

# Federal Office for Radiation Protection



## Approval Certificate

**D/2016/B(U)-85 (Rev. 14)**  
for a type B(U) package for radioactive materials

In response to the application dated 08.04.2013 by the company NTP Radioisotopes (Europe) S. A., Fleurus, Belgium, (file number: JL-130408\_BFS\_TK), the **transport and working container** with the manufacturer designation **GammaMat TK 100** is approved as a type B(U) package for radioactive materials according to the following regulations for road, rail, ocean, inland waterway, and air transportation carriers:

Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA), No. TS-R-1, §817.

European accord dated September 30, 1957 on the international carriage of dangerous goods by road (ADR) (Federal Law Gazette 1969 II pg. 1489), attachments A and B in the version published on November 25, 2010 (Federal Law Gazette 2010 II pg. 1412), last modified by way of the 23rd ADR amendment dated March 08, 2013 (Federal Law Gazette 2013 II pg. 309).

Ordinance on the international carriage by rail of dangerous goods (RID) - attachment to appendix C of the convention concerning international carriage by rail (COTIF) dated May 09, 1980 (Federal Law Gazette 1985 II pg. 130) in the version published on May 16, 2008 (Federal Law Gazette 2008 II pg. 475), last modified by the 17th RID amendment dated November 9, 2012 (Federal Law Gazette 2012 II pg. 1338).

Attachment to the European Accord dated May 26, 2000 on the international carriage of dangerous goods by inland waterways (ADN) (Federal Law Gazette, 2007 II pg. 1906), last modified by the 4th ADN amendment dated December 3, 2012 (Federal Law Gazette 2012 II pg. 1386),

Ordinance on the domestic and international carriage of dangerous goods on road, by rail, and on inland waterways (GGVSEB) in the version published on January 22, 2013 (Federal Law Gazette 2013 I pg. 110),

International Maritime Dangerous Goods Code (IMDG-Code), Amendment 35-10,

Ordinance on the carriage of dangerous goods by sea (GGVSee) in the version published on December 16, 2011 (Federal Law Gazette 2011 I pg. 2784, 2012 I pg. 122), modified by article 4 of the ordinance dated December 19, 2012 (Federal Law Gazette 2012 I pg. 2715),

International Civil Aviation Organization - Technical Instructions for the Safe Transport of Dangerous Goods by Air, Edition 2013/2012,

Regulations on Certification and Licensing in Aviation in the version published on July 10, 2008 (Federal Law Gazette 2008 I pg. 1229), last modified by article 2 of the ordinance dated February 15, 2013 (Federal Law Gazette 2013 I pg. 293), in combination with the ICAO Technical Instructions,

in combination with the Federal Ministry of Transport, Building and Housing (BMVBS) guidelines in the version published on November 17, 2004 (VkBf. 2004 pg. 594) and the BMVBS bulletin on guidelines for the dangerous goods regulations dated July 1, 2010 (VkBf. 2010 pg. 282).

It is confirmed that the Federal Office for Radiation Protection, Salzgitter, is the agency authorized by the Federal Ministry of Transport, Building and Housing in accordance with section 7.9 of the IMDG code.

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**Approval holder:** NTP Radioisotopes (Europe) S. A.  
Zoning Industriel  
Avenue de l'Esperance  
B-6220 Fleurus, Belgium

**Documentation:** GammaMat TK30, TK100 and TK 1000, Renewals as B(U)-85, June 2013, with Table of Contents GammaMat TK 30, GammaMat TK 100, GammaMat TK1000, (file number: JL130611)

