

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(CORRECTED PAGE 6)

NO.: CA0406S118S

DATE: April 21, 2014

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SEALED SOURCE TYPE: Gauging, X-Ray Fluorescence, and Calibration Source

MODEL:

PHI-XXX GFS Series (Formerly GFS Series)
BF-90-SS
G10 Series
IND1500
IND1604

MANUFACTURER/DISTRIBUTOR:

Eckert & Ziegler Isotope Products
dba Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
(661) 309-1010 (voice)
(661) 257-8303 (fax)
or
1800 North Keystone Street
Burbank, CA 91504
or
Eckert & Ziegler Cesio
Radiova 1
102 27 Prague 10
Czech Republic
or
Eckert & Ziegler Nuclitec GmbH
Gieselweg 1
38110 Braunschweig
Germany
or
Eckert & Ziegler Analytics
1380 Seaboard Industrial Boulevard
Atlanta, GA 30318

ISOTOPE:

Sodium-22
Cobalt-57
Cobalt-58
Cobalt-60
Germanium/Gallium-68
Strontium-90
Ruthenium-106
Barium-133

MAXIMUM ACTIVITY:

5 millicuries (185 MBq)
300 millicuries (11.1 GBq)
300 millicuries (11.1 GBq)
10 millicuries (370 MBq)
50 millicuries (1.85 GBq)
125 millicuries (4.63 GBq)
50 millicuries (1.85 GBq)
100 millicuries (3.70 GBq)

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ISOTOPE:

MAXIMUM ACTIVITY:

Cesium-137

300 millicuries (11.1 GBq)

Lanthanide Series

300 millicuries (11.1 GBq)

(Ce, Pr, Sm, Eu, Gd, Yb, Tm)

Actinide Series

300 millicuries (11.1 GBq) or 30 millicuries

(Ac, Th, Pa, U, Pu, Am, Cm)

(1.11GBq) (see description)

Radium-226

50 millicuries (1.85 GBq)

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(D) Gamma Gauges

(E) Beta Gauges

(I) Calibration Sources

(U) X-Ray Fluorescence

(X) Medical Reference Sources

CUSTOM SOURCE:

Yes No

DESCRIPTION:

The PHI-XXX GFS series is represented by EZIP capsule drawings 3201, 3202, 3203, 3203, 3224, 3807, VZ-542-001, and VZ-543-001, VZ-3721-001, and BF-90-SS, by capsule drawing A3226. The G10 Series utilizes an equivalent capsule to A3202-2, which is registered under Model PHI-XXX GFS Series. Model IND1604 is an equivalent capsule to A3201. Model IND1500 is an equivalent capsule to A3203.

These sources are singly encapsulated and constructed of stainless steel or titanium with a minimum wall thickness of 0.008" and a minimum window thickness of 0.002". Some designs have internal tungsten shielding and/or bronze springs. Sources are sealed by fusion welding.

Table 1 lists the source model dimensions.

Table 1. Source Model Dimensions

Source Model	EZIP Drawing No.	Source Dimensions (inches)
PHI-XXX / IND1604	3201	0.312"D x 0.200"L
PHI-XXX / XxY.G10	3202	0.312"D x 0.200"L
PHI-XXX / IND1500	3203	0.312"D x 0.202"L
PHI-XXX	3224	0.08" – 0.28"D x 0.20" or 0.39"L
PHI-XXX	3807	0.120"D x 0.405"L
PHI-XXX	VZ-542-001	0.394"D x 0.197"L

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Source Model	EZIP Drawing No.	Source Dimensions (inches)
PHI-XXX	VZ-543-001	0.394"D x 1.26"L
PHI-XXX	VZ-3721-001	0.315"D x 0.197"L
BF-90-SS	3226	0.315"D x 0.140"L

The chemical form of the active elements in the sources are chlorides, nitrates, or oxides in ceramic, oxides in gold or aluminum, or metal-plated onto substrate.

The actinide loading depends on the chemical form and window thickness. The 300 mCi limit applies to oxides in ceramic with the 0.10" windows, and the 30 mCi limit applies to the plated oxides and 0.002" window.

The source activity range shall be $\pm 20\%$ for all models.

Table 2 lists the source model identification scheme used for sources within each series.

Table 2. Source Model Identification Scheme

Model Number	Description
PHI-XXX GFS	XRF, gauging, medical reference or calibration source; "XXX" represents the radionuclide mass number. This series is represented by capsule numbers 3201, 3202, 3203, 3224, 3807, VZ-542, VZ-543, and VZ-3721.
BF-XXX-SS	XRF, gauging, or calibration source; "XXX" represents the radionuclide mass number; "SS" represents stainless steel, the material the sources are constructed of. This series is represented by capsule number 3226.
For example: BF-090-SS = Sr-90 in a BF stainless steel 3226 capsule.	
XxY.G10	"Xx" is the isotope code; "Y" is the last number of the isotope number; G10 is the capsule type. This capsule is equivalent to 3202-2.
For example: Am1.G10 = Am-241 in G10 capsule.	
INDeeee	XRF, gauging, or calibration source. "IND" represents "Industrial Source"; "eeee" is a numeric designation.
For example: IND1604 is an industrial source.	

Note: XRF sources sold under Model IND1604 are consolidated within this registry and supersede SS&DR No. CA0510S107S. Beta and gamma gauge sources sold under Model IND1500 are consolidated within this registry and supersede SS&DR No. CA0510S125S.

