

East Building, PHH-23 1200 New Jersey Ave, SE Washington, D.C. 20590

U.S. Department of Transportation

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/9299/B(U)-85, REVISION 6

Pipeline and Hazardous Materials Safety Administration

The Competent Authority of the United States certifies that the radioactive material package design described in this certificate satisfies the regulatory requirements for a Type B(U) package as prescribed in the regulations of the International Atomic Energy Agency¹ and the United States of America² The package design is approved for use within the United States for import and export shipments made in accordance with applicable international and domestic transport regulations.

- 1. Package Identification Model No. F-423.
- <u>Package Description and Authorized Radioactive Contents</u> as described in U.S. Nuclear Regulatory Commission Certificate of Compliance No. 9299, Revision 7 (attached).
- 3. General Conditions
 - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Engineering and Research, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.

¹ "Regulations for the Safe Transport of Radioactive Material, 2012 Edition, No. SSR-6" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

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- c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.
- d. Records of Management System activities required by Paragraph 306 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
- Marking and Labeling The package shall bear the marking USA/9299/B(U)-85 in addition to other required markings and labeling.
- 5. <u>Expiration Date</u> This certificate expires on March 31, 2027. Previous editions which have not reached their expiration date may continue to be used.

This certificate is issued in accordance with paragraph(s) 820 of the IAEA Regulations and Section 173.471 of Title 49 of the Code of Federal Regulations, in response to the March 16, 2022 petition by Best Theratronics Ltd., Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:

March 21, 2022 (DATE)

William Schoonover Associate Administrator for Hazardous Materials Safety

Revision 6 - Issued to endorse U. S. Nuclear Regulatory Commission Certificate of Compliance No. 9299, Revision 7.

NRC FORM 618 (8-2000)			U.S. NUCLEAR REGU	ILATORY	COMMISSION
10 CFR 71 CERTIFICATE OF COMPLIANCE FOR RADIOACTIVE MATERIAL PACKAGES					
1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9299	7	71-9299	USA/9299/B(U)-85	1	OF 4

- 2. PREAMBLE
 - a. This certificate is issued to certify that the package (packaging and contents) described in Item 5 below meets the applicable safety standards set forth in Title 10, Code of Federal Regulations, Part 71, "Packaging and Transportation of Radioactive Material."
 - b. This certificate does not relieve 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. THIS CERTIFICATE IS ISSUED ON THE BASIS OF A SAFETY ANALYSIS REPORT OF THE PACKAGE DESIGN OR APPLICATION
 - a. ISSUED TO (Name and Address)

b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION

Best Theratronics 413 March Road Ottawa, Ontario Canada K2K 0E4 MDS Nordion application dated November 29, 2006, as supplemented.

4. CONDITIONS

This certificate is conditional upon fulfilling the requirements of 10 CFR Part 71, as applicable, and the conditions specified below.

- 5.
- (a) Packaging
 - (1) Model No.: F-423
 - (2) Description

A double-walled welded stainless steel overpack for shipping sealed sources within the Gammacell 220 (GC220) gamma irradiator. The packaging consists of concentric box-like stainless steel shells separated by an annulus of rigid polyurethane foam. The overall overpack wall thickness is eight inches on the sides, twelve inches on the front and rear, and four inches on the base. The overpack lid is constructed of a sheet of 1/2-inch thick stainless steel on top, a sheet of 1/4-inch thick cold-rolled steel on the bottom, and 4-inches of polyurethane foam in between. The package is closed by bolting the lid to the body with 40 one-inch diameter bolts.

The GC220 irradiator is positioned inside the cavity formed by the inner stainless steel shell, along with an inner steel frame and a rigid polyurethane foam bonnet and lower crush pad. Shielding is provided by the GC220 irradiator, which is a welded steel lead-filled device. The GC220 is a lead-filled shielding head mounted on a steel stand. The GC220 shielding head consists of inner and outer steel shells with lead in between. The nominal lead thickness is 10 inches. The GC220 has an irregular shape, however, the base is 60-inches long by 40-inches wide. In its shipping configuration, the GC220 is 58-inches high. The GC220 shielding plug is welded from 304 stainless steel and lead filled.

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5(a) (2) (continued)

The maximum package weight (including contents) is 21,000 lbs (9,524 kgs). The approximate package component dimensions and weights are as follows:

Component	Weight (Ibs / kg)	Nominal Dimensions (L x W x H inches)		
Overpack Lid	1,036 / 470	67.50 x 55.00 x 4.75		
Inner Frame	1,257 / 570	60.50 x 48.00 x 54.13		
Bonnet	871 / 395	52.00 x 41.50 x 36.75		
GC220	8,576 / 3.890	60.00 x 40.00 x 58.00		
Overpack Body	8,708 / 3.950	86.50 x 66.00 x 80.37		
Lower Crush Pad	386 / 175	47.00 x 31.00 x 7.00		

(3) Drawings

The packaging is constructed in accordance with MDS Nordion Drawing No. F642301-001, Sheet 1, Revision G, and Sheet 2, Revision D.

(b) Contents

- (1) Type and form of material
- i. Cobalt-60 as sealed sources that meet the requirements of special form radioactive material.
- ii. Cobalt-60 as sealed sources described in Condition No. 6 below.
- (2) Maximum quantity of material per package

26,000 curies, a maximum of 48 sources per package, and a maximum of 5,000 curies per source.

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CERTIFICATE OF COMPLIANCE FOR RADIOACTIVE MATERIAL PACKAGES

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- 6. Sealed sources limited to MDS Nordion sealed source capsules manufactured before February 19, 1973: C-166, C-167, C-185 and C-198. In addition, these sources must meet the following:
 - (a) Sources must conform to the specifications identified in the application in Figure 4.2 for the C-166 source, Figure 4.3 for the C-167 source, Figure 4.4 for the C-185 source and Figure 4.5 for the C-198 source;
 - (b) Sources must be shown to not be leaking within six months prior to shipment; and
 - (c) Sources must not have been damaged during their service life.
- 7. In addition to the requirements of Subpart G of 10 CFR Part 71:

(a) The package must be prepared for shipment and operated in accordance with the Operating Procedures in Chapter 7 of the application.

(b) Each packaging must be acceptance tested and maintained in accordance with the Acceptance Tests and Maintenance Program in Chapter 8 of the application.

8. The package authorized by this certificate is hereby approved for use under the general license provisions of 10 CFR 71.17.

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9. Transport by air of fissile material is not authorized.

- 10. Fabrication of new packages is not authorized.
- 11. Expiration date: March 31, 2027

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REFERENCES

MDS Nordion application dated November, 29, 2006

Supplement dated: February 8, 2007; February 27 (Best Theratronics), March 31 (MDS Nordian), 2009, October 7, 2011, November 8, 2016 and January 24, 2022.





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ORIGINAL REGISTRANT(S):

Best Theratronics Ltd. 413 March Road Ottawa, Ontario, K2K 0E4 CANADA