**Manufacturer name:** GammaMat TK 100

**Number of the package:** D/2016/B(U)-85

**Validity of the approval:** Up to and including June 30, 2016

**Allowable contents:** max. 3.7 TBq cobalt-60 or  
max. 1.5 TBq caesium-137 or  
max. 22 TBq iridium-192 or  
max. 3.7 TBq ytterbium-169 or  
max. 3.7 TBq thulium-170

respectively in a SPECIFIC FORM

**Package design:**

As per the inspection certificate from the Federal Institute for Materials Research and Testing (BAM), file number 1.2/11717, 1.2/11718, dated September 10, 1981 with the 1st addendum, file number 1.5/20452, dated February 22, 1985 and according to the BAM expert review dated 09.04.1991 (file number: 1.61 Ma/Sa/F28), dated 08.04.1994 (file number: 9.31/Nz) and dated 18.03.1997 (file number: III.32/Nz), and dated 18.04.2000 (file number: III.32/Nz), letter dated 08.12.2000 (file number: III.32/Nz), and with regard to radiation shielding according to testing by the Federal Office for Radiation Protection (BfS), the GammaMat TK 100 design meets the requirements imposed for type B(U) packages (Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990) by the International Atomic Energy Agency (IAEA); §§ 549 through 556). With the BAM report dated 05.08.2003 (file number: III.32/Dau), dated 19.02.2004 (file number: III.32/Dau), dated 19.12.2006 (file number: III.3/21211), dated 25.09.2009 (file number: III.3/21328) including the addendum dated 15.12.2009, dated 20.12.2012 (file number: 3.3/21477-2), and dated 14.06.2013 (file number: 3.3/21513-2) and according to BfS testing, it is confirmed that the requirements for continued use of the type B(U) package according to the interim regulation §817 of the Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA), No. TS-R-1, have been met.

**Description of the packaging:**

The shielding out of depleted uranium is permanently installed in a cylindrical stainless steel shell equipped with lugs and a base. A fully enclosed guide tube which can be opened with a control button equipped with a safety lock serves to receive the source and source holder. The control button is covered with a protective cap. The TK 100 design is approved in two versions (see appendix 2), with a steel shell used for version 1 in place of the aforementioned stainless steel shell.

**Dimensions and mass:**

	Version 1 and 2
Length:	423 mm
Width	240 mm
Height:	328 mm
Mass (total): (with protective plug and lid)	156 kg

At this point in time, the packages marked in appendix 2 through the BOM revisions (see also collateral clause no. 2) correspond to the approval at hand.

**Collateral clauses and considerations:**

1. All measures to ensure quality during the planning, fabrication, accompanying inspections, and operation must be performed according to the stipulations of the BAM dangerous goods regulation "Quality Assurance Measures of Packagings for Competent Authority Approved packages for the Transport of Radioactive Material " (BAM-GGR 011, Rev. 0).
2. Re-manufacturing of packages is prohibited.
3. This approval is only applicable in combination with the inspection certificate prepared for the corresponding production sample, which must be sent unsolicited to BAM and BfS. The deviations tolerated by BAM according to BAM-GGR 011, Rev. 0 as well as modifications according to collateral clause no. 7 must be documented in this inspection certificate. For production samples which have already been produced, the deviations tolerated by BAM and the modifications according to collateral clause no. 7 must be documented in the production sample test book.
4. It is necessary to ensure that every user of the packaging have themselves registered with the BfS before using the packing for the first time, and that he/she confirms that they have received and will observe the test book, which in particular contains the approval certificate, the user and maintenance manuals, and the inspection plan for periodic inspections. The user manual dated March 2013 (file number: SM4055.CON (v005)) and the plan for periodic and/or unplanned inspections, rev. 3 dated 23.05.2013 in combination with the checklist for maintenance and repairs (D002-en), version 003 dated May 29, 2013, are mentioned specifically. The use of documents with a higher revision index is only permissible within the framework of this approval following BAM approval and approval by the BfS in the form of an endorsement.
5. Every production sample must be permanently marked with the aforementioned label and with the date (month and year) of the next periodic inspection.
6. Every production sample must be subjected to periodic inspections on time. For production samples which are used outside of the Federal Republic of Germany, the periodic inspections can also be performed and certified by inspection personnel authorised by the responsible agency of the respective country. The certificates for the performed periodic inspections must be sent unsolicited to the BAM and the BfS.
7. Changes with regard to the BOMs and the drawings and material data pages listed therein on which the approval is based must be approved by the Federal Office for Radiation Protection in the form of an expanded type list (according to appendix 2) after approval by the BAM and before the start of fabrication. This also makes them part of this approval.
8. Special measures during transport are not required.
9. This approval doesn't release the consignor from the obligation of adhering to any regulations of a government of any state into or through which the package is being transported.
10. Use of the package for international transport is subject to the requirements of the multilateral approval process according to § 817 of the Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA); No. TS-R-1. Therefore approval of the package by the responsible agencies of all countries affected by the transport is required.

