MDS-REQ 5

Requirements on Importation and Shipments Clearance of Medical Devices and Supplies

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"Translated Copy"

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements of importation and shipments clearance of medical devices/supplies.

Scope

This document applies to medical devices/supplies and their accessories to be imported.

Note: This document does not apply to the following:

- Medical imaging materials (MDS-REQ4)
- Particle accelerators for radioisotope genesis for medical applications (MDS-REQ4)
- Radioactive materials used in medical applications (MDS-REQ6)
- Minimally manipulated biological products intended for human application
- Spare parts of medical devices

A classification request for the products may be submitted through services of products classification , in order to know whether they are subject to SFDA/MDS regulation or not

Background

SFDA has issued this document in reference to the following:

A. Articles (3), (6), (18), (11), (12), (13) and (20) of the "Law of Medical Devices and Supplies" and "Implementing Regulation of Medical Devices and Supplies Law".

B. Announcement No. (47084) dated 12/6/1440 H regarding to keeping the original required documents of Shipment Clearance.

Requirement

Importation for Circulation of Medical Devices/Supplies	1	For importing medical devices/supplies for the circulation purpose, the following shall be obtained: 1) MDMA (see MDS-REQ1) Notes: − For importing medical device accessories, they shall have a "Medical Devices/Supplies National Listing Number" mentioned in the MDMA. − For importing refurbished medical devices, they shall have MDMA after refurbishment, in addition to the previous MDMA. 2) Importer License (See MDS-REQ9) 3) Importation License/Permission (in case of they are chemicals classified as medical devices/supplies, including IVDs), according to: − It shall not contain any of the chemicals mentioned in the the Chemical Weapons Convention. − The quantity to be imported shall be according to the establishment's needs for a period of one year. − Abiding by the provisions of declaration specified in Annex (2) − Submitting the application via GHAD system with providing the "Required Documents" − section (1). − Once satisfied, the SFDA issues an importation license/permission, valid for (1) year, taking into account the validity of the MDMA. 4) Approval for releasing shipment before it arrives at a port of entry, according to: − The devices/supplies shall have an AR holding a valid license, the importer can confirm this by contacting the manufacturer or SFDA. − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via Faseh Services System (SFDA) − Submitting the application via the FASAH (Tabadul) platform − Providing the "Required Documents" − section (11).

Importation of Used Medical Devices/Supplies	2	Used medical devices/supplies shall not be imported unless the purpose of importing is one of the following: A. Returning it to the KSA (after it has been maintained, calibrated, displayed as marketing samples, corrected according to a safety warning notice that requires it, or tested outside the KSA), it will be cleared from customs according to the customs declaration of exportation within (6) months from the exportation date. B. Refurbishing or maintaining them in the KSA and then re-exporting them, for importing them, the following shall be obtained: 1) Importation License/Permission, according to: − Abiding by the provisions of declaration specified in Annex (2) − Submitting the application via GHAD system with providing the "Required Documents" − section (2). − Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 2) Approval for releasing shipment before it arrives at a port of entry, according to: − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via Faseh Services System (SFDA) − Submitting the application via the FASAH (Tabadul) platform − Providing the "Required Documents" − section (11). Note: When re-exporting, they are cleared by customs according to the issued "Importation License/Permission" within (6) months.

Importation for Local Manufacturing	3	For importing semi-finished medical devices/supplies (and raw and non-raw chemicals) for the purpose of local manufacturing (manufacturing includes refurbishing, assembling, packaging, and labelling), the following shall be obtained: 1) Importation License/Permission, according to: − Quantity to be imported shall be corresponds to the production output. − Quantity to be imported shall be according to the establishment's needs for a period of one year. − Medical devices/supplies shall obtain MDMA after their manufacture and before circulation/marketing (see MDS-REQ1). − Abiding by the provisions of declaration specified in Annex (2) − Applicant shall be an establishment holding a manufacturer license (MDS-REQ9), or industrial license if the applicant is a new manufacturer that has not started production yet. − Submitting the application via GHAD system with providing the "Required Documents" − section (3). − Once satisfied, the SFDA issues an importation license/permission, valid for (1) year. 2) Approval for releasing shipment before it arrives at a port of entry, according to: − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via Faseh Services System (SFDA) − Submitting the application via the FASAH (Tabadul) platform − Providing the "Required Documents" − section (11).

