description:				Qty/Failed:
XT104117	Goods inwards inspection_bottle assy				1

Attachments

Engineering Management

Kanban status Accepted 1: High 2: Medium 3: Low

Trac link

Software Problem Report

Software Issue

CAPA

Escalate to CAPA
 Not under CAPA

1	2	3	4
DRAWING No. LA101713		REPORT No. ER No. ER10670 DATE 2021-04-01 ISSUE No. 6	
THIRD ANGLE PROJECTION		EU REP & DATE OF MANUFACTURE ADDED	
		SHELF LIFE INCREASED FROM 29 MONTHS TO 4 YEARS ER10772 2021-09-23 7	

ETIQUETTE CARTON 2
BOX LABEL 2

Coller l'indicateur dans le cercle
Stick the indicator in the diameter

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	E010203
CATALOGUE NUMBER				BATCH CODE	
STERILE R					2021-09-28
STERILIZED USING IRRADIATION	DO NOT REUSE	DO NOT USE IF THE PACKAGE IS DAMAGED	x48	DATE OF MANUFACTURE	
		STORE IN A DARK PLACE AT ROOM TEMPERATURE			
Do not use if package is damaged.		Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά.			
Nepoužívajte, je-li balení poškozeno.		Nón utlízzare az la confezione é danneggiata.			
Må ikke anvendes, hvis emballagen er beskadiget.		Nie stosować, jeżeli opakowanie zostało uszkodzone.			
Niet gebruiken indien de verpakking beschadigd is.		Não utilizar se a embalagem estiver danificada.			
Ei saa käyttää, jos pakkaus on vahingoittunut.		No utilizar si el envase está dañado.			
Ne pas utiliser si l'emballage est endommagé.		Får inte användas om förpackningen är skadad.			
Infatti bei beschädigter Verpackung nicht verwenden.		Nepoužívať, ak je balenie poškodené.			

Date de péremption
4 ans
Expiry date
4 years

NOTE:

LABEL MATERIAL TO BE APPROVED BY PLANER BEFORE USE

DIMENSIONS: mm TOLERANCES DIMS TO 2 DP +/- 0.10mm DIMS TO 1 DP +/- 0.20mm DIMS TO 0 DP +/- 0.40mm HOLE DIA +0.15 -0.05mm ANGLE +/-0.5 DEG UNLESS OTHERWISE STATED	SCALE NTS MATERIAL SEE NOTE SPECIFICATION FINISH CLEAN	IMPORTANT NOTICE 1. COPYRIGHT THIS DRAWING IS THE PROPERTY OF PLANER Ltd WHO OWN THE COPYRIGHT. THIS DRAWING IS SUPPLIED IN CONFIDENCE AND MAY NOT BE DISCLOSED FOR ANY REASON WHATSOEVER TO A THIRD PARTY WITHOUT THE WRITTEN CONSENT OF THE DIRECTORS OF THE COMPANY. 2. INTERCHANGEABILITY THIS DRAWING MAY ONLY BE ALTERED IF THE PART REMAINS INTERCHANGEABLE. IF NOT, A NEW DRAWING No. MUST BE USED. 3. DRAWING ALTERATIONS THIS DRAWING MAY ONLY BE ALTERED ON CAD.	INSTRUCTIONS <ol style="list-style-type: none"> 1. WORK TO DIMENSIONS 2. DO NOT SCALE 3. REMOVE ALL SHARP EDGES AND CORNERS UNLESS OTHERWISE STATED 4. REPORT ANY OMISSION OR ERROR TO THE DESIGN DEPT 5. IF IN DOUBT ASK 6. MUST COMPLY WITH RoHS DIRECTIVE 2002/95/EC
DRAWN DATE SW 28.02.11	TITLE BOTTLE ASSY LABEL BOX No. 2	PARTS LIST No.	
DRAWING SIZE A4 SOLIDWORKS	©2021	PLANER Limited SUNBURY-ON-THAMES MIDDLESEX TW16 7HD UK TEL: 01932 755000	DRAWING No. LA101713

PLANER

PLANER Ltd, 110 Windmill Road, Sunbury-on-Thames
Middlesex, TW16 7HD, United Kingdom
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Web : www.planer.com



DESCRIPTION : STERILIZED BOTTLE ASSEMBLY

REF CN101568-1

Rx ONLY

CE 1639

LOT G005728

CATALOGUE NUMBER



STERILIZED USING IRRADIATION DO NOT REUSE



DO NOT USE IF
THE PACKAGE
IS DAMAGED

STERILE R



2021-10-28

DATE OF
MANUFACTURE



STORE IN A DARK PLACE AT ROOM TEMPERATURE

Do not use if package is damaged.

Nepoužívejte, je-li balení poškozeno.

Må 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.

Infällt bei beschädigter Verpackung nicht verwenden.



2025-10-28

USE BY

Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιό.

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, Swatar, BKR 4013 Malta

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@promepla.com

Site : www.promepla.com

Monaco le 30/11/21

Packing List N° BL212459

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 : PN046271 NOV Code : CPLANER

Shipement : MONACO LOGISTIQUE
N° Tracking : 80CMX1M20X1M94
Number of Cases : 70
Handling Unit : 7
Total Weight : 680

Part N°

OOG00199SR148

Y/ Part N°

CN101568-1

Description

ASSEMBLED BOTTLE AND CAP - DISPOSABLE HUMIDIFICATION ASSY
CUSTOMS 9018390000/ EORI NUMBER: FR00 00 0905900010/ FRANCE ORIGIN
FREIGHT

Batch N° Compl.

G005728

Batch N°

3360

Qty

Still to deliver

_FRAISPORT

1

PROMEPLA S.A.M.

9, Avenue Albert II
Immeuble Le Copori
98000 MONACO

Phone number : (+377) 97 98 42 32

Mail : contact@promepla.com

CERTIFICATE OF COMPLIANCE

Barring 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 what's 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.

S.A. Monégasque au capital de 588.420 € - N.I.E : FR29000009059 - S.S.I.E. 4669 B0 1526 - R.C.I 69 S 1239 -