Declaration and Attestation of Importers

To be printed on the importer's official paper

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| 1. Entity Information | | | | | | | | |
| Name of Establishment/Warehouse/ Healthcare Facility | | | | | | |  | |
| ID Number in GHAD | | | | | | |  | |
| 1. Medical Devices Information (According to Invoice) | | | | | | | | |
|  | Item Name | Quantity | Invoice Number | | | Invoice Date | Manufacturer | Country of Manufacture |
| 1 |  |  |  | | |  |  |  |
| 2 |  |  |  | | |  |  |  |
| 3 |  |  |  | | |  |  |  |
|  |  |  |  | | |  |  |  |
| 1. Medical Device Contents | | | | | | | | |
| Do Medical Device contain | | | | | Yes or No? | | Name of the substance (if yes) | |
| Radioactive Substance | | | | |  | |  | |
| A chemical subject to the control of the Ministry of Interior (MOI) | | | | |  | |  | |
| Narcotic Substance | | | | |  | |  | |
| 1. Purpose of import and port of entry | | | | | | | | |
| Purpose of usage/ import | | | |  | | | | |
| Custom entry port | | | |  | | | | |

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| 1. Acknowledgement and Pledge |

We, the abovementioned entity, pledge to the following:

General Pledges

Laws and Regulations

1. Conformity of the consignment items (shipment) mentioned in the invoice with the international requirements and standards, and requirements contained in the “Law of Medical Devices” and its implementing regulation.
2. Adhere to the “Law of Medical Devices” and its implementing regulation and related requirements.
3. All information entered in the application uploaded to the Unified Electronic System (GHAD) is correct and under the responsibility of the applicant.
4. All documents attached to the application related to the requested items.

Chemicals

1. Medical devices do not contain any of the chemical substances described in the tables attached to the “Chemical Weapons Convention” and do not contain any of those substances in their composition.
2. Medical devices do not contain any narcotic, explosive or radioactive materials or any prohibited materials other than those described above.
3. The Ministry of Interior (MOI) shall be informed before transporting hazardous chemicals.
4. Maintaining documents and records of incoming, outgoing and consumed quantities annually.

Transportation and Storage

1. Adhere to the “Requirements on Transporting and Storage for Medical Devices ([MDS-REQ12](https://www.sfda.gov.sa/en/regulations/88142))” which includes that the transportation and storage shall be in accordance to the manufacturer’s instructions and other competent authorities’ requirements, in addition to clarifying the storage location after the consignment (shipment) clearance.
2. Receiving medical devices upon their arrival without any delay and we take any responsibility resulting from any delay.

Customs Procedures

1. Adhere to the necessary custom procedures.

Staff

1. The staff are scientifically and professionally qualified.

Adverse Events and Complaints

1. Report any adverse events or complaints related to the medical devices to the National Center for Medical Devices Reporting ([NCMDR](https://ncmdr.sfda.gov.sa)) in accordance to the “Requirements for Post-Market Surveillance of Medical Devices ([MDS – REQ11](https://www.sfda.gov.sa/en/regulations/87494))”.
2. Cooperating with the SFDA and/ or the manufacturer and/ or the authorized representative in undertaking post-marketing surveillance activities, including reports’ investigation and following up the field safety corrective actions on the medical devices in accordance to the “Requirements for Post-Market Surveillance of Medical Devices ([MDS – REQ11](https://www.sfda.gov.sa/en/regulations/87494))”.

Promotion and Advertising

1. Not to publish any promotional or advertising material for the medical devices unless it has obtained medical device marketing authorization (MDMA) and adhere to the “Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical devices ([MDS-REQ8](https://www.sfda.gov.sa/en/regulations/68999))”.

Usage

1. The medical devices shall not be used except for the purpose for which they was imported and it shall not be circulated in places other than those designated for that purpose. All damages resulting from misuse or use for purposes other than those for which it was imported shall be borne.

Additional Pledges:

Additional pledge related to import permit for used medical devices

1. Not to circulate used medical devices in the Kingdom even after they have been maintained, refurbished or tested, such devices shall be re-exported with a notification to the SFDA and submitting proof of that.

