

November 5, 2014



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 15852
(FIRST REVISION)

EXPIRATION DATE: September 30, 2018

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Nuance Medical, LLC
Carlsbad, CA
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of small units of certain compressed gas, intended for medical use as limited quantities and/or ORM-D. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 173.304a(a)(1) and 173.306(a) in that non-DOT specification containers are not authorized, except as specified herein.
5. BASIS: This special permit is based on the application of Nuance Medical, LLC dated September 19, 2014 submitted in accordance with § 107.109.

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6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Aerosols, non-flammable, (each not exceeding 1 L capacity)	2.2	UN1950	N/A
Liquefied gas, n.o.s.	2.2	UN3163	N/A
Refrigerant gas R 404A	2.2	UN3337	N/A
Consumer Commodity	ORM-D	N/A	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packagings prescribed are non-DOT specification, non-refillable containers designed, manufactured, and marked in accordance with DOT-SP 12187. The maximum water capacity is 18 fluid ounces (32.5 cubic inches).

b. OPERATIONAL CONTROLS -

- (1) The product is intended for medical use.
- (2) Filling density may not exceed 85 percent. In addition, the liquid content of the lading may not completely fill the container at 130°F.
- (3) The pressure of the lading at 70°F may not exceed 264 psig; and at 130°F, may not exceed 357 psig.
- (4) Containers must be shipped in strong outside packagings in accordance with § 173.301(a) (9).
- (5) Each outside package may not contain more than 24 containers.

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c. MARKING -

(1) In addition to the "DOT-SP 12187" marking, each container must be marked "DOT-SP 15852" as specified in § 172.301(c).

(2) Outside packagings are not required to be marked "INSIDE CONTAINERS COMPLY WITH DOT-SP 15852".

8. SPECIAL PROVISIONS:

a. Packagings that are a "consumer commodity" as defined in § 171.8 may be renamed "consumer commodity" and reclassified as ORM-D material in accordance with § 173.306(i).

b. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package and it is reoffered for transportation in conformance with this special permit and the HMR.

c. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, cargo aircraft only, and passenger-carrying aircraft.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each aircraft used to transport packages covered by this special permit. The shipper must furnish a current copy of this special permit to the air carrier before or at the time the shipment is tendered.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

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- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 Immediate notice of certain hazardous materials incidents, and 171.16 Detailed hazardous materials incident reports.

In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

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Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: BMoore/SG