

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 GR070748
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT G004640
#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	✓	Enter the value here : Cert of Irradiation number FR01S12457829-1-1
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : 13-Jul-2020
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	28.4 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)	✓	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"/> LA200116 D-19603
#14	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.	✓	Enter the value here : 2020-6-28
#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)	✓	Done ? <input checked="" type="checkbox"/> 2022-11-28 Reference results at #13
#16	End of test.	✓	

Approvals:

Signature & Date stamp

PLANER PLC

ASSEMBLER/TESTER

24 JUL 2020

APPROVER (Test auditor)

Name of tester

D. BARBER

Name of Approver

SIGNED:

END OF TEST RESULTS

DRAWING No.
LA200116

REPORT No.	ER No.	DATE	ISSUE No.
INITIAL	ER1005	18-09-19	1
LABEL UPDATED	ER1005	05-02-20	2

**ETIQUETTE PRODUIT
PRODUCT LABEL**

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

PLANER

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DESCRIPTION : STERILIZED BOTTLE ASSEMBLY- SINGLE TUBE VERSION

REF CN200115 CATALOGUE NUMBER	Rx ONLY 	LOT E010203 BATCH CODE
STERILE R STERILIZED USING IRRADIATION	DO NOT REUSE	2022-06-28 USE BY

STORE IN A DARK PLACE AT ROOM TEMPERATURE

Do not use if package is damaged. Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά.
Nepoužívejte, je-li balení poškozeno. Non utilizzare se la confezione è 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.
Inhalt bei beschädigter Verpackung nicht verwenden. Nepoužívat, ak je balenie poškodené.

Date de péremption
29 mois
Expiry date
29 months

NOTE:
LABEL MATERIAL TO BE APPROVED BY PLANER BEFORE USE

DIMENSIONS: mm	SCALE 1:1	IMPORTANT NOTICE	INSTRUCTIONS
TOLERANCES UNLESS OTHERWISE STATED ISO 2768-fH	MATERIAL SEE NOTE	1. COPYRIGHT THIS DRAWING IS THE PROPERTY OF PLANER LIMITED 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.	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. FINISHED PART MUST COMPLY WITH RoHS DIRECTIVE AND ANY AMMENDMENTS APPLICABLE AT THE TIME OF MANUFACTURE. 7. ALL DIMENSIONS NOT SHOWN ON DRAWING TO BE OBTAINED FROM 3D MODEL OR DXF FILE STATED IN MAIN VIEW
DIMENSIONS APPLY AFTER PLATING OR COATING	SPECIFICATION		
SURFACE FINISH UNLESS OTHERWISE STATED 1.6	FINISH CLEAN	DRAWING SIZE A4 SOLIDWORKS	©2020
BREAK ALL EDGES UNLESS OTHERWISE STATED -0.2 -0.1 +0.2 0	THIRD ANGLE PROJECTION 	TITLE BOTTLE ASSY LABEL MK2	APPROVED BY:
DRAWN SW	DATE 18-09-19	PLANER PRESERVE / PROTECT / NURTURE SUNBURY-ON-THAMES MIDDLESEX TW16 7HD UK TEL: 01932 755000 FAX: 01932 755001	DRAWING No. SHEET 1 OF 1 LA200116