Note: This does not apply if there is a desire to circulate the refurbished medical devices inside the Kingdom, provided that there is an adherence to the two articles (20/3) and (20/4) of the “[Implementing Regulations of the Law of Medical Devices](https://www.sfda.gov.sa/en/regulations/86521)”.

Additional pledges related to import permit for the purpose of demonstration

1. Not to publish any promotional or advertising material for the devices unless it has obtained a medical device marketing authorization (MDMA). Some details about it can be provided to specialists only.
2. The device shall not be used unless there is an identification card (external sticker) on the device (or one of its containers or packages if this is not possible) in Arabic and/ or English, indicating that the device is intended for demonstration purpose only, not for sale.
3. Re-export the medical devices on the date of 00/00/0000 (Maximum six months), or destruct them in accordance with the requirements for destruction of used medical devices referred to in “Requirements for Post-Marketing Surveillance of Medical Devices ([MDS-REQ11](https://www.sfda.gov.sa/en/regulations/87494))” with submitting a proof of that to the SFDA. When this could not be applied, an acceptable justification shall be submitted to the SFDA.

Additional pledges related to import permit for the purpose of clinical studies

1. The device shall not be used unless there is an identification card (external sticker) on the device (or one of its containers or packages if this is not possible) in Arabic and/ or English, indicating that the device is intended for clinical studies only.
2. Re-export the medical devices after they no longer have the purpose for which they were imported, or destruct them in accordance with the requirements for destruction of used medical devices referred to in “Requirements for Post-Marketing Surveillance of Medical Devices ([MDS-REQ11](https://www.sfda.gov.sa/en/regulations/87494))” with submitting a proof of that to the SFDA. When this could not be applied, an acceptable justification shall be submitted to the SFDA.

Additional pledges related to import permit for the purpose of education or non-clinical research

1. The device shall not be used unless there is an identification card (external sticker) on the device (or one of its containers or packages if this is not possible) in Arabic and/ or English, indicating that the device is intended for education or non-clinical research only.
2. Re-export the medical devices after they no longer have the purpose for which they were imported, or destruct them in accordance with the requirements for destruction of used medical devices referred to in “Requirements for Post-Marketing Surveillance of Medical Devices ([MDS-REQ11](https://www.sfda.gov.sa/en/regulations/87494))” with submitting a proof of that to the SFDA. When this could not be applied, an acceptable justification shall be submitted to the SFDA.

Additional pledges related to import permit for humanitarian purposes (including custom-made medical devices)

1. The device shall not be used unless there is an identification card (external sticker) on the device (or one of its containers or packages if this is not possible) in Arabic and/ or English, indicating that the device is a custom-made medical device in case of importing custom-made medical devices.
2. Re-export the medical devices after they no longer have the purpose for which they were imported, or destruct them in accordance with the requirements for destruction of used medical devices referred to in “Requirements for Post-Marketing Surveillance of Medical Devices ([MDS-REQ11](https://www.sfda.gov.sa/en/regulations/87494))” with submitting a proof of that to the SFDA. When this could not be applied, an acceptable justification shall be submitted to the SFDA.

Additional pledges related to import permit for the purpose of local manufacturing/point of care (POC) medical devices manufacturing

1. Quantity of imported shall be corresponding to the production outputs.
2. The medical devices shall obtain medical device marketing authorization (MDMA)/approval for POC medical devices manufacturing after manufacturing and before circulating in accordance with the “Requirements for Medical Devices Marketing Authorization ([MDS-REQ1](https://www.sfda.gov.sa/en/regulations/68759))/Guidance for Points of Care (POC) Medical Devices Manufacturing ([MDS-G009](https://www.sfda.gov.sa/en/regulations/87669))”.

Additional pledge related to import permit for of used medical devices for the purpose of maintaining them in the Kingdom and then re-export them.

1. Maintenance shall be conducted by an establishment licensed as a medical maintenance service provider.

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| Signature | |
| Name of the responsible person |  |
| Job title |  |
| Date |  |
| Signature |  |
| Stamp |  |