



U.S. Department
of Transportation

Pipeline and
Hazardous Materials
Safety Administration

IAEA CERTIFICATE OF COMPETENT AUTHORITY
SPECIAL FORM RADIOACTIVE MATERIALS

CERTIFICATE USA/0753/S, REVISION 3

East Building, PHH-23
1200 New Jersey Ave, SE
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 Agency¹ and the United States of America² for the transport of radioactive material.

1. Source Identification - CIT-Alcatel capsule installed in Medtronic Model 9000 Pacemaker, Serial Nos. 5R0017, 4R00291, 3R00287, and 4R00232.
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.

¹ "Regulations for the Safe Transport of Radioactive Material, 2018 Edition, No. SSR-6 (Rev. 1)" 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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5. Management System Activities - Records of Management System activities required by Paragraph 306 of the IAEA regulations 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 requirements of Subpart H of 10 CFR 71.
6. Expiration Date - This certificate expires on October 31, 2029. Previous editions which have not reached their expiration date may continue to be used.

This certificate is issued in accordance with paragraph(s) 804 of the IAEA Regulations and Section 173.476 of Title 49 of the Code of Federal Regulations, in response to the September 23, 2024 petition by Medtronic, Minneapolis, MN, and in consideration of other information on file in this Office.

Certified By:



William Schoonover
Associate Administrator for Hazardous
Materials Safety

October 18, 2024
(DATE)

Revision 3 - Issued to renew the expiration date and revise pacemaker serial numbers.

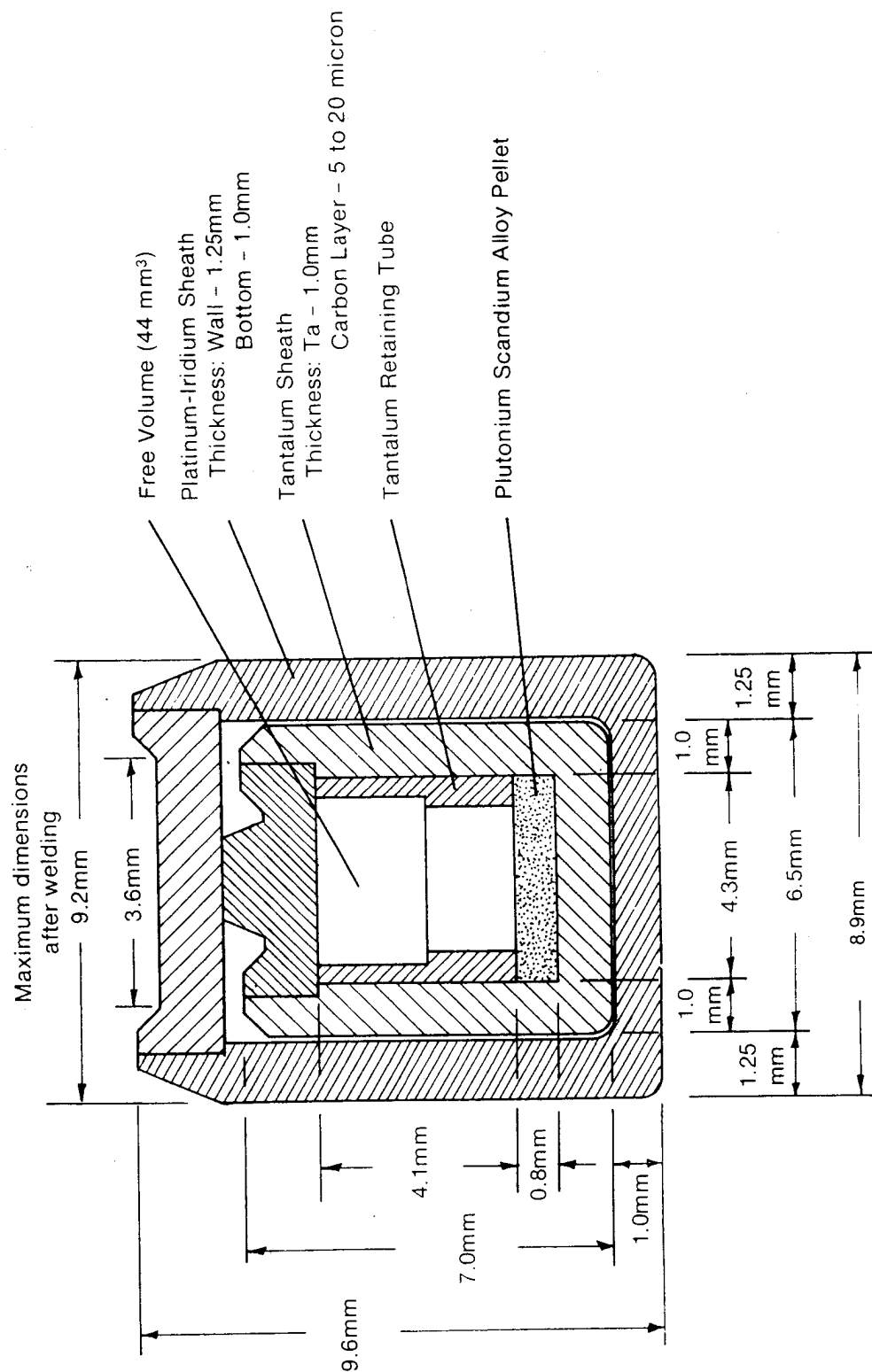


FIGURE 2.3-1 Cut Away of Fuel Capsule Showing Major Construction Features, Dimensions and Component Materials - Not to Scale



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