BIODEX MEDICAL SYSTEMS, INC.
20 Ramsey Road
Shirley, New York 11967-4704

D.O.T. SPECIFICATION 7A, TYPE A
PACKAGING TEST RECORD

DATE: **DECEMBER 22, 2003**

PACKAGE IDENTIFICATION: **DOUBLE UNIT DOSE PIG SHIPPING SYSTEM, MODEL #001-787**

Testing was performed at: Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, NY 11967-4704 USA

PACKAGE	DESCRIPTION	SIGNED OFF BY
Outer Case:		CS
manufacturer of case	Zero Plastic	
construction material	rotation molded polyethylene	
wall strength, lb test	N/A	
dimensions, inches	11.75 x 11.75 x 12.5 (h)	
closure	hinged lid, 2 clasps	
internal cushioning	high density polyurethane foam	
Lead Insert Shielding Package:		
material	cast lead in a contoured shape to supply appropriate shielding to inner pig - open top and bottom on lead - holds 2 pigs	
insert support	metal plate to hold and position lead	
Unit Dose Pig:		
material	lead encased in plastic shell with integral liner Lead: body .5" top 1.44" bottom 1.2"	
closure	plastic screw threads between top and bottom sections, single turn twist lock	
cushioning	N/A	
dimensions, "	10.2" long x 2.4" diameter	
Lead Shielding Combined:	bottom: 1.2" top: 1.44" sides: varies depending on location from .56 to 1.8"	
Weight:		
outer shield and case	40.1 lbs	
unit dose pig #1	8.9 lbs	
unit dose pig #2	8.9 lbs	
Total Weight	58 lbs	
Primary Container Unit Dose Pig:		
syringe	Two 5 cc syringes used in individual pigs	
nominal volume ml	2.4 ml and 2.6 ml	
closure	needle and needle cover or luer cap	
content simulation	water, colored	
absorbent materials	absorbent sheet (001-771)	
Examination of test sample before tests:		
Describe:		
defects	none	
distortions	none	
deterioration	none	
printing imperfections	none	

TESTS	NOTES	SIGNED OFF BY
TEST RECORD:	Perform tests in order and attach a photographic record	
WATER SPRAY TEST: 49 CFR 173.465 (b) (must be performed before remaining tests)	Two (2) cases were sprayed. Case 1 and 2 at the same time. A nozzle was placed on each side of the cases and water sprayed for more than one (1) hour at a rate greater than two (2) inches per hour. A hose was connected to the pipe for a shower head was run and then split into four (4) hoses – each with a nozzle on the end. The hose nozzles were on the four(4) sides of the cases.	CS
Spray Package: from 1 or 4 sides rate approx. 2 inches / hour time at least 1 hour	spray from 4 simultaneously greater than 2 inches / hour sprayed for more than 1 hour	
Describe Results:	The water spray did not affect the plastic shipping container. The case had some water in it. NOTE: If the package was sprayed from 4 sides simultaneously, the other tests may begin up to 2 hrs. after the water is turned off. If the spray is from 1 direction on each side sequentially, the compression test must begin within 1 hour.	

TESTS	NOTES	SIGNED OFF BY
FREE DROP TEST: onto flat concrete surface		
Drop Test one foot onto 8 corners 49 CFR 173.465 (c) (2) (CASE 2)	dropped on all 8 corners	CS
Describe Results:	pigs are OK, small scratches on case corners syringes did not lose any material into caps absorbent material is dry	
Drop Test four feet for maximum damage: 49 CFR 173.465 (c) (1) (CASE 2)	plastic zip tie case closed drop onto latches for maximum damage	CS
Describe Results:	case stayed closed – case is scratched pigs are OK syringes are OK – no leakage into needle caps	CS
Drop Test 30 feet: 49 CFR 173.466 (a) (1) (CASE 1)	case taken to top of building and dropped 30 feet onto concrete apron	CS
Describe Results:	case hit on bottom near edge case stayed closed pigs stayed together lead was bent tapped pigs forward to remove one pig can lift out bottom section plastic is cracked syringe is OK second pig bottom is stuck in case tapped to move threads in top and bottom are cracked. syringe is OK – needle cap is dry absorbent material was dry. some water from outer case Spray Test leaked onto ground	CS
PENETRATION TEST: 49 CFR 173.466 (a) (2) and IATA 10.6.3.5.2 (CASE 2) using 1.25 in. diameter bar with hemispherical end weighing 13.2 lbs.	Determined the top was the weakest location so dropped the rod onto the top of the case	
Drop from 67 inches:		CS
strike point	hit off center near rib	CS
clock time	N/A	
Describe Results:	the bar penetrated the top plastic lid of case case stayed together pigs are OK syringes are OK - no leakage into needle caps	CS
	PASSES TEST	CS

TESTS	NOTES	SIGNED OFF BY
COMPRESSION TEST: 49 CFR 173.465 (d) (CASE 2) performed December 1999 24 hours compression: weight in lbs. clock time - start clock time - finish	 greater than 600 pounds N/A timer, 24 hours NOTE: Compression test was performed by placing a sheet of plywood with lead bricks onto the top of the plastic case. The heaviest system weighs 55.2 lbs. The stacking test is (2 lb./in^2 x vertical projected area of package, which would be 277 lbs. or 5x's the weight of the package) which is 276 lbs. We used over 600 lbs. of lead bricks on top of the shipping system.	CS CS CS
Describe Results:	There was no damage or effect to the plastic container. None of the inner shields were damaged during this test.	CS
ACCEPTANCE CRITERIA:	1. Damage to the packaging may not cause loss or dispersal of simulated contents. 2. Damage to the packaging may not cause an increase in calculated surface radiation exposure. 3. The test record must be complete and accurate, and the photographic record attached.	

Tests performed by:

Clyde Schlein Initials CS

Kenneth Paladino Initials KP

Date: January 22, 2004

Note:

Additional tests were performed by Dayton T. Brown. These tests were for compliance to:

Temperature Test IATA 10.6.2.4.1.4 and 49CFR 178.608

Pressure Test IATA 10.6.1.3; IATA 5.0.2.9 and 49CFR 173.410(c)

Vibration Test IATA 5.0.4.3 (also 49CFR 178.608 and 173.24 (a) (a) (5))

These tests are available from Biodex upon request.

Rev: August 14, 2018