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

U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/0665/B(U)-96, REVISION 9

REVALIDATION OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2083/B(U)-96

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 Agency[1] and the United States of America[2] 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 - Models F-431/GC-1000; F-431/GC-3000 and F-431/Gammator M38.

2. Package Description and Authorized Radioactive Contents - as described in Canadian Certificate of Competent Authority CDN/2083/B(U)-96, Revision 9 (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.

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[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.

CERTIFICATE USA/0665/B(U)-96, REVISION 9

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 regulations[1] 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.

4. Marking and Labeling - The package shall bear the marking USA/0665/B(U)-96 in addition to other required markings and labeling.

5. Expiration Date - This certificate expires on November 30, 2026. Previous editions which have not reached their expiration date may continue to be used.

This certificate is issued in accordance with paragraph(s) 810 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the February 2, 2022 petition by Best Theratronics Ltd., Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:

February 08, 2022

William Schoonover
Associate Administrator for Hazardous Materials Safety

(DATE)

Revision 9 - Issued to revalidate Canadian Certificate of Approval No. CDN/2083/B(U)-96, Revision 9.

Canadian Certificate No.: **CDN/2083/B(U)-96 (Rev. 9)**
Issue Date: **Nov-23-2021**
Expiry Date: **Nov-30-2026**
CNSC File: **30-A2-246-0**

Certificate

CDN/2083/B(U)-96 (Rev. 9)

Transport Package Design

The transport package design identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the *Nuclear Safety and Control Act* and Subsection 10(1) of the *Packaging and Transport of Nuclear Substances Regulations*, 2015 and to the IAEA's *Regulations for the Safe Transport of Radioactive Material*, 2012 Edition.

REGISTRATION OF USE OF PACKAGES

All users of this authorization shall register their identity in writing with the Canadian Nuclear Safety Commission prior to the first use of this authorization and shall certify that they possess the instructions necessary for preparation of the package for shipment.

PACKAGE IDENTIFICATION

Designer:	**Best Theratronics Ltd.**
Make/Model:	**F-431/GC-1000; F-431/GC-3000 and F-431/Gammator M38**
Mode of Transport:	**Air, Sea, Road, Rail**

IDENTIFICATION MARK

The package shall bear the competent authority identification mark **"CDN/2083/B(U)-96".**

PACKAGE DESCRIPTION

The Gammacell 1000, and the Gammacell 3000 irradiators, as shown on Best Theratronics Drawing No. F643101-001, Sheet 1 of 2, (Issue K) and F643101-001, Sheet 2 of 2, (Issue F), consists of an upright inner cylindrical steel jacket filled with lead almost 460 mm in diameter and close to 610 mm high. These drawings are also representative of the Gammator M38 with the exception of the lifting lugs. The Gammacells are packaged in a model F-431 overpack. They are held in position inside the F-431 cavity with shipping braces. A different brace design is used for each irradiator model. The F-431 overpack, as described on Best Theratronics Drawing No. F643101-001, Sheet 1 of 2, (Issue K) and F643101-001, Sheet 2 of 2, (Issue F), consists of a stainless steel cylinder 1067 mm in outside diameter and 1283 mm tall. It is placed on a removable mild steel skid 1118 mm by 1003 mm by 203 mm. It has a cylindrical cavity 559 mm in diameter and 813 mm long. The empty package, including the skid, weighs 1050 kg. The main materials of construction are 304L stainless steel and rigid polyurethane foam.

Three layers of gage 12 (2.67 mm) stainless steel shells, with two layers of polyurethane between them, protect the content. The external polyurethane foam is 150 mm thick and has a density of 128 kg/m³. The internal layer of polyurethane foam is 25 mm thick and has a density of 640 kg/m³. The containment system is the source outer encapsulation.

An illustration of the package model F-431/GC-1000 and F-431/GC-3000 is shown on attached Drawing No. F-431 (Issue C).

Any modification to the package design must be submitted to the CNSC for approval prior to implementation.

The configuration of the package is as follows:

Shape:	**Cylinder**	Shielding:	**Lead**
Mass:	**2270 kg**	Outer Casing:	**Stainless Steel**
Length:	**n/a**	Height:	**1283 mm**
Width:	**n/a**	Diameter:	**1067 mm**

AUTHORIZED RADIOACTIVE CONTENTS

The package is authorized to contain not more than 113 TBq of cesium-134 and cesium-137 with the cesium-134 not to exceed 1% of the cesium-137 in the form of cesium chloride loose powder or compressed powder pellets contained within;

- MDS Nordion or Best Theratronics C-378 and C3100 sources, and Isomedix ISO-1000 sources with valid special form radioactive material certificates;
- MDS Nordion or Best Theratronics C-1000 and C-3000 sources meeting ISO 2919:2012 E65546(6) classification;
- MDS Nordion or Best Theratronics C-1001 and C-3001 sources meeting ISO 2919:2012 E65646(7) classification;
- "ORNL-RAMCO-50" (Radiation Machinery Corp.) sources.

