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447 March Road Fax: 613-592-2006  
Kanata, Ontario  
Canada, K2K 1X8



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**Fax Transmission**

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To: Mr. William R. Ward  
Company: U.S.N.R.C.  
Sender: Marc-André Charette

Fax: (301) 415-5369  
Date: August 30, 2001  
Copy:  
Total # of pages including this page: 14

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Dear Mr. Ward:

Please find attached a letter in response to your email of August 29, 2001. The original will follow in the mail.

If you have any questions or require further information, please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at [mcharette@mds.nordion.com](mailto:mcharette@mds.nordion.com).

Yours sincerely

A handwritten signature in cursive script that reads 'Marc-André Charette'. The signature is written in black ink and is positioned above the printed name.

Marc-André Charette

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If transmission is incomplete or unclear, please contact the sender.

147 March Road  
Kanata, Ontario  
Canada K2K 1X8  
Tel: 613 592-2790



August 30, 2001

Mr. William R. Ward  
Mail Stop: 6F18  
United States Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD  
20852-2738

**RE: Sealed Source Registration for MDS Nordion Haan, GammaMed 212**

Dear Mr. Ward:

Thank you for your email of August 29, 2001, in which you requested further clarifications.

1. In section 9, Quality Assurance and Control, you stated that a tensile load of 60 Newtons (13.5 pounds) is applied to test the attachment of the source capsule to the cable. Please provide the length of time that this stated force is applied.

The tensile load applied to the attachment of the source capsule to the cable during the Mallinckrodt manufacturing process is 60 Newtons for a period of two minutes.

It should be noted that tensile force applied to the attachment of the source capsule to the cable during the MDS Nordion S.A. manufacturing process will be 40 Newtons for a period of ten seconds. Cycle testing was performed on the GammaMed 12i and 12it with the sealed source manufactured by MDS Nordion S.A. The sources were tested to 5000 cycles. Under these conditions the sources performed their cycles without any problems. This exceeds the 740 maximum treatments (10 treatments/day) expected for this source based on the half-life of Iridium 192. Please find attached the test report.

2. For comparison to the testing force mentioned in question 1 above, please provide the maximum tension which can be applied by the GammaMed 12i/12it device which you intend to use this source in.

The maximum force exerted by the GammaMed 12i and 12it is 25 Newtons.

3. Please provide a copy of the current ISO 9001 certificates for both MDS Nordion in Canada, and MDS Nordion Haan GmbH. The copy of the certificate previously provided expired in May 2001.

Please find attached the ISO 9001 certificates for both MDS Nordion and MDS Nordion Haan GmbH.

4. The FDA clearances you received for the GammaMed 12i and 12it devices appear to have been based on use of the device with the currently approved source for the device, a CIS-US Inc. model 724. Please provide documentation showing that these FDA clearances have been updated to include the GammaMed 212 source.

The USFDA clearances received for the GammaMed 12i and 12it included the CIS-US Inc. model 721 and 724 sealed sources. MDS Nordion has performed an assessment based on the USFDA, Center for Devices and Radiological Health, guidance document titled, "Deciding when to submit a 510(k) for a change to an existing device." It was concluded based on the guidance document that a new 510(k) was not required. This decision has been documented.

If you have any questions or require further information please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at [mcharette@mds.nordion.com](mailto:mcharette@mds.nordion.com).

Yours sincerely



Marc-André Charette  
Regulatory Affairs Senior Associate

Enclosed: ISO 9001 Certificate MDS Nordion and MDS Nordion Haan, Test protocol TP/HK100401/01

Copy to: Ann Warbick Cerone, Scott McIntosh, David Gill, MDS Nordion  
Dr. Wolfgang Nuding, Jurgen Handke MDS Nordion Haan



SGS International Certification Services Canada, Inc.  
SGS Services de Certification Internationale Canada Inc.

Certificate Number/Numéro de certificat

**749/97**

This is to certify that the Quality Management System of:  
Le présent certifie que le système de gestion de la qualité de:

***MDS Nordion Inc.,  
Therapy Systems  
447 March Road  
Kanata, Ontario  
K2K 1X8***

Has been assessed and registered as meeting the requirements of ISO 9001:1994.  
The scope of registration is as follows:  
A été évalué et enregistré conformément à la norme ISO 9001:1994. Le domaine  
d'enregistrement est présenté ci-dessous:

**Design, manufacture, distribute and service radiation emitting devices,  
hardware and software used for medical and industrial purposes.  
Manufacture specialty products and supply services under contract.**

Signed for and on behalf of SGS International Certification Services Canada Inc.  
Document signé pour et au nom de SGS Services de Certification Internationale  
Canada Inc.

