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	Part Number:	PI-0097479
	Revision	1
Document Title:	LABEL, CARRIER, CAPSULE PACKAGING-USA	
Project number and name	515 Finch	

Approvals and Revisions

Author

Printed Name	Role	Signature	Date
Raphael Chia	Electronics Engineer	 Electronically signed by: Raphael Chia Reason: Author Date: Mar 4, 2024 14:20 GMT+11	Mar 4, 2024

Quality Review

Printed Name	Role	Signature	Date
NA	NA	NA	NA

Approval

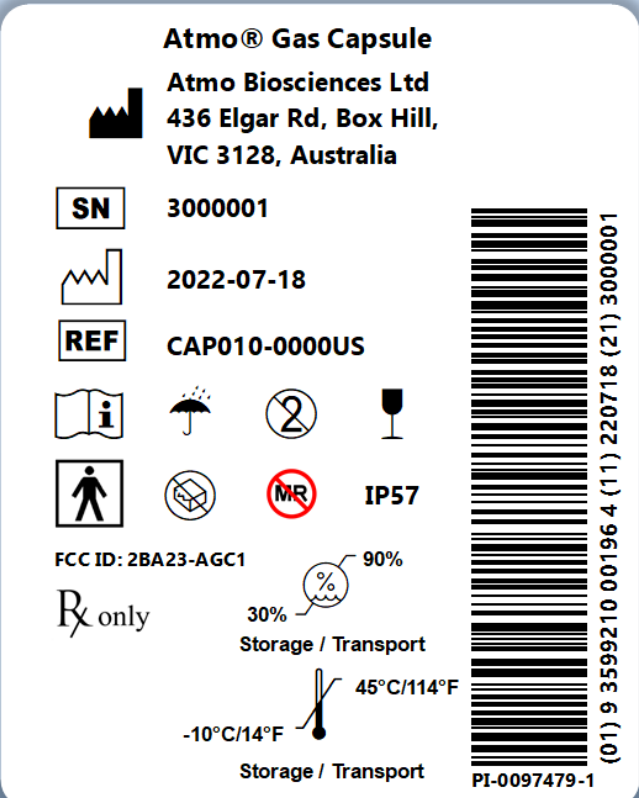
Printed Name	Role	Signature	Date
Matt Reeves	Manufacturing Manager	 Electronically signed by: Matt Aaron Reeves Reason: Approver Date: Mar 4, 2024 15:53 GMT+11	Mar 4, 2024

Revision History

Revision	Date	Description
0	Sep 22, 2023	Interim Release for 60601
1	Mar 4, 2024	Interim Release for FCC Registration

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1.0 Artwork



Atmo® Gas Capsule
Atmo Biosciences Ltd
436 Elgar Rd, Box Hill,
VIC 3128, Australia

SN 3000001
REF CAP010-0000US
2022-07-18

FCC ID: 2BA23-AGC1
Rx only

30%
Storage / Transport
-10°C/14°F

90%
Storage / Transport
45°C/114°F

IP57

PI-0097479-1

Stock: Thermifilm SELECT 21920 (White)
Dimensions: 70mm x 88mm
Corners: 3mm radius

2.0 Device Identification details

Identification type	Identification Description
BOM label description	LABEL, CARRIER, CAPSULE PACKAGING-USA
Label part number	PI-0097479-1
Product Code /SKU	CAP010-0000US
Commercial GTIN / UDI	93599210 00196
GS1 Product Description	Atmo Gas Capsule (USA) 1 each
Application Identifiers (AI)	(11) Manufacture Date, (21) Serial Number

3.0 Identification and traceability summary

A multi-region labelled capsule is packaged into a region-specific box where the serial number and batch details are replicated on the single box label. The label displays the product code for re-ordering. The serial number will trace back to a build record for traceability. This label has a different Device Identifier to the thermoform label as it is region specific once packaged with the patient take home guide.

Signature: *Raphael Chia* Electronically signed by: Raphael Chia
Reason: Author
Date: Mar 4, 2024 14:20 GMT+11

Email: raphael.chia@atmobiosciences.com

Title: Electronics Engineer

Company: Atmo Biosciences Ltd

Signature: *Matt Aaron Reeves* Electronically signed by: Matt Aaron
Reeves
Reason: Approver
Date: Mar 4, 2024 15:53 GMT+11

Email: matt.reeves@atmobiosciences.com

Title: Manufacturing Manager

Company: Atmo Biosciences Ltd

PI-0097479-1 capsule single package USA

Final Audit Report

2024-03-04

Created:	2024-03-04
By:	Raphael Chia (raphael.chia@atmobiosciences.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAno3clJLwx3nVjdWRV_ZlqxmzleVAeAfB

"PI-0097479-1 capsule single package USA" History

 Document created by Raphael Chia (raphael.chia@atmobiosciences.com)

2024-03-04 - 3:18:38 AM GMT

 Document e-signed by Raphael Chia (raphael.chia@atmobiosciences.com)

Signing Reasons

Author (echosign_signatureblock_0)

Author (Sig)

Signature Date: 2024-03-04 - 3:20:15 AM GMT - Time Source: server

 Raphael Chia (raphael.chia@atmobiosciences.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-03-04 - 3:20:15 AM GMT

 Document emailed to Matt Aaron Reeves (matt.reeves@atmobiosciences.com) for signature

2024-03-04 - 3:20:16 AM GMT

 Document e-signed by Matt Aaron Reeves (matt.reeves@atmobiosciences.com)

Signing Reasons

Approver (efield3_Sig)

Approver (echosign_signatureblock_1)

Signature Date: 2024-03-04 - 4:53:29 AM GMT - Time Source: server

 Agreement completed.

2024-03-04 - 4:53:29 AM GMT

 Matt Aaron Reeves (matt.reeves@atmobiosciences.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-03-04 - 4:53:29 AM GMT



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