
CERTIFICATE NO. ZA/SAHPRA 0001/B(U)-96
PACKAGE DESIGN APPROVAL
"EXERTUS FORTES"

This is to certify that the South African Health Products Regulatory Authority (SAHPRA), being, for the purpose of the International Atomic Energy Agency (IAEA), the Competent Authority in the Republic of South Africa, in respect of the transport of radioactive material, has certified the package design, as described herein, as having met the regulatory requirements for Type B(U) packages as described in the IAEA Safety Standards Series No. SSR-6 (Rev.1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Vienna, 2018.

1. Certificate

Effective Date: 1 October 2023

Expiry Date: 30 September 2028

2. Competent Authority

SAHPRA

3. This certificate is issued on the basis of the application submitted by:


Gammatec NDT Supplies SOC Ltd

Vision 21 Industrial Park

Steel Road, Peacehaven

Vereeniging 1939

Republic of South Africa



4. Title and Identification of Reports and Drawings

4.1. Reports

The safety case for the package design comprises of the following reports-

| Document Number | Rev | Date | Title/Description |
|-----------------|-----|---------------|----------------------------------------------------------------------|
| GEROTEK 17636 | 1 | 12 June 2023 | Performance and design evaluation – Industrial Radiography Container |
| 7.1.1.0 | 0 | November 2022 | Exertus Fortes Exposure Container Safety Assessment Report |

4.2. Drawings

The package is fabricated in accordance with the following drawings-

| Drawing no | Rev | Description |
|---------------------------------|-----|-----------------------------------------------------------------------|
| COVER-ASC0006 | 0 | Fortes Rear Dust Cover - Assembled |
| INSERT-SI0066 | 0 | Fortes Rear Dust Cover Insert 10.01.10.001(Anodised-Blue) |
| COVER-SC0319 | 0 | Fortes Rear Dust Cover(Anodised-Blue) |
| BACKING-SB0194 | 1 | Fortes/Dual 120 Rear Dust Cover Ball Backing 8.226.758 |
| BACKING-SB0195 | 1 | Fortes/Dual 120 Rear Dust Cover Spring Backing 10.01.10.002(Machined) |
| SPRING-SS0103 | 1 | Fortes/Dual 120 Compression Spring Short 9.173.011-01 |
| SCREW-SS0396 | 0 | Fortes Rear Dust Cover Chain Screw |
| PIN-SP0210 | 0 | Fortes Rear Dust Cover Pin |
| SEAL-SS0397 | 0 | Fortes Rear Dust Cover O-Ring |
| | | |
| HOUSING-ASH0013 | 0 | Fortes Front Housing - Assembled |
| HOUSING-SH0106 | 0 | Fortes Front Housing (Anodised-Blue) |
| COVER-SC0320 | 0 | Fortes Front Dust Cover (Anodised-Blue) |
| SHAFT-ASS0005 | 0 | Fortes Front Housing Shutter Shaft - Assembly |
| SHAFT-SS0407 | 0 | Fortes Front Housing Shutter Shaft |
| PIN-SP0215 | 0 | Fortes Front Housing Shutter Shaft Pin |
| SHUTTER-ASS0006 | 0 | Fortes Front Housing Shutter - Assembled |
| BODY-SB0408 | 0 | Fortes Front Housing Shutter Body |
| INSERT-SI0068 | 0 | Fortes Front Housing Shutter Selector Insert |
| INSERT-SI0069 | 0 | Fortes Front Housing Shutter Shielding Insert |

