

November 3, 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 15973

**EXPIRATION DATE: September 30, 2016**

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Codman & Shurtleff, Inc.  
Raynham, MA
2. PURPOSE AND LIMITATION:
  - a. This special permit authorizes the transportation in commerce of a small amounts of butane contained within a medical device, designed to disperse medication from within the patient, as unregulated. 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 § Parts 171-180, except as provided herein.
5. BASIS: This special permit is based on the application of Codman & Shurtleff, Inc. dated September 25, 2013 submitted in accordance with § 107.105 and the public proceeding thereon.

November 3, 2014

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

<b>Hazardous Materials Description</b>			
<b>Proper Shipping Name</b>	<b>Hazard Class/ Division</b>	<b>Identification Number</b>	<b>Packing Group</b>
No DOT shipping name required	N/A	N/A	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Each Medstream pump must be packaged in a specially designed inner packaging identified in the application on file with the Approvals and Permits Division (APD) as package design "7439" and Part number "287486-000".

b. OPERATIONAL CONTROLS -

i. Only one Medstream pump may be packaged and shipped in the specially designed packaging described in paragraph 7.(a).

ii. The Medstream pump must be filled and certified to be leak tested and free of leaks in accordance with the production procedures identified in the document "Butane Filling of Chandra" Spec # PC865, Revision H on file with APD.

iii. Each Medstream pump may not contain more than .95 grams of butane.

8. SPECIAL PROVISIONS:

a. 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.

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

**November 3, 2014**

9. MODES OF TRANSPORTATION AUTHORIZED: Cargo aircraft 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 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.
  - 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.

**November 3, 2014**

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

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](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: LAVALLE