

**NITROGEN- nitrogen gas**  
**Aspen Air U.S., LLC**

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**Nitrogen**

**NITROGEN CERTIFICATE OF ANALYSIS**

Customer

\_\_\_\_\_ Aspen Air  
\_\_\_\_\_ 1524 Lockwood Road  
\_\_\_\_\_ Billings, MT

This document is the Certificate of Analysis of nitrogen NF Lot # \_\_\_\_\_ supplied  
\_\_\_\_ To you is a trailer delivery from our Billings Montana location.

\_\_\_\_ Picked up by the customer listed above in their trailer

Following the Aspen Air Medical Gas procedures our location ensures that the nitrogen NF product is manufactured in compliance with the FDA's Current Good Manufacturing Practice regulations and the FDA's Medical Gas Guidelines. This document is intended to serve as a Certificate of Analysis for the nitrogen NF when the results of the product testing are entered below and the product has been delivered to a registered nitrogen NF customer. This document is in compliance with current FDA guidance.

Test	Specification	Results
Assay	$\geq 99.998\%$	_____
Identification	Nitrogen	_____
Odor	None	_____
Oxygen	$\leq 10$ ppm (0.001%)	_____
Carbon Monoxide	$\leq 10$ ppm (0.001%)	_____

\*Trace oxygen analyzer      AIT-21      Model#      Teledyne 3000TAEU

\*Carbon monoxide analyzer      AIT-22      Model#      Teledyne GFC 7001E

\*This analyzer has been validated as an acceptable alternative to the official NF method. The validation study is available for review upon request. Odor Testing was performed using the olfactory method.

Supplier signature: \_\_\_\_\_ Date: \_\_\_\_\_

**For all nitrogen NF installations, the driver shall ensure and document the following:**

Hose caps (plugs) in place prior to delivery      Yes \_\_\_\_ No

\_\_\_\_  
Gaskets are suitable for use or new      Yes \_\_\_\_ No  
\_\_\_\_

Hose purged prior to filling the vessel

Yes \_\_\_ No

Hose recapped (plugged) for storage

Yes \_\_\_ No

Driver signature: \_\_\_\_\_

Date: \_\_\_\_\_

If this nitrogen NF is **not** delivered to a properly registered user the product is "**Not** approved for human drug use".

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## NITROGEN

nitrogen gas

Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42914-010
Route of Administration		RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)			NITROGEN	99 L in 100 L
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42914-010-01	11000000 L in 1 TANK; Type 0: Not a Combination Product	12/15/2007	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA205863	12/15/2007	

**Labeler** - Aspen Air U.S., LLC (790650449)

**Registrant** - Aspen Air U.S., LLC (790650449)

## Establishment

Name	Address	ID/FEI	Business Operations
Aspen Air U.S., LLC		790650449	manufacture(42914-010)

Revised: 10/2023

Aspen Air U.S., LLC