Importation for Clinical Studies	4	For importing medical devices/supplies for pre-marketing clinical studies purpose, the following shall be obtained: 1) Approval (No Objection Letter) for Conducting the Clinical Trial (See MDS-REQ2) 2) Importation License/Permission, according to: – Abiding by the provisions of declaration specified in Annex (2) – Submitting the application via GHAD System with providing the "Required Documents" – section (4). – Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 3) Approval for releasing shipment before it arrives at a port of entry, according to: – Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. – Submitting the application via Faseh Services System (SFDA) – Submitting the application via the FASAH (Tabadul) platform – Providing the "Required Documents" – section (11).

Importation for Research and Education	5	For importing medical devices/supplies for non-clinical research and education purpose, the following shall be obtained: 1) Importation License/Permission, according to: – Abiding by the provisions of declaration specified in Annex (2) – Abiding by the provisions of declaration specified in Annex (4) – Applicant shall be one of the following: • Establishment holding an importer license (See MDS-REQ9) • Establishment holding a manufacturer license (See MDS-REQ9) • Healthcare provider registered in the GHAD system. • Educational facility registered in the GHAD system • Research center registered in the GHAD system • Independent researcher registered in the GHAD system. – Submitting the application via GHAD system with providing the "Required Documents" – section (5). – Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 2) Approval for releasing shipment before it arrives at a port of entry, according to: – Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. – Submitting the application via Faseh Services System (SFDA) – Submitting the application via the FASAH (Tabadul) platform – Providing the "Required Documents" – section (11).

Importation for Demonstration	6	For importing samples medical devices/supplies used in exhibitions, festivals or workshops for the purpose of demonstration, the following shall be obtained: 1) Importation License/Permission, according to: − The advertisement of medical devices/supplies that have not obtained MDMA is prohibited. Only specialized persons can be informed about such details. − Abiding by the provisions of declaration specified in Annex (2) − Applicant shall be one of the following: • Establishment holding an importer license (MDS-REQ9) • Healthcare provider registered in the GHAD system. • Facilities organizing exhibitions registered in the GHAD system • Educational facility registered in the GHAD system • Other relelavent establishment registered in the GHAD system − Submitting the application via GHAD system with providing the "Required Documents" – section (6). − Once satisfied, the SFDA issues an importation license/permission, valid for (6) months. 2) Approval for releasing shipment before it arrives at a port of entry, according to: − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via the "FASAH (Tabadul)" platform, and provide the "Required Documents" – section (10).

Importation for National Emergency	7	For importing medical devices/supplies in national emergency situations (e.g. natural disaster, war, or epidemics) for the own use of healthcare providers, the following shall be obtained: 1) Importation License/Permission, according to: − It shall not have an alternative that has obtained MDMA unless there is a justification. − It shall only be imported from an establishment holding an importer license (see MDS-REQ9) unless there is justification. − Abiding by the provisions of declaration specified in Annex (2) − Abiding by the provisions of declaration specified in Annex (5) − Submitting the application via GHAD system with providing the "Required Documents" − section (7). − Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 1) Approval for releasing shipment before it arrives at a port of entry, according to: − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via Faseh Services System (SFDA) − Submitting the application via the FASAH (Tabadul) platform − Providing the "Required Documents" − section (11).