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LABELING:

The sources are engraved or labeled with the manufacturer or manufacturer's logo, nuclide, nominal activity, and serial number. Due to the dimensional limitations inherent to the source, the standard radiation caution symbol may not be included on the source.

The source storage and shipping container is labeled with the manufacturer or manufacturer's logo, the radiation symbol, isotope, activity, serial number, and the words, "RADIOACTIVE MATERIAL".

In addition, when this source is manufactured for medical reference use, a label is affixed to the storage or shipping container that states, "CA DPH has approved distribution of this source to persons licensed to use radioactive material identified in Cal Code Regs. title 17, §30170- §30237 & in 10 CFR 35.65, 35.400, 35.500, & 35.600 as appropriate, & to persons who hold an equivalent license issued by the US NRC or an Agreement State. See IFU for additional instructions, as applicable."

DIAGRAM:

Attachment 1:	Model PHI-XXX GFS Series / IND 1604 (Capsule 3201) Drawing
Attachment 2:	Model PHI-XXX GFS / G10 Series (Capsule 3202) Drawing
Attachment 3:	Model PHI-XXX GFS Series / IND 1500 (Capsule 3203) Drawing
Attachment 4:	Model PHI-XXX GFS Series (Capsule 3224) Drawing
Attachment 5:	Model PHI-XXX GFS Series / BF-90-SS (Capsule 3226) Drawing
Attachment 6:	Model PHI-XXX GFS Series (Capsule 3807) Drawing
Attachment 7:	Model PHI-XXX GFS Series (Capsule VZ-542) Drawing
Attachment 8:	Model PHI-XXX GFS Series (Capsule VZ-543) Drawing
Attachment 9:	Model PHI-XXX GFS Series (Capsule VZ-3721) Drawing

CONDITIONS FOR NORMAL USE:

The source is designed and manufactured for use in beta and gamma gauging, x-ray fluorescence (XRF) or as a medical reference or calibration source. For beta and gamma gauging and XRF applications, the source is intended to be mounted in a gauging or XRF device. The source is also designed and manufactured for used as a component of a medical gamma camera system used in the nuclear medicine department of a hospital or clinic by trained personnel.

The sources should not be subjected to conditions of normal use requiring a higher rating than the ANSI N542-1977 / ISO 2919:2012 classifications listed in the prototype testing section.

Other applications such as oil-well logging and research and development are acceptable provided that the sources are not subjected to environmental conditions exceeding those listed below. Typical useful life of

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the source is dependent on nuclide; a sample of nuclides is listed below. Capsules 3203, IND1500, and VZ-3721 capsules have a maximum useful life of ten years.

<u>Nuclide</u>	<u>Typical Useful Life (years)</u>
Americium-241	15
Barium-133	5
Cesium-137	15
Cobalt-57	2
Cobalt-60	15
Germanium-68	2
Radium-226	10
Sodium-22	5
Strontium-90	10
Thorium-228	10

PROTOTYPE TESTING:

Prototype sources have undergone testing per ANSI N542-1977 / ANSI/HPS N43.6-1997 / ISO 2919:2012 and meet or exceed the required ratings for the recommended usages as noted below.

<u>Capsule</u>	<u>ANSI/ISO classification tested to:</u>	<u>Typical Usage</u>	<u>Minimum ANSI/ISO classification requirement:</u>
A3201	77C66545	Gamma Gauges (medium and high energy)-- Source in device	C43232
A3202	77C66545	Gamma Gauges (medium and high energy)-- Source in device	C43232
A3203	ISO/99/C33222	Beta gauges and sources for low energy gamma gauges or XRF	C33222
A3224	77C66444	Gamma Gauges (medium and high energy)-- Source in device	C43232
A3807	77C66444	Gamma Gauges (medium and high energy)-- Source in device	C43232
A3224-X4	77C33222	Beta gauges and sources for low energy gamma gauges or XRF	C33222
A3226	77C43343	Beta gauges and sources for low energy gamma gauges or XRF	C33222
IND1500	77C33222	Beta gauges and sources for low energy gamma gauges or XRF	C33222
IND1604	77C64444	Beta gauges and sources for low energy gamma gauges or XRF	C33222

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Capsule	ANSI/ISO classification tested to:	Typical Usage	Minimum ANSI/ISO classification requirement:
VZ-542	ISO/12/C66543	Gamma Gauges (medium and high energy)-- Source in device	C43232
VZ-543	C66543	Gamma Gauges (medium and high energy)-- Source in device	C43232
VZ-3721	ISO/12/C33222	Beta gauges and sources for low energy gamma gauges or XRF	C33222
XxY.G10	ISO/80/C64545	Gamma Gauges (medium and high energy)-- Source in device	C43232

EXTERNAL RADIATION LEVELS:

The radiation level of the source will vary with the contained radionuclide and the activity level. Listed below are radiation levels in R/hr. Data has been taken where available from references 8 and 9. For nuclides not listed in the referenced tables, measurements were taken at 30 cm with an ion chamber type survey meter and radiation levels were calculated at 5 and 100 cm using the inverse square law (for gamma or X-ray radiation), and calculations for Beta radiation were performed according to the method described in reference 10.

