



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

**IAEA CERTIFICATE OF COMPETENT AUTHORITY  
SPECIAL FORM RADIOACTIVE MATERIALS  
CERTIFICATE USA/0753/S-96, REVISION 2**

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

This certifies that the source described has been demonstrated to meet the regulatory requirements for special form radioactive material as prescribed in the regulations of the International Atomic Energy Agency<sup>1</sup> and the United States of America<sup>2</sup> for the transport of radioactive material.

1. Source Identification - CIT-Alcatel capsule installed in Medtronic Model 9000 Pacemaker, Serial Nos. 5R00017, 4R00291, 4R00014, 5R00052, 2R00214, 4R00041, 3R00287, 4R00009, 4R0211N, 4R00025, 4R00066, 5R00292, and 5R00039.
2. Source Description - Cylindrical double encapsulation made of tantalum (inner encapsulation) and platinum iridium (outer encapsulation). The inner encapsulation is electron beam welded. The outer encapsulation is tungsten inert gas heliarc welded. Approximate capsule outer dimensions are 9.2 mm (0.36 in.) in diameter and 9.6 mm (0.38 in.) in length. Construction shall be in accordance with attached Figure 2.3-1.
3. Radioactive Contents - No more than 0.1073 TBq (2.9 Ci) of Plutonium-238. The Pu-238 is in the form of a plutonium scandium alloy.
4. Special Conditions -
  - a. The CIT-Alcatel capsule and Medtronic pacemaker must have no known or suspected defects.
  - b. The Medtronic pacemaker must have satisfactorily passed (<0.005 microcurie detected) a leak test within the previous six months.
  - c. This certificate authorizes transportation for disposal purposes only, including transport to interim storage locations.

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<sup>1</sup> "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.

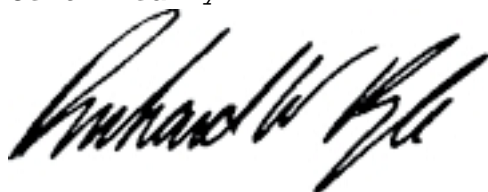
<sup>2</sup> Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

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5. Quality Assurance - Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations<sup>1</sup> 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.
  
6. Expiration Date - This certificate expires on July 31, 2022.

This certificate is issued in accordance with paragraph 804 of the IAEA Regulations and Section 173.476 of Title 49 of the Code of Federal Regulations, in response to the June 25, 2017 petition by Medtronic, Minneapolis, MN, and in consideration of other information on file in this Office.

Certified By:



**Aug 02 2017**

William Schoonover  
Acting Associate Administrator for Hazardous Materials Safety

(DATE)

Revision 2 - Issued to renew the expiration date and revise pacemaker serial numbers.

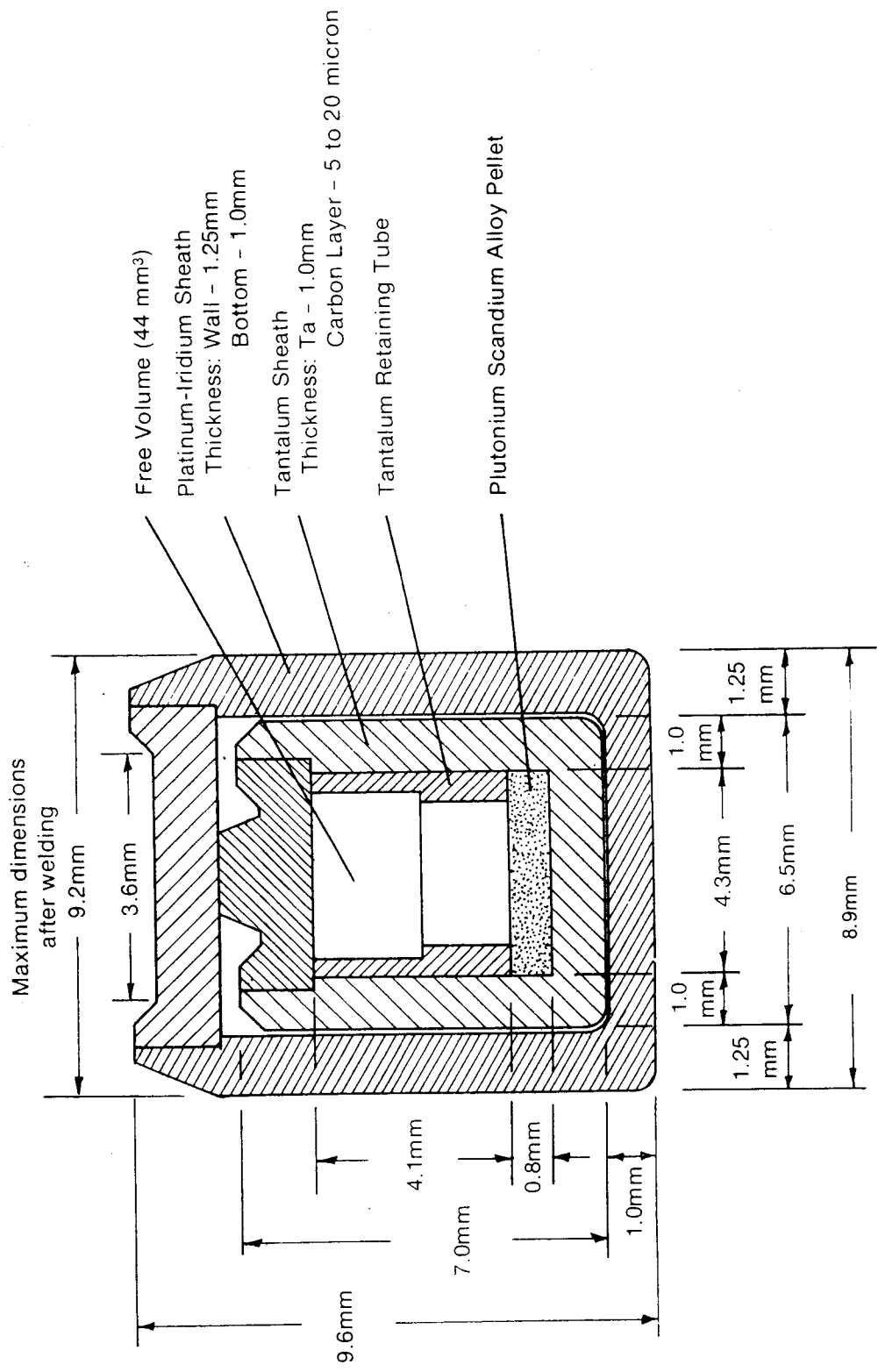


FIGURE 2.3-1 Cut Away of Fuel Capsule Showing Major Construction Features, Dimensions and Component Materials - Not to Scale



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**CERTIFICATE NUMBER:** USA/0753/S-96, Revision 2

**ORIGINAL REGISTRANT(S):**

Mr. Mike Sanders  
Dangerous Goods Compliance Program Manager  
Medtronic  
710 Medtronic Pkwy.  
Minneapolis, MN 55432

**REGISTERED USER(S):**

Gilbert Torres  
Deputy Group Leader  
Los Alamos National Laboratory  
A194  
LANL  
Los Alamos, NM 87545

Ms. Cristy Abeyta  
Technical Staff Member, Environmental Scientist  
Los Alamos National Laboratory  
P.O. Box 1663, Mail Stop: J552  
Los Alamos National Laboratory  
Los Alamos, 87545  
USA

Donald Thorp  
Group Leader  
Los Alamos National Laboratory  
A194  
LANL  
Los Alamos, NM 87545