*September 3, 1999 - Issue 2*  
(Registered since November 27, 1997)  
(Revision 2 - June 22, 2001)

*Le 3 septembre, 1999 - Édition 2*  
(Enregistré depuis le 27 novembre, 1997)  
(Révision 2 - le 22 juin, 2001)

This certificate remains valid subject to satisfactory maintenance of the system.  
Certificat valide sous réserve du maintien satisfaisant du système.

**SGS International Certification Services Canada Inc.  
SGS Services de Certification Internationale Canada Inc.**  
Unit 2, 6275 Northam Drive, Mississauga, Ontario, Canada L4V 1Y8



This is not a legal document and cannot be used as such. This  
certificate remains the property of SGS ICS to whom it must be  
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Ce document n'est pas légal et ne peut être utilisé à cette fin. Ce  
certificat demeure la propriété de SGS SCI, à qui il doit être renvoyé  
sur demande.





# CERTIFICATE

The TÜV CERT Certification Body  
of RWTÜV Anlagentechnik GmbH

hereby certifies in accordance with TÜV CERT  
procedure that

**MDS Nordion Haan GmbH**  
42781 Haan  
Germany

has established and applies a quality system for

- Devices and accessories for non-destructive testing with gamma radiation and
- Medical devices and accessories for radiation therapy

An audit was performed, Report No. 20454247

Proof has been furnished that the requirements according to

DIN EN ISO 9001 : 1994 / DIN EN ISO 46001 : 1996

are fulfilled. The certificate is valid until 14.12.2003

Certificate Registration No. 041056328



Essen, 10.07.2001

**RWTÜV**

*[Signature]*  
TÜV CERT Certification Body  
of RWTÜV Anlagentechnik GmbH



<b>TP</b>	<b>Test protocol</b>  <b>Cycle Testing on GammaMed 12i(t) medical Needles manufactured by MDS Nordion S.A. / Fleurus/B</b>	Identification: TP/Hk100401/01
		Rev. 01

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Author:

18.04.2001  
Date:

*M. K. eda*  
Signature / Manager Design Support MDS Nordion Haan GmbH

Released:

23.04.01  
Date:

*W. Neuling*  
Signature / Manager Quality Assurance MDS Nordion Haan GmbH



### 1. Purpose

The purpose of these tests was to evaluate the quality of the welding process and the mechanical parameters of GammaMed 12i(t) medical needles manufactured by MDS Nordion S.A. / Fleurus/B in comparison to the specifications for use at clinical site.

In addition the stability of the mechanical parameters of the drive system were controlled over their lifetime cycle.

### 2. Description of the Hardware and Software / Test Standard

#### 2.1 Hardware and Software

The tests were performed at MDS Nordion Haan GmbH in Germany by:

Mr. Michael Hoppe

Mr. Jürgen Handke

from the local Design Support Group.

The following test materials and equipment were used:

- GAMMAMED 12i(t) serial No: Device 700  
Device 731  
Device 748  
Device Testgerät EE
- Firmware: TS 000002
- Control-Software: ServPlus SP01.08
- Source guide tube: Muster A3 / X40; for use with applicator  
11-00204, Catheter 3,2 (no Lot#)  
no applicator attached
- Applicator: different metallic, bend probes

#### 2.2 Test Standard

The tests were performed according to the test standard PA M 0207/Revision 01 „Prüfplanung für Antriebe, Strahler und Dummykabel für GammaMed 12i(t) Geräte“.

### 3. Test Results and Summary

#### 3.1 Cycle Testing medical needles

A total of ten needles have been tested.

According to the specifications needle one to five had the following configuration:

- HDR capsule size
- Capsule not filled with pellet
- He leak test and tensile test (15 N) on capsule prior to cycle testing
- Tensile test (40 N) on cable assembly prior to cycle testing

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According to the test instructions the cycle specification for needle one to five was set to the user specifications of 5000 cycles.

According to the specifications needle six to ten had the following configuration:

- HDR capsule size
- Capsule filled with pellet

The cycle specification for needle six to ten was set to a maximum of 15000 cycles.

All data regarding the manufacturing of these needles are summarized in the document "Validation Program: Step 2: Manufacture of Needles for Validation".