| | | |
|---------------------------------|---|--------------------------------------------------------|
| SPRING-SS0408 | 0 | Fortes Front Housing Shutter Spring |
| INSERT-SI0067 | 0 | Fortes Front Housing Insert |
| BUSH-SB0405 | 0 | Fortes Front Housing Bush |
| BODY-SB0406 | 0 | Fortes Front Housing Body(coupling lock body) |
| PIN-SP0211 | 0 | Fortes Front Housing Pin |
| SPRING-SS0398 | 0 | Fortes Front Housing Spring |
| | | |
| ROD-ASR0006 | 0 | Fortes Locking Rod |
| PLATE-SP0212 | 0 | Fortes Locking Rod Plate (Anodised-Blue) |
| ROD-SR0098 | 0 | Fortes Locking Rod Front |
| ROD-SR0049 | 0 | Fortes/Dual 120 Locking Rod 10.01.04.007 |
| | | |
| HOUSING-ASH0005 | 1 | Fortes/Dual 120 Shielding Unit Assembly - Complete |
| HOUSING-ASH0003 | 1 | Fortes/Dual 120 Rear D(u) housing 10.01.06.000 C6 |
| FLANGE-SF0062 | 1 | Fortes/Dual 120 Rear D(U) Housing Flange 10.01.06.002 |
| BARREL-SB0145 | 1 | Fortes/Dual 120 Rear D(u) Housing Barrel 10.01.06.001 |
| HOUSING-ASH0004 | 1 | Fortes/Dual 120 Front D(u) Housing 10.01.07.000 C6 |
| FLANGE-SF0060 | 1 | Fortes/Dual 120 Front D(u) Housing Flange 10.01.07.002 |
| BARREL-SB0151 | 1 | Fortes/Dual 120 Front D(u) Housing Barrel 10.01.07.001 |
| SHIELD-ASS0001 | 1 | Fortes/Dual 120 Shielding Unit 10.01.03.000 |
| PLUG-SP0067 | 1 | Fortes/Dual 120 D(u) Shielding Plug 8.633.586 |
| CAP-SC0097 | 1 | Fortes/Dual 120 Labyrinth Cap 10.01.03.001 |
| LABYRINTH-SL0050 | 1 | Fortes/Dual 120 Labyrinth 10.01.03.002 |
| BARREL-SB0196 | 1 | Fortes/Dual 120 Labyrinth Barrel 10.01.03.003 |
| CUP-SC0101 | 1 | Fortes/Dual 120 Plunger Cup 10.01.03.004 |
| INSERT-SI0034 | 1 | Fortes/Dual 120 Labyrinth Insert 10.01.03.006 |
| TUBE-ST0050 | 1 | Fortes/Dual 120 Front Locking Bar Tube 10.01.03.007 |
| BUSH-SB0203 | 1 | Fortes/Dual 120 Locking Bar Bush 10.01.03.008 |
| RING-SR0045 | 1 | Fortes/Dual 120 D(u) Guide Ring 10.01.03.009 |
| PLATE-SP0055 | 1 | Fortes/Dual 120 Shielding Plate 10.01.03.010 |
| INSERT-SI0035 | 1 | Fortes/Dual 120 Threaded Insert 10.01.03.011 |
| TUBE-ST0051 | 1 | Fortes/Dual 120 Rear Locking Bar Tube 10.01.03.012 |
| CHANNEL-SC0098 | 1 | Fortes/Dual 120 Source Channel 10.01.03.015-02 |
| | | |
| LOCK-ASL0007 | 0 | Fortes Rear Locking Mechanism - Assembly |
| FITTING-ASF0009 | 0 | |
| FITTING-SF0120 | 0 | Fortes Rear Locking Mechanism Fitting |
| INSERT-SI0030 | 1 | Fortes/Dual 120 Rear Housing Fitting Insert 8.243.099 |
| LOCK-ASL0008 | 0 | Fortes Rear Lock Structure |
| LOCK-SL0023 | 1 | Fortes/Dual 120 /TSI Lock 8.675.178 plus two keys |

