



U.S. Department of Transportation

IAEA CERTIFICATE OF COMPETENT AUTHORITY SPECIAL FORM RADIOACTIVE MATERIALS

Pipeline and Hazardous Materials Safety Administration CERTIFICATE USA/0723/S-96, REVISION 4

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

- 1. Source Identification Varian Medical Systems Models 212 and 232.
- 2. Source Description The Model 212 is a cylindrical single encapsulation made of stainless steel and either tungsten inert gas, laser, or plasma seal welded. Approximate outer dimensions of the encapsulation are 1.1 mm (0.04 in.) in diameter and either 3.36 mm (0.13 in.) or 4.96 mm (0.2 in.) in length. Minimum wall thickness is 0.17 mm (0.007 in.). A stainless steel connector and cable is welded to one end of the encapsulation. The overall length of the encapsulation, connector, and cable is 2,100 mm (82.7 in.). Construction shall be in accordance with either attached Varian Medical Systems Drawing Nos. GM212.13-020-SFC, Rev. D00 or GM212.13-010-SFC, Rev. D00. The Model 232 is a cylindrical single encapsulation made of stainless steel and either tungsten inert gas, laser, or plasma seal welded. Approximate outer dimensions of the encapsulation are 0.9 mm (0.04 in.) in diameter and either 2.97 mm (0.12 in.) or 4.52 mm (0.18 in.) in length. Minimum wall thickness is 0.08 mm (0.003 in.). A stainless steel connector and cable is welded to one end of the encapsulation. The overall length of the encapsulation, connector, and cable is 2,100 mm (82.7 in.). Construction shall be in accordance with either attached Varian Medical Systems Drawing Nos. GM232.03-000-SFC, Rev. E00 or GM232.02-000-SFC, Rev. D00.

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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- 3. Radioactive Contents No more than 51.8 GBq (1.4 Ci) of Iridium-192 for the short version of either Model or 555.0 GBq (15.0 Ci) of Iridium-192 for the long version of either Model. The Ir-192 is in the form of a solid metal.
- 4. 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.
 - 5. Expiration Date This certificate expires on February 28, 2026. 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 January 19, 2021 petition by Varian Medical Systems, Palo Alto, CA, and in consideration of other information on file in this Office.

Certified By:

William Schoonover

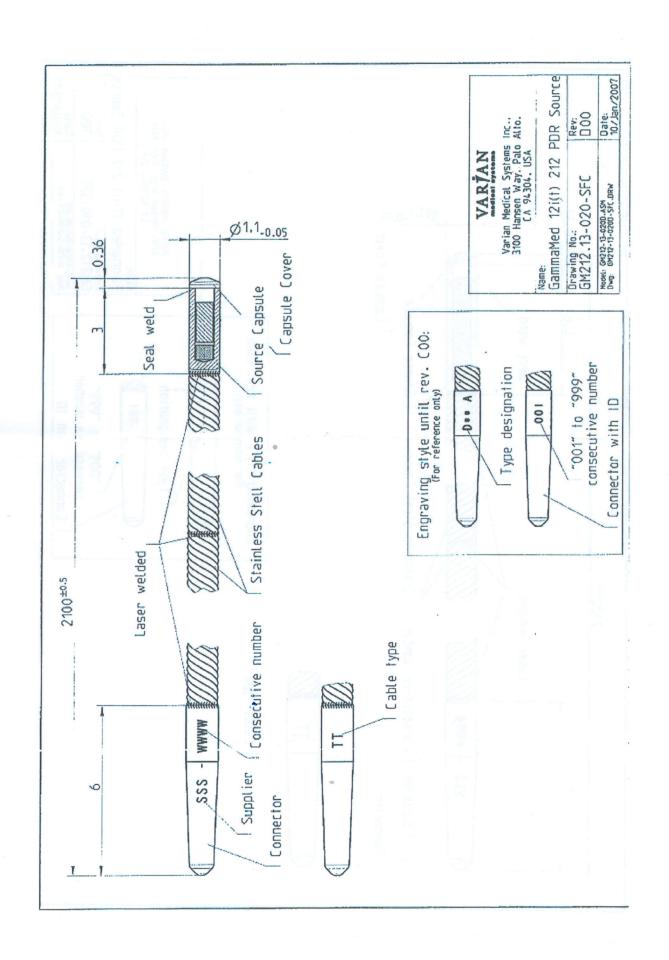
Associate Administrator for Hazardous

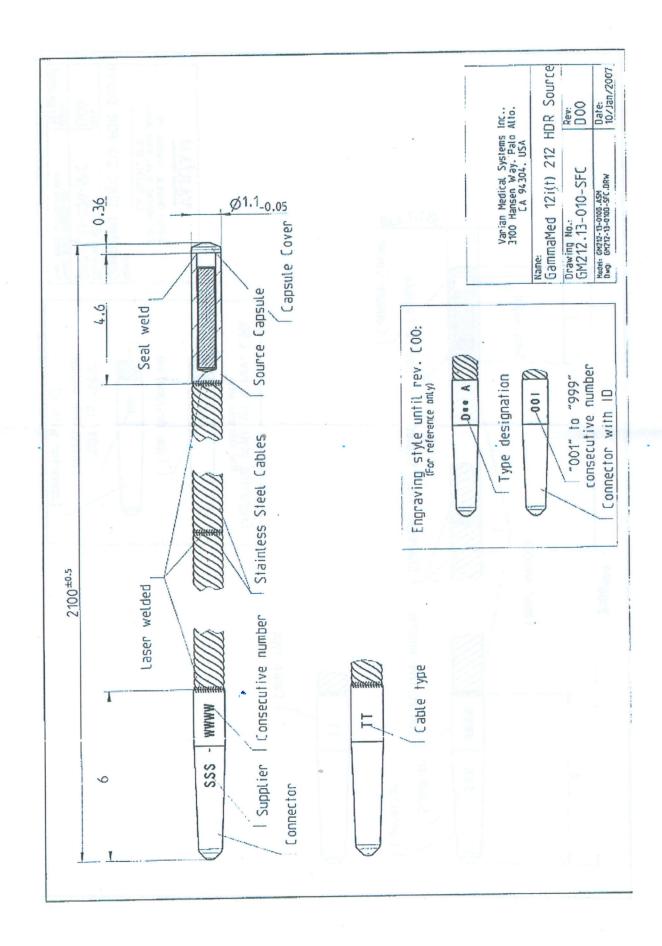
Materials Safety

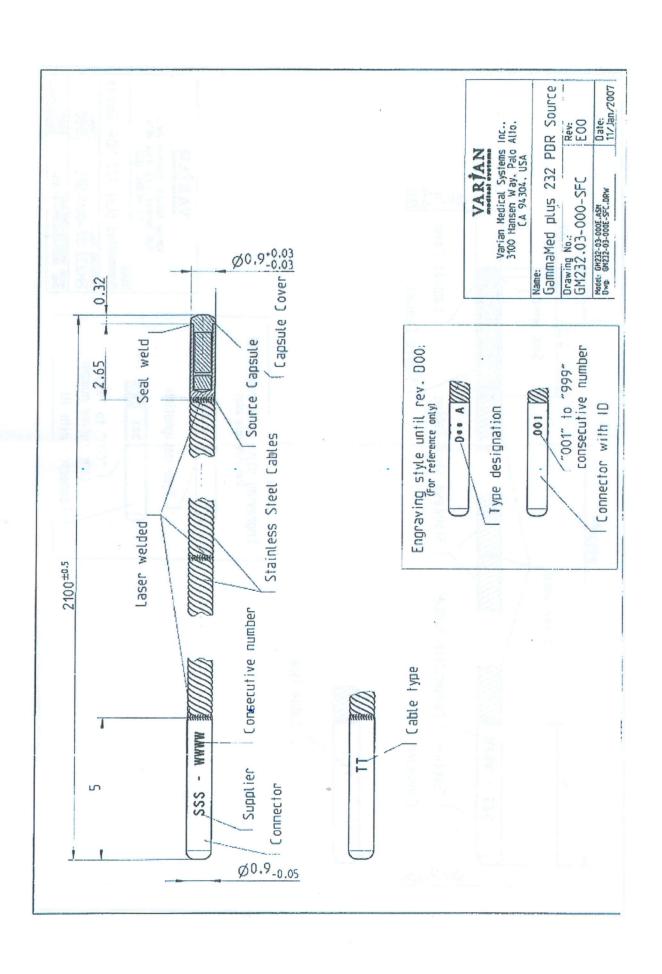
February 11, 2021

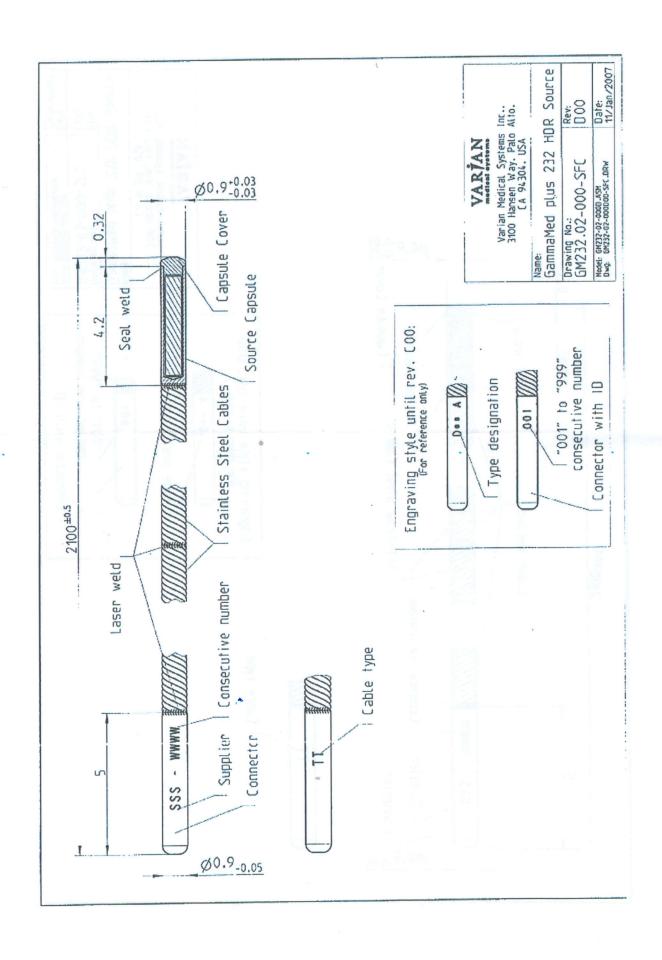
(DATE)