Nuclide	Activity (mCi)	Distance from source (R/hr)		
		5 cm	30 cm	100 cm
Sodium-22	5	2.4	0.067	0.006
Cobalt-57	300	10.8	0.3	0.027
Cobalt-58	300	66	1.83	0.165
Cobalt-60	10	5.28	0.147	0.0132
Germanium-68	50	10.5	0.29	0.026
Strontium-90	125	2975	66	3.0
Ruthenium-106	50	3.4	0.094	0.0085
Barium-133	100	9.6	0.267	0.024
Cesium-137	300	39.6	1.1	0.099
Lanthanides	300	74.4	2.07	0.186 (from Eu-154)
Actinides	300	6700	195	17.5 (from Th-228)
Radium-226	50	2190	60.8	5.46

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QUALITY ASSURANCE AND CONTROL:

Program: The Eckert & Ziegler Isotope Products Quality Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR 50 Part 50 Appendix B and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records, source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders.

Activity: Activity levels are held to within $\pm 20\%$ of nominally desired activity.

Eckert & Ziegler Isotope Products maintains a quality system, which has been deemed acceptable for licensing purposes by the California Department of Public Health. A copy of the program is on file with the California Department of Public Health.

For medical applications, the manufacturing of Model PHI-XXX GFS Series sources and related operations are carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR 820, under the supervision of the Quality Operations group at Eckert & Ziegler Isotope Products.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- a. Distribution: These sources shall be distributed to specific licensees of the NRC, Agreement States, or a Licensing State.
- b. Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- c. Leak Test: Sources containing radioactive material in excess of 100 microcuries, and alpha and/or neutron emitting sources containing radioactive material in excess of 10 microcuries shall be leak tested at intervals not greater than six months. Such tests must be capable of detecting 0.005 microcuries (185 Bq) of removable radioactivity, and be performed by specific licensees of the NRC, Agreement States, or a Licensing State.
- d. Use: Models PHI-XXX GFS Series, BF-90-SS, G10 Series, IND1500, and IND1604 sources are intended to be used by trained personnel in a laboratory environment for checking or calibration of nuclear instrumentation, or to be permanently installed in devices. These sources should not be subjected to conditions exceeding their ANSI N542-1977 or ISO 2919 classification.
- e. The registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Public Health.

SAFETY ANALYSIS SUMMARY

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Based on a review of Models PHI-XXX GFS Series, BF-90-SS, G10 Series, IND1500, and IND1604 sealed sources, their ANSI / ISO classification, and the information and test data cited below, we conclude that the source is acceptable for licensing purposes.

Furthermore, we conclude that the sources would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document:

1. Isotope Product Laboratories letters, with attachments, dated February 11, March 11, and April 10, 1975.
2. Isotope Product Laboratories letters, with attachments, dated January 9, January 18, and February 18, 1982.
3. NBS Handbook No. 126, ANSI N.542, "Sealed Radioactivity Sources, Classification", 1977.
4. Isotope Products laboratories letter dated March 26, 1985, with attached Special Form Certificate No. USA/0357/S.
5. Isotope Products Laboratories letter, with attachments, dated February 6, 1990.
6. Isotope Products Laboratories letter, with attachments, dated April 20, 1990.
7. Isotope Products Laboratories letter, with attachments, dated July 21, 1992.
8. Appendix to ANSI N44.2-1973 "American National Standard for Leak Testing Radioactive Brachytherapy Sources."
9. "Radiological Health Handbook", page 131, 1970.
10. "The Health Physics and Radiological Health Handbook", Table 13-14—Beta Ray Dose Rates for an Isotropic Source in Air of Density 1.205 mg/cm³", Revised Edition, Edited by Bernard Sheien, 1992.
11. Isotope Products Laboratories letters, with attachments, dated January 7, May 20, August 8 and August 12, 1994.
12. Isotope Products Laboratories letter, with attachments, dated April 2, 1999.
13. Isotope Products Laboratories letter, with attachments, dated February 24, 2003.
14. Isotope Products Laboratories letter, with attachments, dated August 30, 2005.
15. Eckert & Ziegler Isotope Products letter, with attachments, dated 05 August 2008.
16. Eckert & Ziegler Quality Manual dated 03 October 2012 (current copy on file with issuing agency).
17. Eckert & Ziegler Isotope Products letter, with attachments, dated 03 October 2012.
18. Eckert & Ziegler Isotope Products electronic mail, with attachments, dated 07 March 2013.
19. Eckert & Ziegler Isotope Products letter, with attachments, dated 09 April 2013.
20. Eckert & Ziegler Isotope Products Electronic Mail, dated April 16, 2014.

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ISSUING AGENCY: California Department of Public Health

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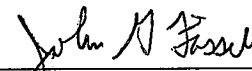
REVIEWED BY:



Mina Goeders, Ph.D.

DATE: April 21, 2014

CONCURRED BY:



John Fassell, CHP

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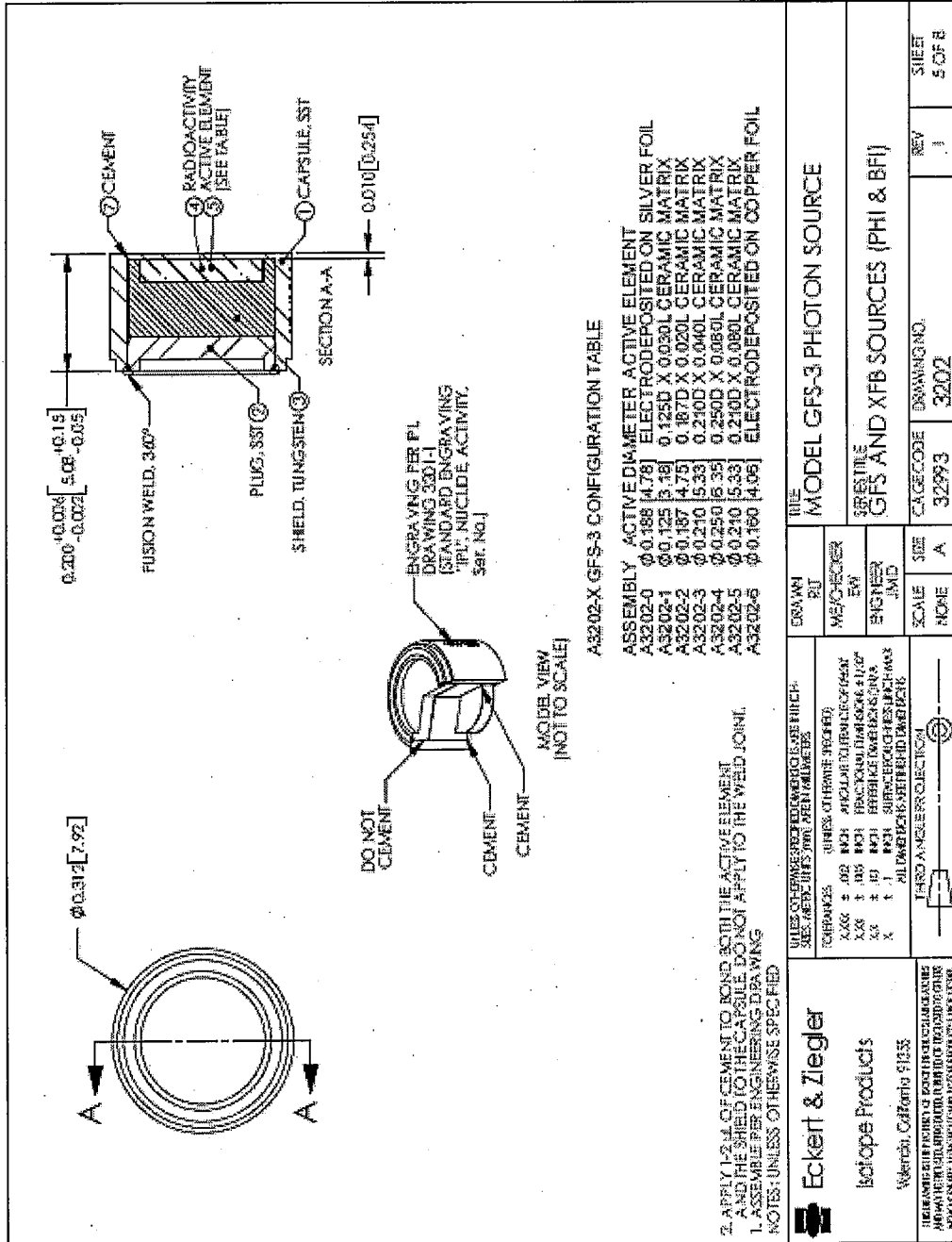
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SEALED SOURCE TYPE: Gauging, X-Ray Fluorescence, and Calibration Source

Model PHI-XXX GFS Series (Capsule 3202) / XxY.G10 (Capsule 3202-2)



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Isotope Products		CHECKED: [Blank]		DATE: [Blank]	
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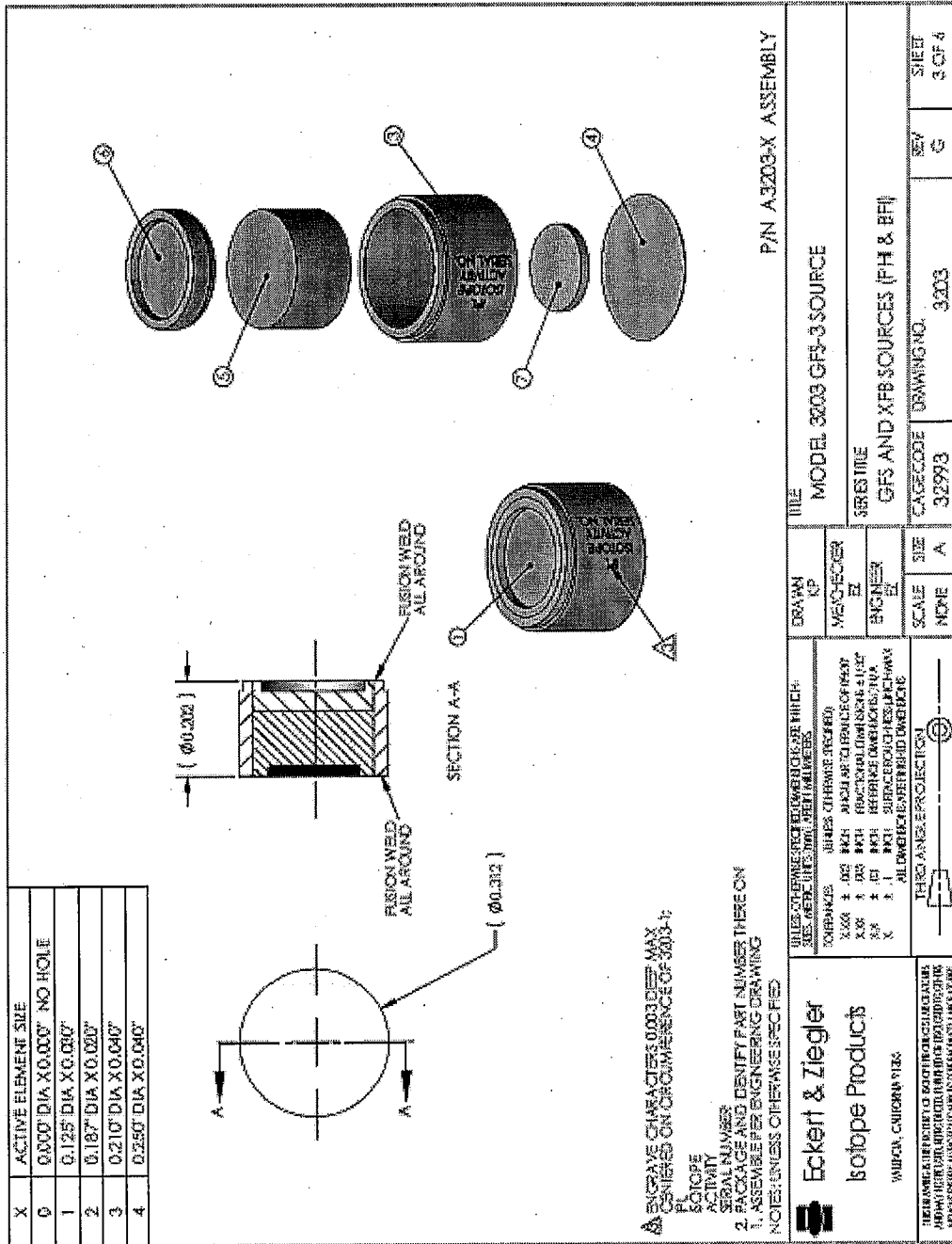
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Model PHI-XXX GFS Series / IND1500 (Capsule 3203)



