

**CERTIFICATE OF COMPLIANCE FOR RADIOACTIVE MATERIALS PACKAGES
D.O.T. SPECIFICATIONS 7A, TYPE A**

**Model #001-794 PET Shipping System
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1. Package Identification:

Common Name: Double-Ended Single Dose Shipping System Syringe w/Needle
Ground or Air Shipment
Catalog Name: **Shipping System, PET, Single Compact , Double-Ended**
Model Number: **#001-794**

2. Preamble:

- a. This certificate is issued to satisfy section 178.350 including sections 171.2, 173.403, 173.410, 173.412, 173.415, 173.431, 173.465, 173.466, 178.350 and 178.608 of the Department of Transportation Hazardous Materials Regulations (49 CFR).
- b. The packaging and contents described in item 4 below were found to meet the safety standards set forth in, and tested, according to the more stringent recommendations for general performance testing from:

IATA Dangerous Goods Regulations, 60th Edition Sections 5.0.4.3, 10.5, and 10.6.1 thru 10.6.3.5.

49 CFR as listed in item 2a above.
- c. This certificate does not release the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. Descriptions of Packaging and Authorized contents, Other Conditions, and References:

- a. **Outer Container:** Model #001-783-A005
Medium Density Polyethylene:
Dimension: 11.75" x 11.75" x 12.5" with high density polyurethane foam cushioning and insert support weldment
- b. **Shielded Insert:** Model #001-794-C200
Contour lead shield with open top and bottom and more lead in the vertical center
- c. **PET Unit Dose Pig:** Model #001-793
0.065" polycarbonate with 0.6" lead with single turn twist lock top and bottom, with 0.875" tungsten top plug, and 1.5" lead in bottom. Double-Ended Pig.

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- d. **Absorbent Material:** Model #001-771
 One piece of 3"x3" Quick Solid absorbent material in the bottom of the pig
- e. **Syringe:** B-D or Monoject plastic 3 ml or 5/6 ml Syringe with needle and cap or luer cap

Authorized Contents:

Normal Form Radioactive Materials in Type A quantities
Tested with F-18, 235 mCi and 160 mCi in appropriate parts of the shield as Yellow II.
Must comply with A₂ value limits from 49CFR 173.435.

Specifications and Restrictions:


Ground or Air Transportation

4. This certificate is issued on the basis of the test results and safety analysis of the package design.

5. Certification

This document is to certify that to the best of our knowledge, information and belief, the construction methods, the packaging design, and the materials of construction for this specification package comply with the standards described in items 2a, 2b, 2c herein. Any deviation from these conditions must be approved prior to use.

Approved:



Signature

Clyde Schlein
Vice President, Compliance & Regulatory Affairs
Biodex Medical Systems, Inc.

Date: Jan 4, 2013
Rev: Dec 5, 2017
Rev: Aug 22, 2018