BUNDESAMT FÜR STRAHLENSCHUTZ

Certificate of Approval

D/2011/B(U)-85 (Rev. 12)

Authorisation Certificate for a Package Model for radioactive material

Based on the application by MDS Nordion S.A, Fleurus of May 15th, 2009 (ref ACl/IG/09018), the container specified by the manufacturer as **GammaMat TI** has been approved as package design of the Type B(U) for the carriage of radioactive materials for transportation by road, rail, sea, inland waters and air according to the following regulations:

Regulations for the Safe Transport of Radioactive Materials, 2005 Edition, International Atomic Energy Agency (IAEA), No. TS-R-1 &817,

European agreement of September 30th 1957 on the international transport of dangerous goods by road (ADR) (BGBI. 1969 II S. 1489), In the version of the announcement of the new version of appendix A and B of April 7th, 2009 (BGBI 2009 II S. 396), Appendix A and B,

Decree for the International Transport of Dangerous Goods by Rail (RID), appendix I to appendix C of the Agreement on the International traffic by Rail (COTIF) of May 9th, 1980 (BGBI. 1985 II S.130), In the version of the May 16th 2008 announcement (BGBI. 2008 II S. 475), last amended by the 14 RID modification of November 14th, 2008 (BGBI. 2008 II S. 1334),

Regulation about the transportation of dangerous goods on the Rhine (ADNR) (BGBl. 2003 II S. 648), Lately amended by the 8th ADNR regulation change of June 17th, 2009 (BGBl. 2009 II S. 595);
Appendix to the European agreement of May 26th, 2000 about the international transportation of dangerous goods on inland water (ADN) (BGBl. 2007 II S. In 1906), lately amanded by the 1th change regulation ADN of June 05th, 2009 (BGBl. 2009 II S. 534),

Regulations on the national and border crossing transport of dangerous goods by road, by railways and on inland waters (GGVSEB) of June 17th 2009 (BGBI.2009 I S.1389).

International Maritime Dangerous Goods Code (IMDG-Code), Amendment 33-06,

Regulations on the Transport of Dangerous Goods by vessel (GGVSee) of December 3rd 2007 (BGBI. 2007 I S. 2815),

International Civil Aviation Organisation – Technical Instructions for the Safe Transport of Dangerous Goods by Air, Edition 2009/2010,

Decree on Transport by air – version published on July 10th, 2008 (BGBI. 2008 I S. 1229), in connection with the ICAO Dangerous Goods Instructions (ICAO Technical Instructions),

in connection with the rules of the Federal Ministry of Transport, Building and Urban Development (BMVBW) of November 17th 2004 (VkBl. book 23, p. 594, 2004) and February 20th 1991 (VkBl, book 4, page 231, 1991),

It is confirmed that Bundesamt für Strahlenschutz (BAM) at Salzgitter, is the authorised administration appointed by the Federal Ministry of Transport, Building and Urban Development, according to chapter 7.9 of the IMDG - Code, German.

Owner of approval:	MDS Nordion S.A. Zoning Industriel Avenue de l'Espérance B-6220 Fleurus, Belgium
Documents:	GammaMat TI, TI-F and TI-FF, renewals as B(U)-85, May 2009, with table of contents GammaMat TI, GammaMat TI-F, GammaMat TI-FF, (ref.: AC1090514)
Marking of the Package design:	**D/2011/B(U)-85**
Validity of the certificate:	**until December 31, 2012**
Authorised contents:	0,19 TBq of Cs-137 or 1,5 TBq of Ir-192 or 3.7 TBq of Yb-169 or 3.7 TBq of Tm-170 all in Special Form

