**Application for Imaging Products Importation and Clearance**

All fields must be filled with relevant and descriptive information.

1. ***Applicant Details***

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| --- | --- | --- | --- |
| **Applicant’s Name** |  | | |
| **Applicant’s Address** |  | | |
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|  | | |
| **Telephone No.** |  | **Fax No.** |  |
| **Mobile No.** |  | | |
| **E-mail Address** |  | | |
| **MDEL\* No.** |  | | |

*\* Medical Devices Establishment License Number that was assigned by SFDA for your establishment*

1. ***Recipient Details***

|  |  |  |  |
| --- | --- | --- | --- |
| **Institute** |  | | |
| **Authorized Person** |  | | |
| **Telephone No.** |  | **Fax No.** |  |
| **Mobile No.** |  | | |
| **E-mail Address** |  | | |
| **Dept. License No.** |  | | |
| **The Nature of Usage** |  | | |

**Product Details** All information regarding your products must be described in the next page, as appropriate.

***products details (applicant FORM) (1/2)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Product Model and Lot No. | Product Description  (Proper Shipping Name) | Quantity | Dosage Form  or  Physical State | Production Date  (dd/mm/yy) | Unit Weight  (g) | Gross Weight  (Kg) |
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1 If applicable

***products details (applicant form) (2/2)***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Product Code | Product Model | Product Description | External Market Authorization2 | | | | |
| License Holder | License Holder Status3 | Certifying Authority | Validity Period | |
| From | To |
|  |  |  |  |  |  |  |  |
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*2 These fields must be filled if the product holds any international recognition from the International Medical Device Regulators Forum (IMDRF) founding members*

*3 Please choose either (A), (B) or (C) for the license holder: A. Manufactures the radionuclide and the finished dosage form*

*B. Manufactures the finished dosage form*

*C. Packages and labels the finished dosage form*

1. **Declaration**

* I certify that the information contained herein is complete, accurate and true to the best of my knowledge.
* I attest that all items listed in the invoice conform to the international provisions and standards as well as to the requirements of SFDA Medical Devices Interim Regulation.
* I undertake not to supply any of the mentioned products to an unapproved user.
* The shipment does not contain: narcotics, explosives or any other prohibited substances as described by the Ministry of Interior.
* I hereby declare that the shipment does not contain radioactive materials.
* I hereby declare that the contents of the above consignment are fully and accurately described including proper shipping name, classification, packaging, and labeling. In addition, it is in a proper condition to be transported according to the applicable international and national regulations.

**Name of the Applicant Date**

**Applicant’s Signature**