



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Monaghan Medical Corporation
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	K181649
Medical Device Class, if applicable:	Class II without exemptions
DUNS:	056332380
Proprietary Name (If Applicable) and Established Name:	AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber - Mouthpiece
Selling Unit NDC:	Unit of Use NDC:
UDI	UPC: 604351500129
	CVX Code:
	MVX Code:
Description:	AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber with Mouthpiece for use with either Metered Dose Inhalers or Soft Mist Inhalers
Active Ingredient(s):	
URL for Additional Product Information:	<a href="https://www.monaghanmed.com/product/aerochamber-plus-flow-vu-avhc/">https://www.monaghanmed.com/product/aerochamber-plus-flow-vu-avhc/</a>
Address:	153 Industrial Boulevard
City:	Plattsburgh
Key Contact:	Lisa Badura
Phone Number:	(262) 433-8319
Product Therapeutic Classification:	NVP

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Avoid Excessive Heat – above 40 C (>104° F)
Other Temperature Range Requirement (write in)	Storage and operating range 41°F–104°F (5°C–40°C) at 15 to 95% relative humidity
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	
Name:	
Number:	
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	<input checked="" type="checkbox"/> Yes	Is the Product... Direct And Drop-Ship	
if yes, enter class #	Class II	Is the Product... Neither	
a product kit?	<input type="checkbox"/> No	Orphan Drug Status	
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	<input type="checkbox"/> No	Allergens Present	None
co-licensed?	<input type="checkbox"/> No	Country of Origin	USA
latex-free?	<input checked="" type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input checked="" type="checkbox"/> Yes
preservative-free?	<input checked="" type="checkbox"/> Yes		
correctional institution block?	<input type="checkbox"/> No		
opioid?	<input type="checkbox"/> No		
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:			
		Size:	1
		Strength:	
		Dosage Form:	
		Product Shape:	Cylinder
		Product Color:	Orange
		Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Box of 1 Valved Holding Chamber
<input type="checkbox"/> X Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/> Tube	<input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> 1 Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 12 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/>
II. Generic Equivalent to What Brand?:	<input type="text"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/> 1 Each	<input type="text"/> 1 Each
(Write-in, e.g. 1 Vial)	<input type="text"/> Gram
	<input type="text"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/>
Is product exempt from DSCSA?	<input type="checkbox"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/>
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/>
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/>
If yes, attach documentation from FDA.	
GLN:	<input type="text"/>
GCP:	<input type="text"/>
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces		
		Depth	Width	Height		
Item/Each:	0.164	7	2.5	2.5	43.75	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	2.33	10.125	7.625	7.125	550.07227	12
Pallet:	357.26	48	40	47.75	91680	1728

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00604351502123	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input type="checkbox"/> Case				
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$43.54	Whsl. Code #:	
As of date:		Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:

Lisa Badura



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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)  No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)  No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:  No

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  No (if yes, identify method below)

- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No      Controlled Substance Code
- Controlled by State(s)?  No      Listed Chemical (List I or II)  No
- ARCOS Reportable?  No      If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:  No

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  No

Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
If Yes, is it managed with a pharmacy registry?   
Website URL:

Med Guide Required  No  
Limited Distribution Requirement  No  
Comments / Details: (For example, iPledge program?)

**REMS:**  No  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  
Wholesale distributor support:  No  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  No  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: (518) 561-7330

Is product returnable for credit:  Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No

If so, which states? Other requirements? Comments?



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing															
Purchase orders may be accepted by: <table border="1"> <tr><td>a. EDI</td><td><input type="checkbox"/></td><td>Yes</td></tr> <tr><td>b. Autofax</td><td><input type="checkbox"/></td><td>Yes</td></tr> <tr><td>c. Fax</td><td><input type="checkbox"/></td><td>Yes</td></tr> <tr><td>d. Phone only</td><td><input type="checkbox"/></td><td>No</td></tr> <tr><td>e. Supplier Web Site only</td><td><input type="checkbox"/></td><td>No</td></tr> </table> Fax Number: (518) 561-5660 Fax Number: (518) 561-5660 Phone No.: Site Address: Minimum Order Quantity: 12 Units Supplier's Customer Service Number: (518) 561-5660 Contracted 3PL company / contact #: Name: Phone:	a. EDI	<input type="checkbox"/>	Yes	b. Autofax	<input type="checkbox"/>	Yes	c. Fax	<input type="checkbox"/>	Yes	d. Phone only	<input type="checkbox"/>	No	e. Supplier Web Site only	<input type="checkbox"/>	No	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: 12:00 PM (Noon) Eastern Shipping lead time of PO: Hours Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
a. EDI	<input type="checkbox"/>	Yes														
b. Autofax	<input type="checkbox"/>	Yes														
c. Fax	<input type="checkbox"/>	Yes														
d. Phone only	<input type="checkbox"/>	No														
e. Supplier Web Site only	<input type="checkbox"/>	No														
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing															
Expedited freight fees billed with each order: <input type="checkbox"/> Yes Drop Ship service fee billed with each order: <input type="checkbox"/> Yes Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes Comments: Customer to pay for any expedited shipping fees; billed with each order	<b>Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt cut off time: 10:00 AM Eastern Days of week overnight is available: <table border="1"> <tr><td><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt Cut off time: 10:00 AM EST <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> No PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Yes/No Overnight Fees apply: Yes/No Other fees apply: Yes/No	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday					
<input checked="" type="checkbox"/>	Monday															
<input checked="" type="checkbox"/>	Tuesday															
<input checked="" type="checkbox"/>	Wednesday															
<input checked="" type="checkbox"/>	Thursday															
<input checked="" type="checkbox"/>	Friday															
Class of Trade Restriction:																
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes Restricted to retail pharmacy only: <input type="checkbox"/> No Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments:																
Other Data Information Required to Process PO:	Return Instructions															
Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Contact # if product is received damaged: (518) 561-7330 Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No If so, which states? Other requirements? Comments?															
Miscellaneous Notes:																
	ADDITIONAL INFORMATION															
	Is product order for scheduled patient procedure? <input type="checkbox"/> No Is product order for restocking purposes? <input type="checkbox"/> Yes															