Packaging design:
According to test certificate by BAM of 10th September 1981 (ref no. 1.2/11713, 1.2/11719 in connection with experts' opinion of 8th December 1989 (ref no. 1.52 Ma/sei), and the letter from BAM of 9th December 1992 (ref no. 9.31/Nz), of 23rd February 1996 (ref no. III.33/Nz), of 2nd December 1998 (ref: III.32/Nz), of 22nd November 2000 (ref: III.32/Nz), of 7th February 2001 (ref: III.32/Nz) the design GammaMat TI fulfils the requirements for a Type B(U) Package (IAEA Regulations 1985 Edition - as amended 1990). With BAM statement of 04.03.2004 (ref.: III.32/Dau), of 19.12.2006 (ref.: III.3/21210) as well as of25.09.2009 (AZ: III.3/21327), including the addendum from 15.12.2009 and further to examination by the BFS, it is confirmed that the requirements for the further usage as a type B(U) shipment package are as per the temporary arrangement, § 817, the regulations for the safe transport of radioactive material, 2005 edition, International Atomic Energy Agency (IAEA), No. TS-R-1 fulfilled.

Description of the packaging:
The shielding of depleted uranium is firmly incorporated in a cylindrical stainless steel shell furnished with handle and base. A universally enclosed guide channel adapted to be opened by a switch button including a safety lock, serves to receive the radioactive source on its source-holder. The switch button is covered by a protective cap.

The design model GammaMat TI has been approved in various versions VA, version 100.10, version 100.11 and version 100.13.

Dimensions and weight:

	Version VA	Version 100.10 and Version 100.11	Version 100.13
Height	156 mm	156 mm	156 mm
Width	110 mm	110 mm	110 mm
Length	246 mm	238 mm	252 mm
Mass	12,5 kg	12,5 kg	13,0 kg

Drawings
Version Va:
Drawing no.: TI 100.00 Va of 11.06.1969 to amendment index "f"

Version 100.10 and Version 100.11:
Drawing no.: 100.10-000 and 100.11-000 of 28.08.1980

Version 100.13:
Part List no.: TI 100.13-000, Sheet 1 Index "E" of 10.11.2000, Sheet 2 Index F of 15.08.2000 and Sheet 3 Index C of 15.08.2000 together with the respective assembly drawing: TI 100.13-000 Index "B" of 27.03.2000

Link Type Source Holder:
Drawing no.: K 126204-005 index "B" of 02.05.2006 together with part list no.: K 126204-005 index "B" of 02.05.2006.

Special Requirements and Recommendations:

1. All quality ensuring measures during planning, manufacture, the accompanying controls and the operation must correspond to the regulations according to the technical measures on quality-ensuring (QM) and controlling (QÜ) of packages for the transport of radioactive materials (TRV 006) of BMV (Publication VkBl. Book 4, 233, 1991).

2. New manufacture of the packages is not allowed.

3. This certificate is valid only for devices till Serial number 1550 without certificate of acceptance and beginning with serial number 1550 only with the relevant certificate of acceptance of the device. Every time a copy of the certificate of acceptance has to be sent unrequested to BAM and BfS. Changes tolerated by BAM according to TRV 006 as well as changes according to rider No.8 have to be documented in this certificate of acceptance. On devices which are still produced the tolerated changes of BAM and the changes of the changes according to rider No. 8 have to be documented inside of the checking book.

4. It has to be ensured that prior to the first use of the package, every user of the same must apply for registration with the BfS confirming that he has obtained the test book which contains in particular the approval certificate, the operating and maintenance instructions and the test schedule for recurrent inspections, and will observe the same. Specifically stated are the User's manual (ref. SI14050.CON – de), version 1 of December 5, 2003 and the Test Plan for recurring and/or extraordinary maintenance, rev. 2, of February 16, 2004 in relation with the check List for maintenance and repairs (ref. D003-de), version 2 of March 2004. The use of documentations with a higher Revision Index is only allowed in scope of the existing accreditation after an agreement of the BAM and of the approval through the BFS

5. Prior to each transport it has to be ensured that the guide channel is closed and te protective caps are tightened.

6. Each production model must be permanently provided with the above stated characteristics and date (month, year) showing the next recurrent inspection.

