1. **GRANTEE:** Channel Medsystems, Inc.
   Berkeley, CA

2. **PURPOSE AND LIMITATION:**
   a. This special permit authorizes the transportation in commerce of medical devices containing nitrous oxide, via air, within an outer packaging that has not passed the Thermal Resistance Test. This special permit provides no relief from the Hazardous Materials Regulations (HMR) or the International Civil Aviation Organization’s Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) 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.
   
   d. This special permit serves as an exemption to the ICAO TI and as a “Competent Authority Approval” as defined under 49 CFR § 107.1.

3. **REGULATORY SYSTEM AFFECTED:** 49 CFR Parts 106, 107 and 171-180.

4. **REGULATIONS FROM WHICH EXEMPTED:** 49 CFR § 173.304(f)(4) and US Variation 18 of the ICAO TI in that no thermal resistance testing was performed on the completed packaging.

5. **BASIS:** This special permit is based on the application of Channel Medsystems, Inc. dated January 21, 2022, submitted in accordance with § 107.105 and the public proceeding thereon.

Tracking Number: 2022015101
6. **HAZARDOUS MATERIALS (49 CFR 172.101):**

<table>
<thead>
<tr>
<th>Hazardous Materials Description</th>
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<tr>
<td><strong>Proper Shipping Name</strong></td>
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<td>Nitrous oxide</td>
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7. **SAFETY CONTROL MEASURES:**

a. **PACKAGING:** Prescribedpackagings areCerene medical devices which contain a specification DOT-3AL 1800 cylinder equipped with a pressure relief device. Each cylinder contains up to 164.5 g nitrous oxide.

   (1) Devices are packaged for retail sale and end use by medical professionals and placed in a form fit plastic clamshell tray and sealed with a Tyvek cover to ensure sterility and prevent movement and unintentional actuation.

   (2) The sealed tray is placed in a fiberboard box.

   (3) Two completed fiberboard boxes are then placed within a DOT31FP chemical oxygen generator packaging meeting the requirements of § 173.304(f)(3) for shipment.

b. **HAZARD COMMUNICATION:**

   (1) The outer package must be labeled with the Division 2.2 Compressed Gas label, the Division 5.1 Oxidizer label and UN1070.

   (2) The special permit number, “SP-21326” must be marked on the outer package.

c. **OPERATIONAL CONTROLS:**

   (1) For transportation by the air mode, the following limits apply:

      (i) Not more than one (1) package is permitted per each Unit Load Device (ULD); and
(ii) Not more than five (5) packages will be permitted per cargo-only aircraft (i.e., not more than five ULDs where each ULD may not contain more than one package).

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 or its contents 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.

9. MODES OF TRANSPORTATION AUTHORIZED: Cargo-only 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.

“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 William Schoonover
Associate Administrator for Hazardous Materials Safety


Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: ae