



U.S. Department
of Transportation
**Pipeline and
Hazardous Materials
Safety Administration**

East Building, PHH-23
1200 New Jersey Avenue Southeast
Washington, D.C. 20590

**COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0665/B(U)-96, REVISION 8**

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

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency¹ and the United States of America².

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 Canada Certificate of Competent Authority CDN/2083/B(U)-96, Revision 8 (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 Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
 - 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.

¹ "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," 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 8

- d. Records of Quality Assurance activities required by Paragraph 310 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.
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, 2021.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the November 30, 2016 petition by Best Theratronics Ltd., Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:



William Schoonover
Acting Associate Administrator for Hazardous Materials Safety

Jan 10 2017
(DATE)

Revision 8 - Issued to revalidate Canadian Certificate of Approval No. CDN/2083/B(U)-96, Revision 8.



Certificate

CDN/2083/B(U)-96 (Rev. 8)

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

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; Isomedix ISO-1000 sources meeting the requirements for special form radioactive material; MDS Nordion or Best Theratronics C-378, C-1000, C-3000, C3100 sources meeting the requirements for special form radioactive material; MDS Nordion or Best Theratronics C-1001 and C-3001 sources meeting ISO 2919:2012 E65646(7) classification; CIS Bioindustries CSL-12, or "ORNL-RAMCO-50" (Radiation Machinery Corp.) sources.

QUALITY ASSURANCE

Quality assurance for the design, manufacture, testing, documentation, use, maintenance and inspection of the package shall be in accordance with:

- Best Theratronics Document No. 5.05-QA-01 (C)*, "Radioactive Material Transport Package Quality Plan"
- Best Theratronics Document No. 5.05-QA-02 (2)*, "Sealed Source Quality Plan"
- IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition
- * or latest current revision



SHIPMENT

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

- Best Theratronics Procedure No. IN/DS 1892 F431 (C), "Design, Operating and Maintenance for the F-431 Transport Package"
- Packaging and Transport of Nuclear Substances Regulations, 2015
- IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition

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.