7. Every production model must be subject to the recurrent inspections in due time. The recurrent inspections for all production models which are used exclusive out of Germany can be executed by inspectors authorised from the country authorities. The certificates about the recurrent inspections have to be sent to the BAM and BfS unsolicited.

8. Amendments regarding the drawings, part lists and material data sheets on which the approval is based, have to be approved – after released by the BAM - by the BfS in the form of a consent to the amendment certificate – prior to starting manufacture (in accordance to Appendix 1). After that they will be an integral part of this approval.

9. Special measures during transport are not required.

10. This approval certificate does not exempt the sender from the necessity of observing possible regulations of the respective country which is involved in the transport with this package.

11. The use of the shipping package by international transports is subject to the requirements of the multilateral approval operation according to §817 of the regulations for the Safe Transport of radioactive Material, 2005 Edition, International Atomic Energy Agency (IAEA); No TS-R-1. In consequence, the approval of the shipping package by the competent authorities of all the transport bordering countries is required.

Costs:

1. Based on paragraph 12, part 1 and 2 of the Regulations on the Transport of dangerous Goods (Law on Transport of Dangerous Goods – GGBefG) in the version of notification of September 29, 1998 (BGBI. I p. 3114), last amended by article 294 of the new adaptation of competence regulation of October 31st 2006 (BGBI. I S 2407), in connection with article 1 and appendix (to article 1), chapter I, charge code 007 of the Regulation on costs for Measures for the Transport of Dangerous Goods (GGKostV) of November 13, 1990 (BGBI. I p. 2490), amended by the third regulation on the Amendment of Legal provisions on Dangerous Goods of December 17, 2004 (BGBI. I. S. 3711), cost shall be raised – fees and expenses – for this document.

2. According to the paragraph 12, part 1 of the Regulations of the Transport of Dangerous Goods in connection with paragraph 13, part 1, n° 1 of the Regulation on management Costs of June 23rd 1970 (BGBI. I p.821), last amended by the regulation Article 3 of the law related to the change of liability riles of the nuclear law and to the change of some legal rules dates August 29th, 2008 (BGBI. I, S. 1793) MDS Nordion S.A., Fleurus, Belgium has to bear the costs.

3. The definition of these costs results by separate information.

Instructions for legal remedy
An opposition may be lodged from this office action within one month after publication. The opposition should be lodged to the Bundesamt für Strahlenschutz, Willy-Brandt-Straße 5, 38226 Salzgitter, in writing or raised for record.