Revision 4 - Issued to extend the expiration date.











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CERTIFICATE NUMBER: USA/0723/S-96

ORIGINAL REGISTRANT(S):

Varian Medical Systems M/S LV1 6883 Spencer Street Las Vegas, NV, 89119 USA East Building, PHH-23 1200 New Jersey Ave, SE Washington, D.C. 20590



Varian Medical Systems Haan GmbH Bergische Strasse 16 42781 Haan Germany Phone +49-2129-551 1001 varian.com

Certificate for Type "A" Package

GAMMAMED two channel transport container: GM11001310

Drawing-No.: Tr131.08-000 (up to rev. K)

BAM approved QM-Plan: L12982 (rev. 2) / D/BAM/002/2018 Rev. 0

Maximum Activity: 1 TBq (27 Ci) Ir-192 for Varian Ir-192 sealed source

The Gammamed two channel transport container meets the Type "A" package requirements of the International Atomic Energy Agency Standards Series No. SSR-6 Regulations for the Safe Transport of Radioactive Material - 2012 Edition. The Gammamed two channel transport container meets the Type "A" requirements of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR release 01 January 2017).

Evaluation of the GAMMAMED two channel transport container has been done in form of physical and shielding integrity tests. A GAMMAMED two channel transport container was subjected to individual tests as prescribed in the IAEA and ADR regulation with no loss or dispersal of the radioactive contents. The damage sustained to the package did not result in a loss of shielding integrity which would result in a 20% increase in the radiation level at any surface of the package.

It is hereby certified, that the testing of the above mentioned Type "A" package has been completed and compliance with the requirements has been demonstrated.

The quality management plan according to BAM-GGR 016 rev 0 for design, manufacturing, testing, use, maintenance and periodic testing of transport containers is approved by the German competent authority BAM (Bundesanstalt für Material Forschung und -Prüfung - Federal Institute for material research and testing) D/BAM/002/2018.

Varian Medical Systems Haan GmbH

Managing Director / May 2, 2018

Varian Medical Systems Haan GmbH – Handelsregister Amtsgericht Wuppertal HRB 12701 Geschäftsführer: Rüdiger Grimm, John W. Kuo Commerzbank AG Wuppertal • IBAN: DE18330800300505437000 • BIC: DRESDEFF332

Doc-ID: TR3_003e rev05

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Note before transport:

- The GAMMAMED two channel transport container must be prepared for transport in accordance with the instructions provided (according to Tr131.09-006 rev. J and SVM-GM-WIRESHIP-B Dec 2016).
- Prior to transport the shipper must ensure, that the package is in good condition and free from contamination. If any damage is observed, the GammaMed transport container <u>must not</u> be used and the manufacturer or authorised agent must be contacted (according to PA M0022 rev 12).

Appendix: Pictures of transport container

Pictures of a typical Varian Ir-192 source

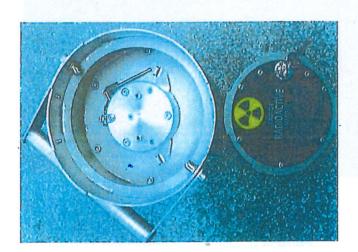
Pictures of the overpack of the transport container

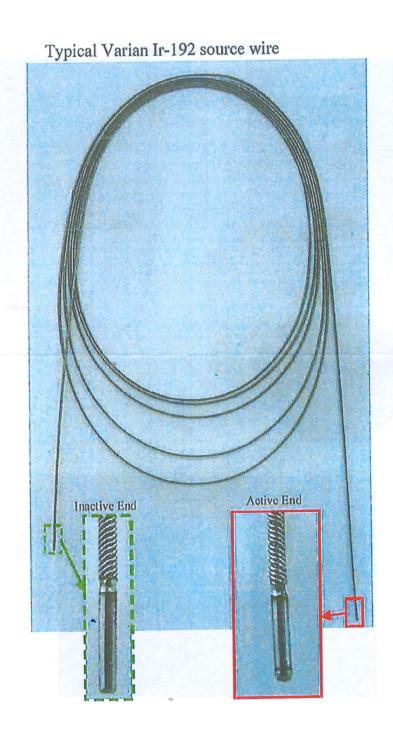
Transport Container











Overpack

