



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

Certificate of Irradiation

Date Issued: 18-Aug-2020

FR01S12471088-1-1

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:	375/PLANER - 14/08/2020
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:	G004637

Irradiation Data

Date and Time of Irradiation:	18-AUG-2020 02:07
Calculated Minimum Dose kGy:	29.8
Calculated Maximum Dose kGy:	42.9

GR070958 / 1
Qty : 960
Rohs : ?

PN044745/1
CN200115
OOG00799SR148
QS / 1

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	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. 		GR0700158
#2	Record GRN number (goods received number) for shipment under inspection.	✓	Enter the value here : GRN number GR4637
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT G004637
#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 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 FR015124 710 88-1-1	✓	Enter the value here : Cert of Irradiation number
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : 18-08-20
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	29.8 kGy > 25 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)	N/A	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 : 28-07-20
#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
#16	End of test.		

Approvals:

Signature & Date stamp

ASSEMBLER/TESTER

Name of tester

PLANER PLC

26 APR 2021

PRODUCTION

SIGNED:

APPROVER (Test auditor)

Name of Approver

END OF TEST RESULTS

PLANER

PLANER Ltd, 110 Windmill Road, Sunbury-on-Thames
Middlesex, TW16 7HD, United Kingdom
Tel : +44(0)1932 755000 Fax : +44(0)1932 755001
E-mail : sales@planer.co.uk Web : www.planer.com



DESCRIPTION : STERILIZED BOTTLE ASSEMBLY - SINGLE TUBE VERSION

REF CN200115
CATALOGUE NUMBER

RX ONLY


LOT G004637
BATCH CODE

STERILE



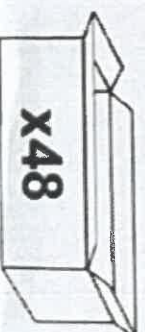
STERILIZED USING IRRADIATION

DO NOT REUSE

 2022-12-28
USE BY



STORE IN A DARK PLACE AT ROOM TEMPERATURE



Do not use if package is damaged.
Nepoužívejte, je-li balení poškozeno.

Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά

.Non utilizzate se la confezione è danneggiata.

Må ikke anvendes, hvis emballagen er beskadiget.

Niet gebruiken indien de verpakking beschadigd is.

Nie stosować, jeżeli opakowanie zostało uszkodzone.

Ei saa käyttää, jos pakkaus on vahingoittunut.

Ne pas utiliser si l'emballage est endommagé.



Não utilizar se a embalagem estiver danificada.

Får inte användas om förpackningen är skadad.

Inhalt bei beschädigter Verpackung nicht verwenden.

Nepoužívat, ak je balenie poškodené.