| | | |
|---------------------------------|---|------------------------------------------------------------------------|
| RING-SR0101 | 0 | Fortes Rear Locking Mechanism Ring (Anodised Blue) |
| HOUSING-SH0108 | 0 | Fortes Rear Locking Mechanism Corbin Lock Housing (Anodised Blue) |
| RING-SR0099 | 0 | Fortes Rear Housing Fitting Ring (Anodised-Blue) |
| FLANGE-SF0119 | 0 | Fortes Rear Locking Mechanism Flange |
| PLATE-SP0213 | 0 | Fortes Rear Mechanism Slider Plate |
| BUSH-SB0407 | 0 | Fortes Rear Locking Mechanism Bush |
| SPRING-SS0403 | 0 | Fortes Rear Locking Mech Locking Bush Spring |
| RING-SR0100 | 0 | Fortes Rear Locking Mechanism Ring |
| PIN-SP0214 | 0 | Fortes Rear Locking Mech Anti-rotation Pin |
| SPRING-SS0404 | 0 | Fortes Rear Mechanism Anti-Rotation Pin Spring |
| SPRING-SS0405 | 0 | Fortes Slider Plate Spring |
| BODY-SB0415 | 0 | Fortes Rear Locking Mechanism Body (Anodised-Blue) |
| | | |
| SLEEVE-ASS0004 | 0 | Fortes Shielding Unit Sleeve-Assembled |
| SLEEVE-SS0406 | 0 | Fortes Shielding Unit Sleeve-Welded |
| | | |
| JACKET-SJ0008 | 0 | Fortes Jacket-Polyurethane Blue |
| SCREW-SS0393 | 0 | M6 x 50mm Tri Security Screw - Stainless Steel 304 |
| SCREW-SS0394 | 0 | M6 x 30mm Tri Security Screw - Stainless Steel 304 |
| | | |
| PIGTAIL-NCP0428 | 0 | Fortes Link Type Pigtail |
| RECEPTOR-SR0043 | 1 | Fortes/Dual 120 Pigtail Receptor - Engraved & Welded 19.01.12.000C6 |
| LINK-SL0031 | 1 | Fortes/Dual 120 Pigtail Connector Link S/S - 19.01.11.002 |
| LINK-SL0034 | 1 | Fortes/Dual 120 Pigtail Slider Link S/S - 19.01.11.001 |
| LINK-SL0032 | 1 | Fortes/Dual 120 Pigtail Capsule Link Tungsten 17.5mm - 19.01.11.003-01 |
| LINK-SL0033 | 1 | Fortes/Dual 120 Pigtail Link Tungsten 20mm - 19.01.11.003 |
| LINK-SL0055 | 1 | Fortes/Dual 120 Pigtail Capsule Link Tungsten 16mm - 19.01.11.003-02 |
| CAPSULE-SC0184 (A+B) | 1 | Fortes/Dual 120 Source Capsule (Jan 2015) - Engraved |
| LINK_SL0084 | 0 | Fortes Activation Link - SS |

5. Package Identification

The package is identified by the model number:
ZA/SAHPRA 0001/B(U)-96

6. Package Description

The package will be used as an Exposure Container for Industrial radiography and for the transportation of Special Form Sources used in Industrial Radiography.

The package assembly consists of a stainless steel 304 housing surrounding the Depleted Uranium shield. A Tungsten channel and Labyrinth in the Depleted Uranium shield house the Source Assembly whilst an Automatic Securing Mechanism, Remote Control and Projection Sheath connectors and a Keyed Security Lock ensure that the Radioactive Source is in the secured position and unauthorised and accidental exposure of the Source is prevented.