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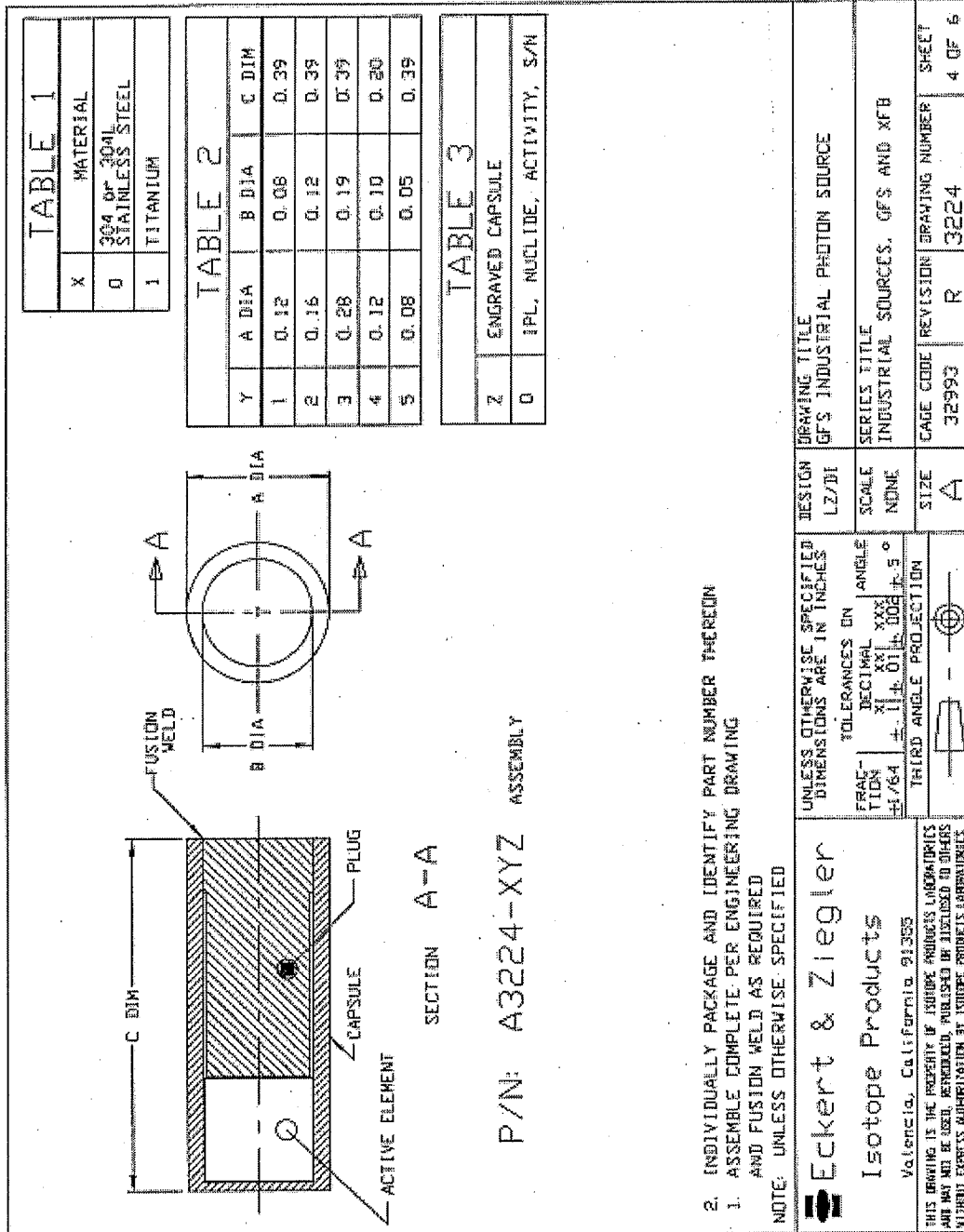
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SEALED SOURCE TYPE: Gauging, X-Ray Fluorescence, and Calibration Source