11. The transfer of ownership of the approval to a third party requires the prior written consent of the BfS. For this purpose, the following documents must be submitted to the BfS at least 4 weeks before the intended transfer: An agreement between the current and future holder of the approval which attests to the transfer of all rights and obligations associated with the approval, the quality management system of the future approval holder and the associated quality assurance program for the affected design, which need to be approved by the BAM according to the BAM-GGR 011 Rev. 0 requirements.

**Costs:**

1. Costs, fees, and expenses are charged for this report on the basis of §12 paragraph 1 and 2 of the law on the transport of dangerous goods (Gefahrgutbeförderungsgesetz - GGBefG) in the version published on July 7, 2009 (Federal Law Gazette 2009 I pg. 1774, amended pg. 3975), in combination with §1 paragraph 2 of the regulation concerning the costs involved with transporting dangerous goods (Gefahrgutkostenverordnung - GgKostV) dated March 7, 2013 (Federal Law Gazette 2013 I pg. 466). The fees are determined according to § 2 in combination with appendix 2 of the GgKostV.

2. In accordance with §12 paragraph 1 of the GGBefG in combination with §13 paragraph 1 no. 1 of the Administrative Costs Act (VwKostG) dated June 23, 1970 (Federal Law Gazette 1970 I pg. 821), last modified by article 6 of the law dated December 05, 2012 (Federal Law Gazette I pg. 2415), the costs shall be borne by the company NTP Radioisotopes (Europe) S. A., Belgium.



3. The costs are assessed through a separate report.

**Right of appeal:**

An appeal to this report can be entered within one month of notification. The appeal must be entered with the Bundesamt für Strahlenschutz, Willy-Brandt-Straße 5, 38226 Salzgitter, in writing or to be written down.

**Salzgitter, June 25, 2013**

On behalf of

Müller, U.

**Attachments**

Appendix

Attachment 1: Overview illustration: TK 30/ TK 100 by the company MDS Nordion Haan GmbH

Attachment 2: Types list

**- Attachment to the approval certificate D/2016/B(U)-85 (Rev. 14) -**

<b>Rev.-No.</b>	<b>Date of issue</b>	<b>Validity period</b>	<b>Reason for the revision</b>
0	20.02.1979	01.03.1982	Initial version
1	01.03.1982	01.03.1985	Extending the validity
2	25.02.1985	01.03.1988	Extending the validity, addition of the version 2 design
3	29.03.1988	31.03.1991	Extending the validity, modification of the requirements and/or the quality assurance measures
4	10.04.1991	30.04.1994	Changes to the traffic regulations, amending the collateral clauses and the identifier, extending the validity
5	27.04.1994	30.04.1997	Extending the validity, amending the collateral clauses
6	10.04.1997	30.04.2000	Extending the validity, amending the collateral clauses, revision of the drawings and BOMs
7	27.04.2000	30.04.2003	Extending the validity, revision of the collateral clauses, revision of the drawings and BOMs
8	14.05.2001	30.04.2003	Changing the company name, revision of the drawings and BOMs, revision of the collateral clauses, implementation of the types list
9	07.08.2003	29.02.2004	Extending the validity, changing the approval holder, revision of the user manual, adaptation to modified legal requirements
10	27.02.2004	31.12.2006	Extending the validity, new quality management system, adaptation to modified legal requirements, amending the collateral clauses
11	08.01.2007	31.12.2009	Extending the validity, adaptation to modified legal requirements, quality management system revised, amending the collateral clause 2, expanding on the source holder types list
12	18.12.2009	31.12.2012	Extending the validity, adaptation to modified legal requirements, quality management system revised.
13	21.12.2012	30.06.2013	Extending the validity, new approval holder, documentation revised, adaptation to modified legal requirements, new collateral clause no. 11
14	25.06.2013	30.06.2016	Extending the validity, new approval holder, documentation revised, adaptation to modified legal requirements