### 3.1.1 Results

The following table shows the results of the cycle testing for each individual needle. The mechanical parameter that were controlled were:

- Length
- Flexibility
- Diameter

The measurements of the different mechanical parameter is displayed with ok or not ok:

needle	cycles	length	diameter	flexibility		Applicator
				rigid cable	flexible cable	
1	5000	ok	not ok <sup>2)</sup>	ok	ok	bend <sup>1)</sup>
2	5000	ok	ok	ok	ok	bend
3	5000	ok	ok	ok	ok	bend
4	5000	ok	ok	ok	ok	bend
5	5000	ok	ok	ok	ok	bend
6	12500	not ok <sup>1)</sup>	ok	ok	ok	straight
7	10000	ok	not ok <sup>2)</sup>	ok	ok	straight
8	10000	ok	not ok <sup>2)</sup>	ok	ok	straight
9	7500	not ok <sup>1)</sup>	not ok <sup>2)</sup>	ok	ok	straight
10	10000 <sup>3)</sup>	ok	ok	ok	ok	straight

Table 1: Overview of cycle data needle



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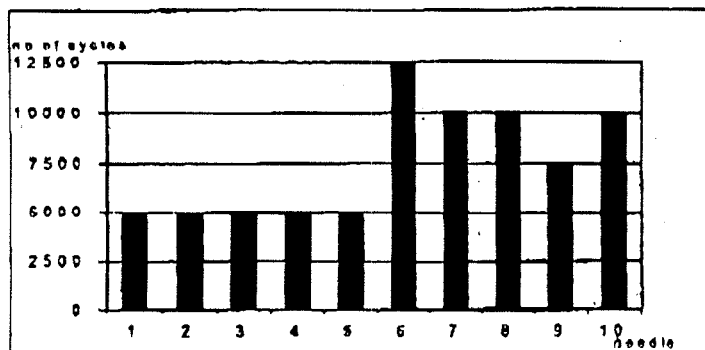


Diagram 1: cycle data needle

**Summary:**

- 1) Needles out of length specification:
  - Needle 6: after 12500 cycles 0.5 mm out of length specification
  - Needle 9: after 7500 cycles 0.5 mm out of length specification
- 2) Needles out of diameter specification
  - Needle 1: after 5000 cycles 0.1 mm out of diameter specification



Picture 1: Needle 1 at proximal end at the end of cycle testing

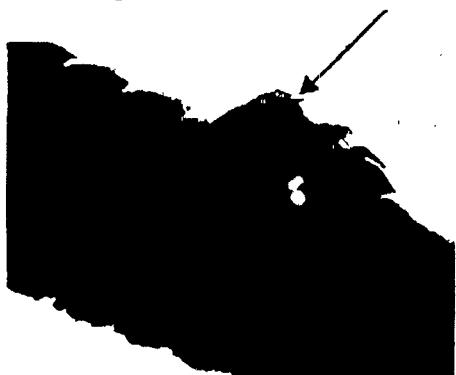


- Needle 7: after 10000 cycles 0.03 mm out of diameter specification, the needle was cycled up to 12500 cycles with no indication for problems resulting out of the diameter extension. Final change in diameter + 0.23 mm.



Picture 2: Needle 7 at proximal end at the end of cycle testing

- Needle 8: after 5000 cycles 0.06 mm out of diameter specification, the needle was cycled up to 10000 cycles with no indication for problems resulting out of the diameter extension. Final change in diameter + 0.2 mm.

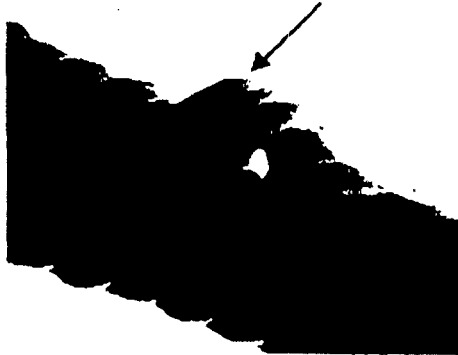


Picture 3: Needle 8 at proximal end at the end of cycle testing

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- Needle 9: after 5000 cycles 0.13 mm out of diameter specification, the needle was cycled up to 7500 cycles with no indication for problems resulting out of the diameter extension. Final change in diameter + 0.16 mm.



Picture 4: Needle 9 at proximal end at the end of cycle testing

- <sup>3)</sup> Needle 10 was destroyed by the test Device after 10443 cycles. The needle was ruptured apart approx. 60 cm from the proximal end. The test was stopped and both Device and needle were investigated.
  - Investigation on the test device:  
The test device was internally investigated and the following explanation is seen as the reason for an unexpected appearance of shearing forces that led to the needle break. In the assembly "Shielding" was an old version of the subassembly # 20 "Lagerflansch" built in. The following picture in comparison with the attached drawing # GM 212.31-000 "shielding complete" shows the difference in the missing part of drawing # GM212.01-022 "Hülse":



Picture 5: Lagerflansch

The old revision of the "Lagerflansch" leads to less guidance for the both the dummy and source cable in this area. In case of dummy cycling when the dummy hits the end of the source guide tube the force that is applied to the cable is able to push the cable itself against the edge of the outlet (see arrow) and shearing forces can be applied to this area of



the cable. The point of break on the cable (approx. 600 mm from the proximal end) supports this theory because the distance from the limit switch ESUD to the "Lagerflansch" is measured with approx. 600mm.