Model PHI-XXX GFS Series (Capsule 3224)



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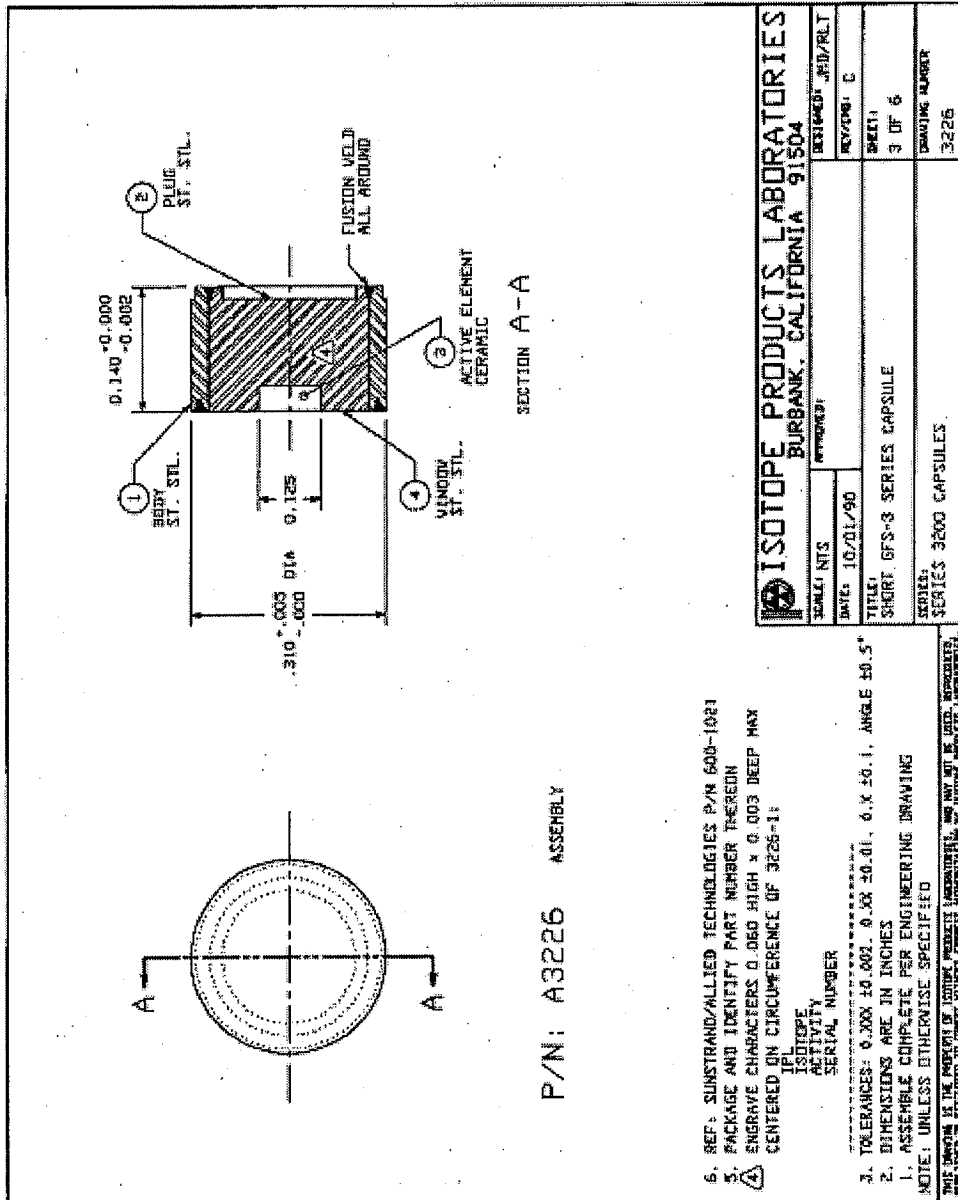
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Model PHI-XXX GFS Series / BF-90-SS (Capsule 3226)



