NITROGEN- nitrog Aspen Air U.S., Li	_						
Nitrogen							
NITROGEN CERTI	FICATE (OF ANALYSIS	5				
Customer							
			,	Aspen	Air		
			1	L524 L	ockwood Roa	d	
			E	Billings	, MT		
This document is th	e Certific	ate of Analysi	s of nitroge	en NF	Lot #	S	upplied
To you is a traile	er delivery	/ from our Bill	ings Monta	na loc	ation.		
Picked up by the	e custom	er listed abov	e in their tr	ailer			
Following the Asper NF product is manu Practice regulations serve as a Certificat testing are entered NF customer. This of	Ifactured and the te of Anal below an	in compliance FDA's Medica ysis for the ni d the product	e with the F I Gas Guide itrogen NF : has been	DA's (elines. when deliver	Current Good This documen the results of red to a registo	Manufact is inter the proceed of the proceed of the proced of the procedor of the proced	cturing nded to duct
Test	Specif	fication		Result	:S		
Assay	≥ 99.9	998%					
Identification	Nitrog	gen					
Odor	None						
Oxygen	إ 10 ≥	opm (0.001%))				
Carbon Monoxide	≤ 10 p	pm (0.001%)					
*Trace oxygen anal	yzer	AIT-21	Model#		Teledyne 300	DOTAEU	
*Carbon monoxide	analyzer	AIT-22	Model#		Teledyne GF0	C 7001E	
*This analyzer has the validation study using the olfactory	ı is availal		•				
Supplier signature:				Date:	·		
For all nitrogen N following:	F install	ations, the d	driver sha	ll ens	ure and doc	ument 1	the
Hose caps (plugs) ii	n place pi	rior to delivery	/			Yes _	No
Gaskets are suitable	e for use	or new				Yes	No

Hose purged prior to filling th	Yes No				
— Hose recapped (plugged) for	storage			Yes No	
— Driver signature:		Date:			
If this nitrogen NF is not deliv approved for human drug us	-	roperly regist	tered user the pr	oduct is " Not	
This document is the Certificate of A	nalysis of nitro	gen NF Lot #		supplied	
☐ To you in a trailer delivery from	our Billings Me	ontana location.			
☐ Picked up by the customer listed	above in their	trailer			
Following the Aspen Air Medical Gas manufactured in compliance with the Medical Gas Guidelines. This docum when the results of the product testin nitrogen NF customer. This document	FDA's Curren nent is intended ng are entered nt is in complia	it Good Manufact d to serve as a C below and the pr nce with current	turing Practice regulat ertificate of Analysis for roduct has been delive FDA guidance.	ions and the FDA's or the nitrogen NF ered to a registered	
Test	Charles and the sales	cification	R	Results	
Assay Identification		0.998%			
Odor		rogen			
Oxygen	None ≤ 10 ppm (0.001%)				
Carbon Monoxide	≤ 10 ppm (0.001%)				
* Trace oxygen analyzer	AIT-21	Model #	Teledyne 30	OOTAFU	
*Carbon monoxide analyzer	AIT-22	Model #	Teledyne Gf		
* This analyzer has been validated a study is available for review upon reconstructions. Supplier signature For all nitrogen NF installa	quest. Odor T	esting was perfo	Date:	ory method.	
Hose caps (plugs) in place prior to	o delivery		YES	No No	
Gaskets are suitable for use or ne			YES	No	
Hose purged prior to filling the ver Hose recapped (plugged) for store			YES YES	No No	
nose recapped (plugged) for stor	age		TES	NO	
Driver signature			Date:		
If this nitrogen NF is <u>not</u> delivered to a	properly register	red user the produc	t is "Net approved for h	uman drug use",	
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		

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