MANAGEMENT SYSTEM

The management system for the design, manufacture, testing, documentation, use, maintenance and inspection of the package shall be in accordance with:

- Best Theratronics Document No. IN/DS 1892 F431 (C), "Design, Manufacturing and Operating Specification for the F-431 Transport Package"
- Best Theratronics Document No. 5.05-QA-01 (D)*, "Radioactive Material Transport Package Quality Plan"
- Best Theratronics Document No. 5.05-QA-02 (2)*, "Sealed Source Quality Plan"
- Packaging and Transport of Nuclear Substances Regulations, 2015
- * or latest current revision

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SHIPMENT

The preparation for shipment of the package shall be in accordance with:

- Best Theratronics Document No. IN/DS 1892 F431 (C), "Design, Manufacturing and Operating Specification for the F-431 Transport Package"
- Packaging and Transport of Nuclear Substances Regulations, 2015

This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

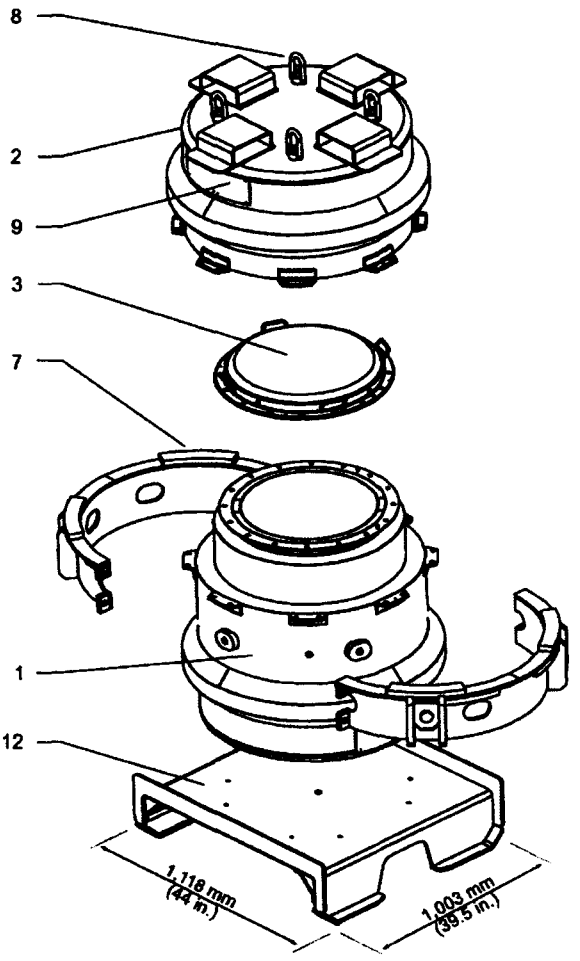
I. Tremblay
Designated Officer pursuant to paragraph 37(2)(a)
of the Nuclear Safety and Control Act

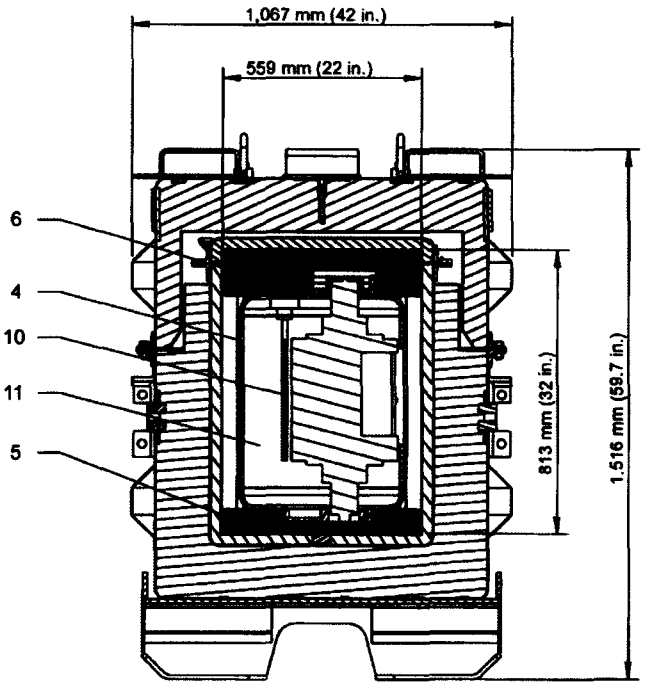
NOTES

Revision 5: September 20, 2012. Certificate renewed.
Revision 6: May 7, 2015. Certificate amended to add C3100 source and ISO classification for C-1001 and C-3001 sources.
Revision 7: October 7, 2015. Certificate amended to correct minor error.
Revision 8: November 28, 2016. Certificate renewed.
Revision 9: November 23, 2021. Certificate renewed.

Parts List

1. Overpack - Body
2. Overpack - Lid (16 Bolts, 5/8-UNC, Gr. 5, 1 Security Seal)
3. Overpack - Inner Lid (16 Bolts, 5/8-UNC, Gr. 5)
4. Gammacell Irradiator (GC1000 or GC3000)
5. Lower Shipping Brace
6. Upper Shipping Brace
7. Tie-Down Collar (2 pieces)
8. Lifting Hoist Rings (4 pieces)
9. Radiation warning and identification plates (2 sides)
10. Cesium-137 Sources
11. Lead Shielding
12. Shipping Skid





SIDE CROSS-SECTIONAL VIEW

Notes

1. Meets IAEA Type B(U)-96 requirements (CNSC Package Design Certificate No. CDN/2083/B(U)-96)
2. Gross weight: 2,270 kg (5,000 lb.)
3. Floor Loading (based on projected floor area 2,025 kg/m^2 (415 lb./ft.^{2})
4. Maximum Radioactive contents: 113 TBq (3,050 Ci) of Cs-137
5. Maximum Contents weight: 1,225 kg (2,700 lb.)

JUN 1 1 2012

Best® Theratronics

413 March Road
Ottawa, Ontario
Canada, K2K 0E4
Tel: (613) 591-2100

TITLE

F-431 Transport Package

REF	IN/SS 1915 F431	REVISED	June 12	DC30855	
DATE	April 2003	No.	F-431		ISSUE
DRAWN	CHECKED	APPROVED			C
	JBR	VM	SHEET 1 OF 1		

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

U.S. Department of
Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

CERTIFICATE NUMBER: USA/0665/B(U)-96

ORIGINAL REGISTRANT(S):

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