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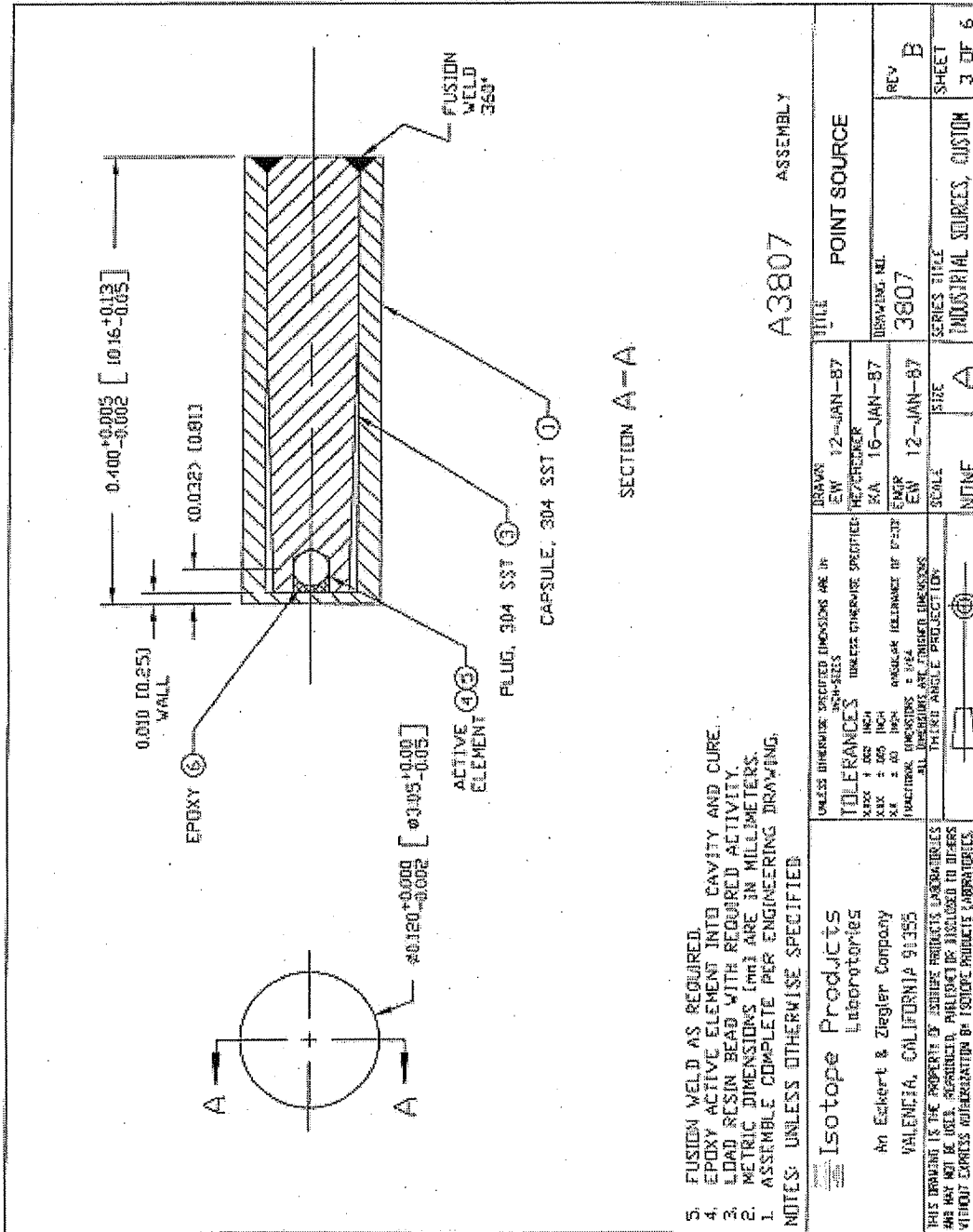
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Model PHI-XXX GFS Series (Capsule 3807)



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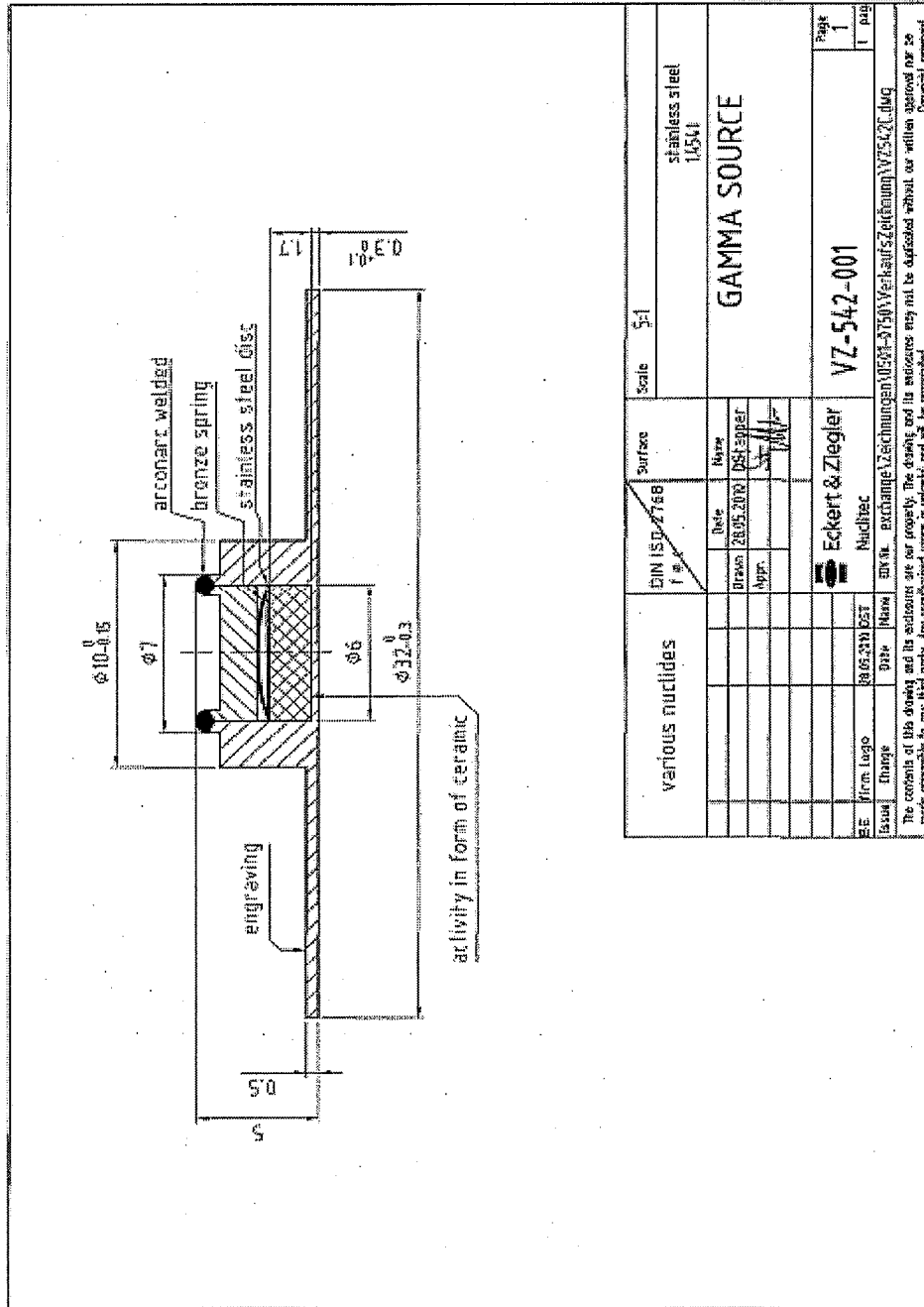
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Gamma Source VZ-542 Drawing