S. Faille

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



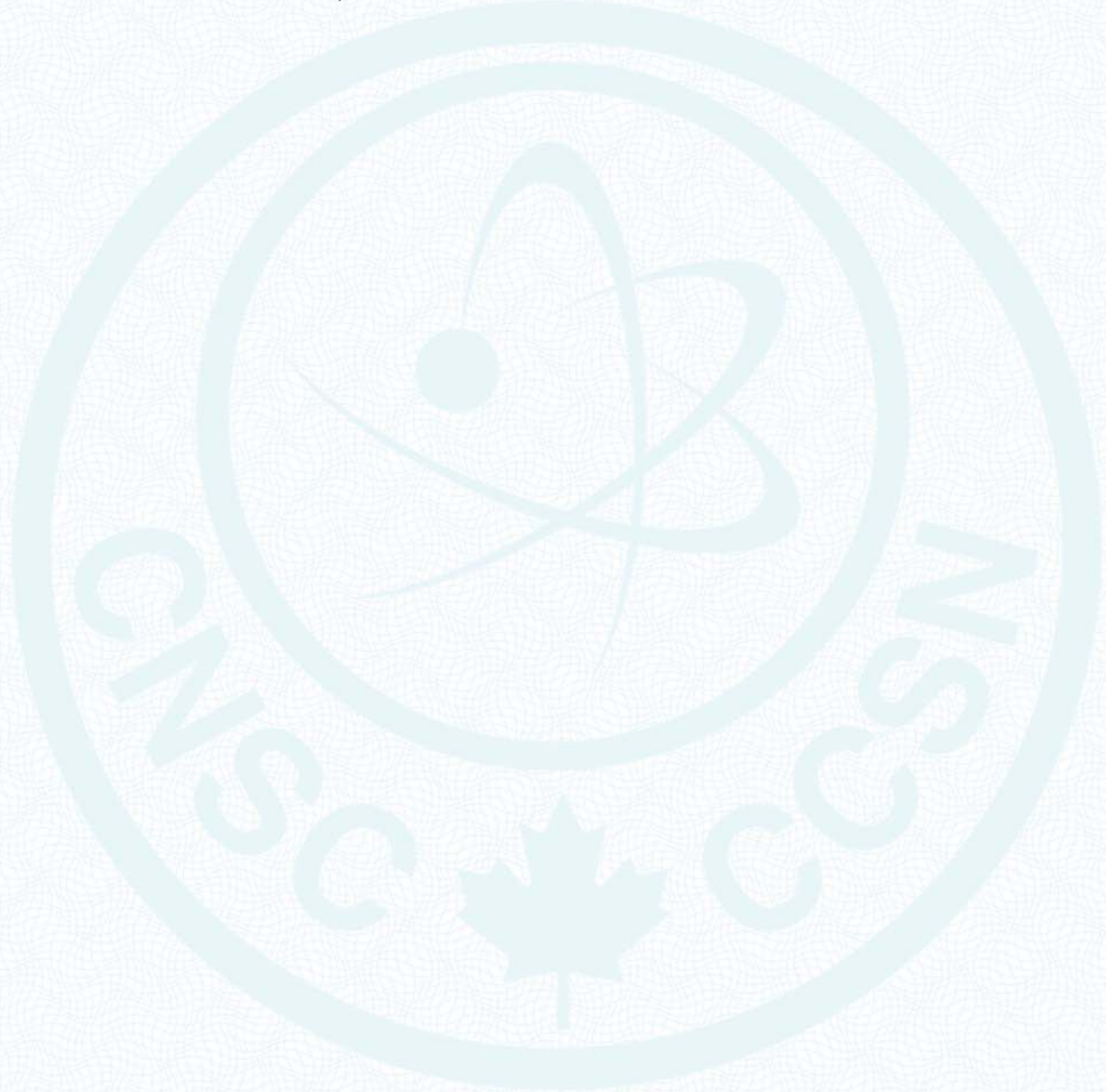
NOTES

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.

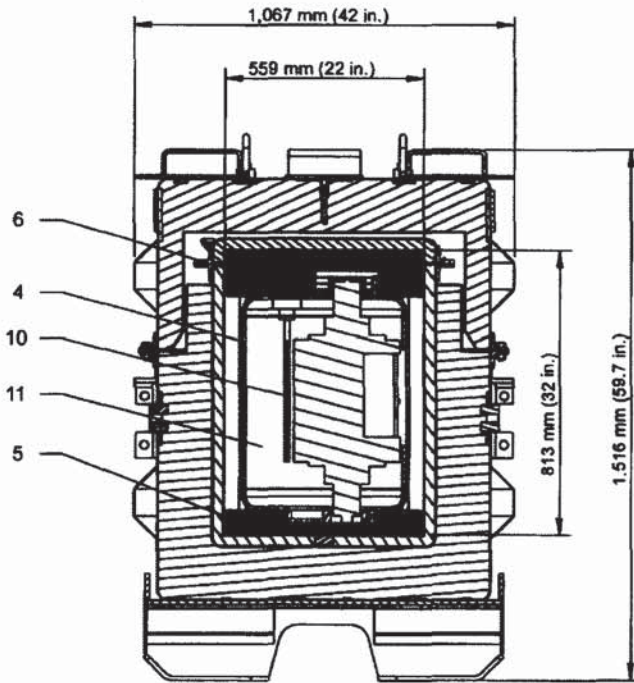
Revision 7: October 7, 2015. Certificate amended to correct minor error.

Revision 8: November 28, 2016. Certificate renewed.

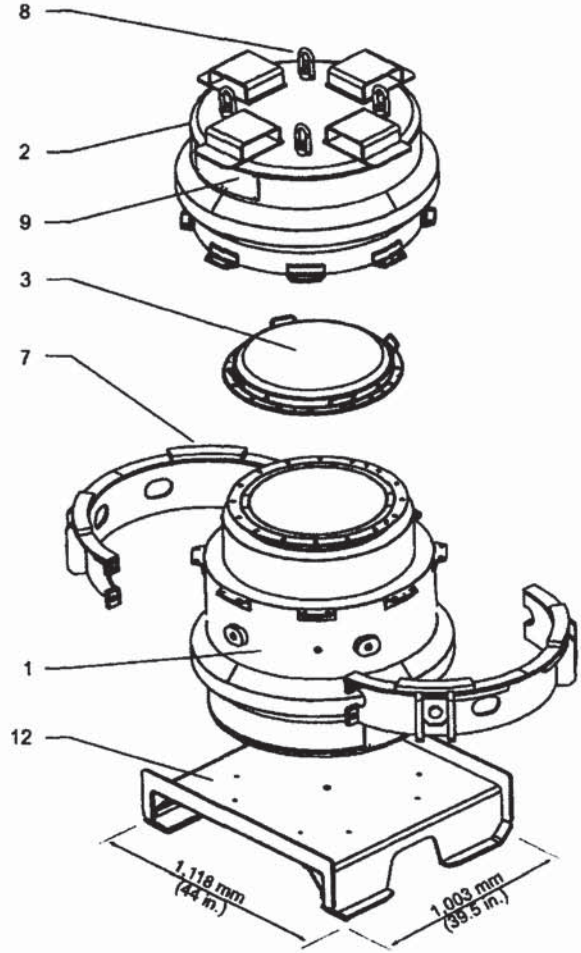


Parts List

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/m² (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 11 2012

**Best
Theratronics**

413 March Road
Ottawa, Ontario
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THIS DRAWING IS THE PROPERTY OF BEST THERATRONICS LTD. AND IS SUBMITTED FOR CONSIDERATION ON THE UNDERSTANDING THAT THERE SHALL BE NO EXPLOITATION OF ANY INFORMATION CONTAINED HEREIN EXCEPT WITH THE SPECIFIC WRITTEN AGREEMENT OF BEST THERATRONICS LTD.

TITLE

F-431 Transport Package

REF IN/SS 1915 F431

REVISED June 12 DC30855

DATE April 2003

No. **F-431**

ISSUE

DRAWN CHECKED APPROVED

SHEET 1 OF 1

C



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1200 New Jersey Avenue SE
Washington, D.C. 20590

**Pipeline and
Hazardous Materials
Safety Administration**

CERTIFICATE NUMBER: USA/0665/B(U)-96, Revision 8

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