- Investigation on the needle:

The needle was investigated by an independent material expert from the Initiative zur rechnerintegrierten Fertigung e.V. in Dortmund, Germany. As a summary of the investigation report it can be stated that shearing is seen as the cause of the rupture (see also investigation report "Analyse des Bruchs eines Dummy-Strahlerkabels")

<sup>4)</sup> e.g. 12i applicator probe 320mm 11-00252

### 3.2 Cycle Testing drive system

A total of four systems have been tested.

According to the specifications the drive systems had the following configuration:

- Dummy Drive System
- Drawing No.: GM 212.09-000
- Drive System adjusted at start of the test to  $17 \pm 0.5$  N

According to the test instructions the cycle specification for the drive system was set to 15000 cycles. Within these 15000 cycles the drive system is specified to a max of  $25 \pm 1$  N

#### 3.2.1 Results

The following table shows the results of the cycle testing for each individual drive system. The mechanical parameter that was controlled was:

- Friction force

The measurements of the mechanical parameter is displayed with the actual measuring result, at 0 cycles the drive system was adjusted according to AW M0030 "Fertigung und Test von Dummy- und Quellenantrieben":

Cycles	No Drive System			
	57	293	744	782
0	17	17	17,25	17
5000	17,5	20	17,5 <sup>1)</sup>	20,5
10000	18	19	18,5	18
15000	18	19,5	18,5	21

Table 2: Overview of cycle data drive system

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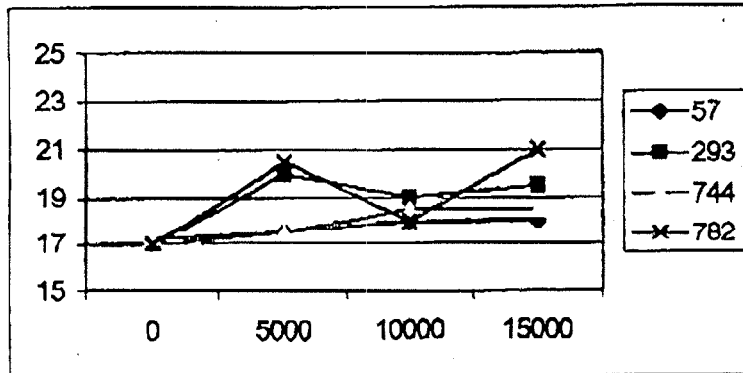


Diagram 2: Diagram of cycle drive system

**Summary:**

- The drive systems have been cycled up to 15000 cycles and remained within the specification of  $25 \pm 1$  N.
- <sup>1)</sup> The drive system # 744 had to be adjusted to 17.5 N because the measurement showed a result of 15 N (the min. specification is 17 N).

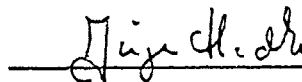
**4. Date and Signature**

- All ten needles have been tested up to 5000 cycles. Four out of ten needles have been out of specification in diameter by 0.03 to 0.13 mm. Under these conditions the needles still performed there cycle program without problems. The cycle program on needle 9 was interrupted after 7501 cycles with the error message "Dummy pushed in channel 01 at xx mm" and the device was returned to a save status. No further indication for mechanical problems within the mechanical parameters were observed at 5000 cycles.
- Five needles have been further tested and reached their cycle limitation between 7500 and 12500 cycles.
- The drive systems have been cycled up to 15000 cycles and remained within the specification of  $25 \pm 1$  N.
- The test results for the He leak test and the destructive tensile test for needle one to five have to be documented separately.

Date:

18.04.2001

Signature:



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## 5. Listing of Tests

/	Validation Program	/
	Step 1: Destructive tensile test on welding	
DOSD 6.04e	Test Readiness Review	Rev. 01
	Validation tests for GammaMed source production in Fleurus	
/	"Analyse des Bruchs eines Dummy-Strahlerkabels"	/

## 6. Accompanying Documentation

/	Test Data	/
M01010.JLR	Validation Program	/
	Step 2: Manufacture of Needles for Validation	
PA M0207	Prüfplanung für Antriebe, Strahler und Dummykabel für GammaMed 12i(t) Geräte	Rev. 01
AW M0030	Fertigung und Test von Dummy und Quellenantrieben	Rev. 01
FO 09.11	Antriebe GammaMed	16.09.1996
DT M003	Datenblatt Strahler -/ Dummykabel für GammaMed 12i	Rev. 04