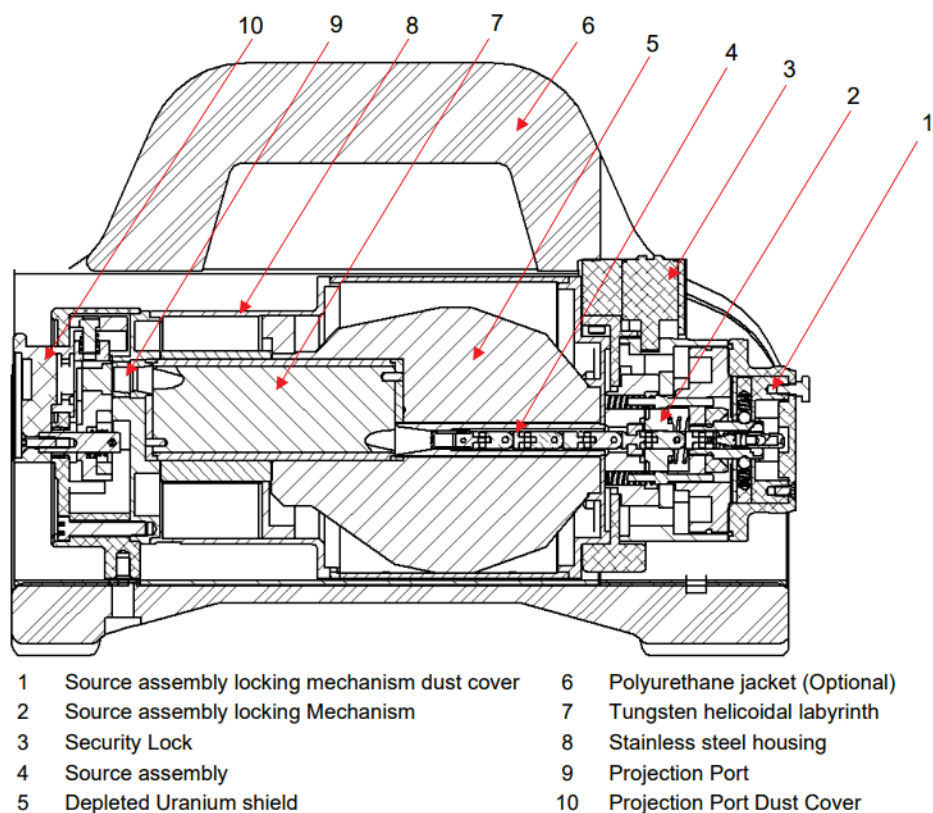


Figure 1: "EXERTUS FORTES" Package Assembly Drawing

Packaging Dimensions

| Item | Length (mm) | Width (mm) | Height (mm) |
|------------------------------------|-------------|------------|-------------|
| Assembled Package | 310 | Dia. 125 | |
| Assembled Package (With Jacket) | 310 | 150 | 230 |

Package Mass

| Item | Approximate Mass (kg) |
|---------------------------------|-----------------------|
| Package Weight – with jacket | 23 |
| Package Weight – without jacket | 21.5 |
| Source assembly | 0.047 |

7. Authorised Contents

The package contents will not exceed either:

| Radionuclide | Activity | Physical State | Chemical Form | Use |
|--------------|--------------|----------------|----------------|-------------|
| Ir-192 | 1 x 4.44TBq | Solid | Iridium metal | Radiography |
| Se-75 | 1 x 4.44 TBq | Solid | Selenium alloy | Radiography |

8. Conditions for the use of the packaging

- 8.1 The maintenance required on this package is described in the document WI/GSA/LOG-007.01.006.00 Operational Manual for the “EXERTUS FORTES”, or any future revisions thereof, as accepted by the competent authority.

9. Notification

- 9.1 The owner of a package, manufactured in accordance to the design covered by this certificate, shall forward the package serial number to the competent authority.
- 9.2 Should the package be disposed of or change ownership, then this change must be notified to the competent authority.
- 9.3 Accordingly, the party relinquishing ownership of a package shall forward the name of the new owner to the competent authority.
- 9.4 The consignor of a package compliant with the design covered by this certificate shall check that the package bears a Model Number as identified in “5” above, as well as a serial number.

10.Mode(s)

- 10.1 The package described by this certificate may be transported by air, land, sea or inland waterways.

11.Specifications of quality assurance programme.

- 11.1 Quality assurance programmes as described in the Gammatec Quality Manual, PO/GSA/CORP-010.00.000.000 and its supporting documentation must be applied to the fabrication, testing and usage of the package.

- 11.2 All packages must be periodically inspected and as necessary, repaired and maintained in good condition so that they continue to comply with the relevant requirements and specifications, even after repeated use.

12.General Conditions

- 12.1 Each user of the transport package must have in their possession a copy of this certificate and all documents necessary to properly prepare the package for transportation.
- 12.2 This certificate does not relieve the consignor or carrier from the compliance with any requirements of the government of any country through or into which the package will be transported.

13.Marking and Labels

The packing must bear the marking ZA/SAHPRA 0001/B(U)-96 in addition to any other required markings and labelling.

14.Relevant Regulations

IAEA Safety Standards Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, 1018 Edition, Vienna 2018.

15.Expiry Date

This certificate expires at midnight on 1 October 2028

Boitumelo Semete Makoketjete

31/10/2023 10:03:30(UTC+02:00)

Dr. Boitumelo Semete
Chef Executive Officer
SAHPRA

31 October
2023

Date