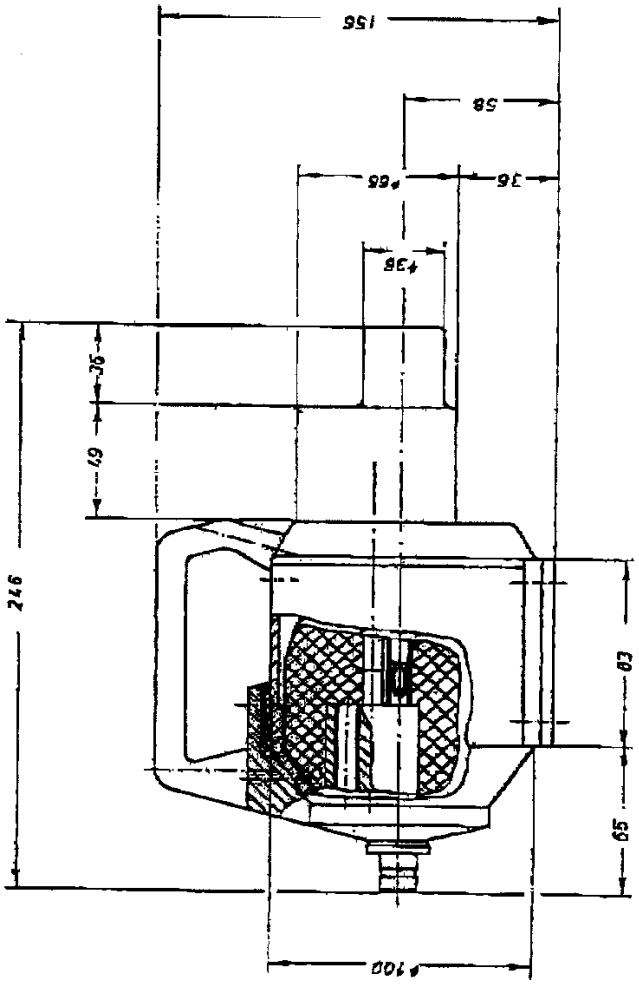
Salzgitter, December 18th 2009

By delegation,

Signed Müller

Enclosures
Appendix
Annex with 3 Drawings
Sheet 1 for version Va,
Sheet 2 for version 100.10 as well as 100.11 (Gammamat TI series 2) and
Sheet 3 for version 100.13 with the new drawing number K425602-001, Is. A, of the Fa. MDS.

Rev.N°	Date of issue	Date of validity	Reason for revision
0	01.02.1979	01.02.1982	First issue
1	03.07.1980	03.07.1983	Extension of validity, modification of contents
2	07.03.1983	07.03.1986	Extension of validity, supplement for the design versions TI 100.10 and TI 101.11
3	06.03.1986	28.02.1989	Extension of validity, supplement for the design version TI 100.13-000
4	20.02.1989	28.02.1992	Extension of validity, modification of injunctions
5	28.02.1990	28.02.1993	Extension of validity, additional quality ensuring measures
6	16.02.1993	28.02.1996	Amendment of transport regulations, amendment of special requirements and recommendations, extension of validity
7	28.02.1996	28.02.1999	Extension of validity, amendment of drawings and regulations
8	16.02.1999	28.02.2002	Amendment of validity and regulations
9	20.03.2001	20.03.2004	Prolongation of validity, new owner of Approval, amendment of Part Lists and drawings, revision of Side Regulations
10	18.03.2004	31.12.2006	Extension of validity, new Quality Management System, Adaptation on the base of the changed statutory provisions, change of side regulations.
11	05.01.2007	31.12.2009	Extension of validity, revision of the Quality Management System, change of side regulations 2, adjustment to changed regulation, new part list for the source-holder.
12		31.12.2012	Extension of validity, review quality management system of the adaptation to the legislation changes