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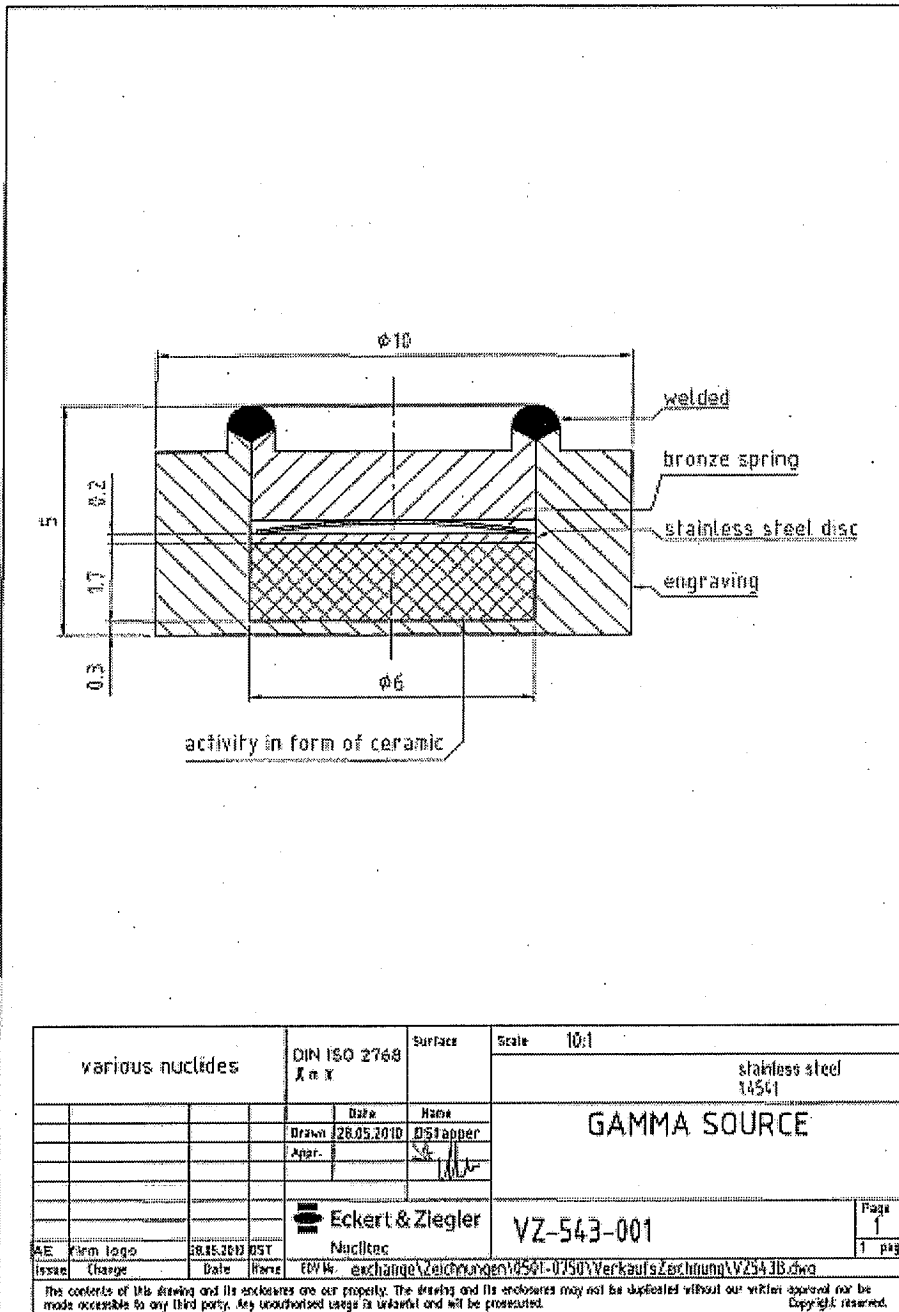
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Gamma Source VZ-543 Drawing



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Beta Source VZ-3721 Drawing

