**Application for Imaging Products**

**Importation and Clearance**

All fields must be filled with relevant and descriptive information.

1. **Applicant Details**

|  |  |
| --- | --- |
| **Applicant’s Name** |  |
| **Applicant’s Address** |  |
|  |
|  |
| **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 is 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.

**Applicant’s Signature**

**Name of the Applicant**

**Date**