MDS Nordion SA
B 6220 Belgium

Gammamat T1

Bl. Nr. 1
Bl. pos. 1
Index A

Zeichnungs Nr: T1100.00 Va

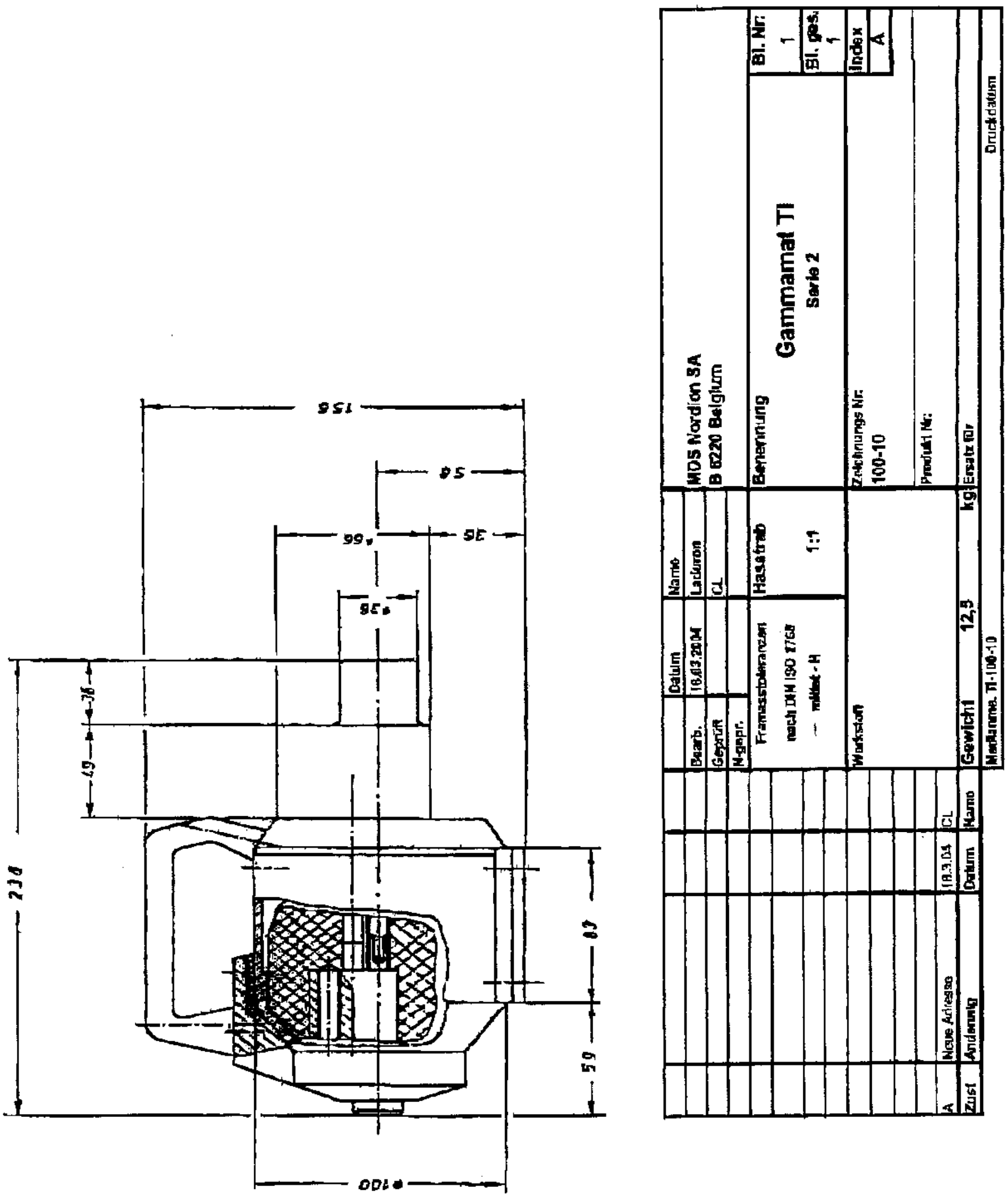
Werkstoff

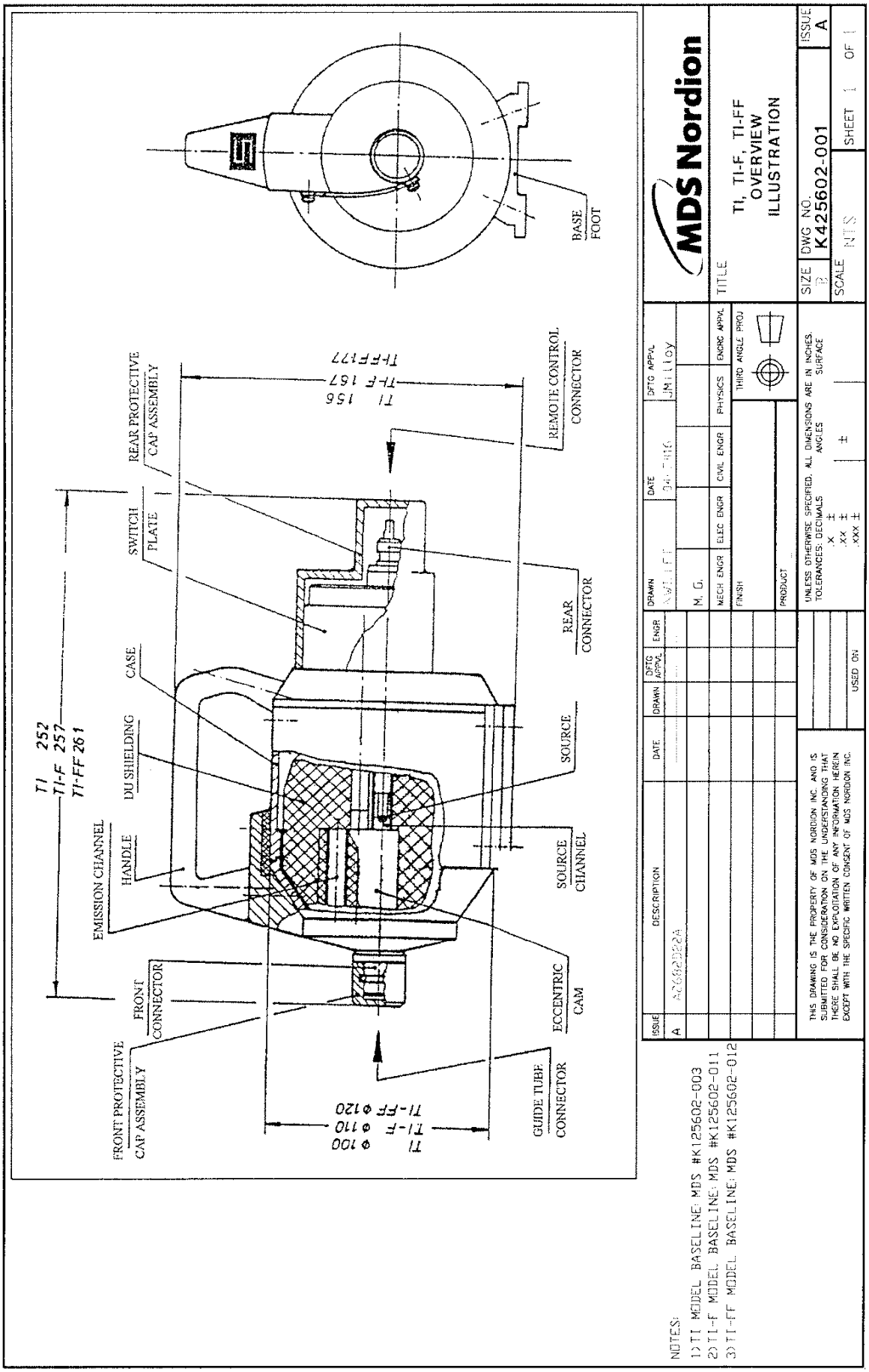
Gewicht 12,5 kg

Ersatz für

Neuanlage T1-100.00 VA

Druckdatum


MDS Nordion SA
B 6220 Belgium
Gammamat TI
Serie 2
100-10
1:1
12,5


TI 252
TI-F 257
TI-FF 261
EMISSION CHANNEL
HANDLE
DU SHIELDING
CASE
SWITCH PLATE
REAR PROTECTIVE CAP ASSEMBLY
FRONT CONNECTOR
FRONT PROTECTIVE CAP ASSEMBLY
ECCENTRIC CAM
GUIDE TUBE CONNECTOR
SOURCE CHANNEL
SOURCE
REAR CONNECTOR
REMOTE CONTROL CONNECTOR
BASE FOOT
TI Φ100
TI-F Φ110
TI-FF Φ120
TI 155
TI-F 167
TI-FF 177
NOTES:
1) TI MODEL BASELINE: MDS #K125602-003
2) TI-F MODEL BASELINE: MDS #K125602-011
3) TI-FF MODEL BASELINE: MDS #K125602-012
MDS Nordion
TITLE
TI, TI-F, TI-FF
OVERVIEW
ILLUSTRATION
SIZE B
DWG NO. K425602-001
ISSUE A
SCALE NTS
SHEET 1 OF 1