

**NITROGEN - nitrogen gas**  
**Messer LLC**

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**Nitrogen NF Bulk Liquid**

**WARNINGS SECTION**

**Should the material not be delivered to a NF customer, the material is “Not Approved for Human Drug Use.”**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Certificate of Analysis - Nitrogen NF

Product: Nitrogen NF

<b>Date</b>	
<b>Facility Name</b>	
<b>Facility Address</b>	
<b>Lot#</b>	<b>Batch #</b>

**Final Analysis Results**

<b>Analyzer #</b>	<b>Test/Units</b>	<b>NF Specs</b>	<b>Analysis Results</b>
<b>N/A</b>	<b>Odor</b>	<b>None</b>	
	<b>ppm O2</b>	<b>≤ 10,000 (Messer Spec ≤5.0)</b>	<b>ppm</b>
	<b>ppm CO</b>	<b>≤ 10.0</b>	<b>ppm</b>
	<b>ppm THC</b>	<b>N/A</b>	<b>ppm</b>
	<b>ppm H2O</b>	<b>N/A</b>	<b>ppm</b>
	<b>ppm CO2</b>	<b>N/A</b>	<b>ppm</b>
	<b>ppm H2</b>	<b>N/A</b>	<b>ppm</b>
<b>Assay Results</b>	<b>Nitrogen min %</b>	<b>≥ 99.0% (Messer Spec ≥99.999%)</b>	<b>%</b>

NT= not tested

<b>PPM O2 Method Used:</b>	<b>Manufacturer/Model #:</b>
	<b>Manufacturer/Model</b>

<b>PPM O2 Method Used:</b>	<b>#:</b>

**This analyzer has been validated by Messer as acceptable alternatives to the official NF for Nitrogen Assay. Validation study documentation is maintained by Messer at the corporate offices.**

<b>Analyst</b>	<b>Date</b>	

<b>Quality Reviewer</b>	<b>Date</b>	

**Should the material not be delivered to a NF customer, the material is “Not Approved for Human Drug Use.”**

## Certificate of Analysis – Nitrogen NF

Product:

Nitrogen NF

Date			
Facility Name			
Facility Address			
Lot #		Batch #	

### Final Analysis Results

Analyzer #	Test / Units	NF Specs	Analysis Results
N/A	Odor	None	
	ppm O2	$\leq 10,000$ (Messer Spec $\leq 5.0$ )	ppm
	ppm CO	$\leq 10.0$	ppm
	ppm THC	N/A	ppm
	ppm H2O	N/A	ppm
	ppm CO2	N/A	ppm
	ppm H2	N/A	ppm
Assay Results	Nitrogen min %	$\geq 99.0\%$ (Messer Spec $\geq 99.999\%$ )	%

NT = not tested

ppm O2 Method  
Used:

Manufacturer/  
Model # :

ppm CO Method  
Used:

Manufacturer/  
Model # :

These analyzers have been validated by Messer as acceptable alternatives to the official NF for Nitrogen Assay. Validation study documentation is maintained by Messer at the corporate offices.

Analyst	Date

Quality Reviewer	Date

Should the material not be delivered to a NF customer, the material is "Not Approved for Human Drug Use."

## NITROGEN

nitrogen gas

### Product Information

Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52438-016
Route of Administration		RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Nitrogen (UNII: N762921K75) (Nitrogen - UNII:N762921K75)			Nitrogen	995 mL in 1 L
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52438-016-20	25000 L in 1 TANK; Type 0: Not a Combination Product	01/01/1960	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA205766	01/01/1960	

**Labeler** - Messer LLC (001368141)

**Registrant** - Messer LLC (001368141)

**Establishment**

Name	Address	ID/FEI	Business Operations
Messer LLC		943812438	manufacture(52438-016) , api manufacture(52438-016)

**Establishment**

Name	Address	ID/FEI	Business Operations
Messer LLC		026946218	manufacture(52438-016) , api manufacture(52438-016)

**Establishment**

Name	Address	ID/FEI	Business Operations
Messer LLC		041268947	manufacture(52438-016) , api manufacture(52438-016)

**Establishment**

Name	Address	ID/FEI	Business Operations
Messer LLC		101889988	manufacture(52438-016) , api manufacture(52438-016)

**Establishment**

Name	Address	ID/FEI	Business Operations
Messer LLC		003000197	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		081695020	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		872699181	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		002123321	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		092191712	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		839692303	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		791242337	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		192602431	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		945417111	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		042263707	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		147344667	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Messer LLC		102835006	manufacture(52438-016) , api manufacture(52438-016)

Establishment			
Name	Address	ID/FEI	Business Operations

Messer LLC		940070527	manufacture(52438-016) , api manufacture(52438-016)
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Name	Address	ID/FEI	Business Operations
Messer LLC		969312248	manufacture(52438-016) , api manufacture(52438-016)

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Name	Address	ID/FEI	Business Operations
Messer LLC		004212362	manufacture(52438-016) , api manufacture(52438-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		019983468	manufacture(52438-016) , api manufacture(52438-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		799311001	manufacture(52438-016) , api manufacture(52438-016)

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Name	Address	ID/FEI	Business Operations
Messer LLC		079481211	manufacture(52438-016) , api manufacture(52438-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		809794592	manufacture(52438-016) , api manufacture(52438-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		108034669	api manufacture(52438-016) , manufacture(52438-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		093220150	manufacture(52438-016) , api manufacture(52438-016)

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Messer LLC