**- Attachment 2 to the approval certificate D/2016/B(U)-85 (Rev. 14) -**

**Types list for the shipping and working container GammaMat TK 100**

Shipping/working container type GammaMat TK 100, including the associated source holder, which are or were fabricated according to the following BOMs, corresponding to the design described in this approval certificate (also see collateral clauses no. 2, 3, and 7).

BOM revisions	BAM approval
<b>Version 1</b>	
TK 320.02 MA "b" dated 25.08.1971 (drawing with BOM)	Inspection certificate no. 1.2/11717 and 1.2/11718 dated 10.09.1981
<b>Version 2</b>	
TK 320.02 dated 21.08.1980	Inspection certificate no. 1.2/11717 and 1.2/11718 dated 10.09.1981
TK 102.03-000 dated 14.11.1984	1. Addendum to the inspection certificate (file number: 1.5/20452) dated 22.02.1985
TK 102-03.000, page 1 index A dated 16.01.1989 page 2 index A dated 16.01.1989 page 4 index A dated 16.01.1989 page 5 index A dated 16.01.1989	Letter (file number: 1.2/13183) dated 19.01.1990
TK 102-03.000, index B dated 05.09.1990	Letter (file number: 9.31/Nz) dated 08.04.1994
TK 102.03-000, page 1 index B dated 16.01.1996 page 2 index C dated 16.01.1996 page 3 index A dated 16.01.1996 page 4 index B dated 16.01.1996 page 5 index B dated 16.01.1996	Letter (file number: III.32/Nz) dated 20.06.1996
TK 102.03-000, page 1 index C dated 13.03.2000 page 2 index D dated 13.03.2000 page 3 index A dated 16.01.1996 page 4 index C dated 13.03.2000 page 5 index B dated 16.01.1996	Letter (file number: III.32/Nz) dated 18.04.2000
TK 102.03-000, page 2 index E dated 30.08.2000 page 3 index B dated 30.08.2000	Letter (file number: III.32/Nz) dated 08.12.2000
<b>BOM Revision Source holder</b>	<b>BAM approval</b>
H 811.15-000 dated 20.11.1984 H 811.18-000 dated 20.11.1984 H 814.05-000 dated 20.11.1984 H 814.14-000 dated 20.11.1984	1. Addendum to the inspection certificate (file number: 1.5/20452) dated 22.02.1985
H 811.28-000 "-" dated 09.03.1993 H 811.29-000 "-" dated 09.03.1993	Letter (file number: III.32/Nz) dated 30.11.1993
H 811.06-2, index A dated 10.03.1994 H 811.29-00, index A dated 15.03.1994	Letter (file number: 9.31/Nz) dated 25.04.1994
H 811.15-000, index B dated 18.10.1994 H 811.18-000, index B dated 18.10.1994 H 811.28-000, index C dated 21.03.1995 H 811.29-000, index D dated 21.03.1995	Letter (file number: III.32/Nz) dated 20.06.1996
K 126204-002 index C dated 02.05.2006	Report dated 19.12.2006 (file number: III.3/21211)

Salzgitter, June 25, 2013

Im Auftrag

  
Müller, U.