Importation for Humanitarian Purposes (including Custom-Made Medical Devices)	8	For importing medical devices/supplies for the humanitarian purpose, the following shall be obtained: 1) Importation License/Permission, according to: − Medical device/supplies intended to be imported shall be custom-made, or not available in the KSA (not suitable for patient treatment, or intended to be used in emergency cases), and according to the request and responsibility of a healthcare professional. Note: "Patient-Specific Medical Device" and "Adaptable Medical Devices" are excluded, and they shall have obtain MDMA. − A separate application shall be submitted for each patient. − For importing custom-made medical devices, labels of medical device/supplies shall include that it is custom-made in Arabic and/or English. − Abiding by the provisions of declaration specified in Annex (2) − Abiding by the provisions of declaration specified in Annex (3) − Submitting the application via GHAD system with providing the "Required Documents" − section (8). − Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 2) Approval for releasing shipment before it arrives at a port of entry, according to: − Complying with the "Medical Devices/Supplies Shipments Procedures" in Annex (7), when applicable. − Submitting the application via Faseh Services System (SFDA) − Submitting the application via the FASAH (Tabadul) platform − Providing the "Required Documents" − section (11).

Personal Importation	9	For importing medical devices/supplies for the personal use, the following shall be obtained: 1) Importation License/Permission, according to: – Medical devices/supplies shall be home-use and intended for lay persons, unless there is justification. – Quantity shall be limited and the single shipment shall not exceed (3) months of use, and the total number of shipments shall not exceed (5) shipments for each calendar year, unless there is justification, according to a medical report indicating the quantity required for use. – Medical devices/supplies shall not to be used for commercial purposes. – Abiding by the provisions of declaration specified in Annex (1). – Submitting the following via GHAD system: • Medical report (when required) • Declaration specified in Annex (1) • Information of the medical device/supply (e.g. purchase invoice, catalog, website screenshot) – Once satisfied, the SFDA issues an importation license/permission, valid for (3) months. 2) Approval for releasing shipment before it arrives at a port of entry – Submitting the application via Faseh Services System (SFDA) – Submitting the application via the FASAH (Tabadul) platform – Providing the issued " Importation License/Permission" according section (1) above.

Note: If the request of importation license/permission includes chemical substances that falls under MOI control, SFDA will refer the request to the MOI represented by the HCIS (Central Licensing Unit), and provide the reference number to the applicant for the follow up. The HCIS will be responsible for issuing importation license/permission, and approval for releasing shipment.

Free Sale Certificate	10	Manufacturer can, upon its request, obtain "Certificate of Free Sale" according to: − Medical devices/supplies shall be hold MDMA (see MDS-REQ1). − Abiding by the provisions of declaration specified in Annex (6) − The KSA market shall not be affected by medical devices/supplies exportation and there shall be no delay in the supply of market requests, or requests of healthcare providers, and shall have sufficient supply of the devices/supplies when exported. − Applicant shall hold a manufacturer license (see MDS-REQ9). − Submitting the application via <IM.MDS@SFDA.gov.sa> with providing the "Required Documents" − section (9). − Once satisfied, the SFDA issues an certificate, valid for (1) year, taking into account the validity of the MDMA.

Required Documents

	Required Documents	Notes
(1) Required Documents for License of Importing for Circulation		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number (not required In case of annual needs), manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any
5	Importer License	– It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
6	Civil Defense License	– If it is not available, provide the PO from the beneficiary – If the importer is a government entity, provide Civil Defense Approval of instead of the license
7	Material Safety Data Sheet	– It shall be issued by the manufacturer
8	Chemical details in terms of weight or volume	– Required only if the product contains chemical substances under MOI control – It shall be issued by the manufacturer – Measuring unit shall be in Kilogram or Liter – Quantity shall be for annual needs

9	Application and attestation forms required, for chemicals importation, by MOI that are specified in Article Two of "Regulation for Law of Chemicals Import and Management"	– Required only if the product contains chemical substances under MOI control – The attestation of responsible person for chemical warehouse shall contain his contact information – They shall contain storage warehouse location (Sketch)
10	Medical Devices Marketing Authorization (MDMA)	–
11	AR License	– Automatically verified without the need to provide it in the application – It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
(2) Required Documents for License of Importing Used Medical Devices/Supplies		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Bill Of Lading	– If any
3	Country of Origin Certificate	– If any
(3) Required Documents for License of Importing for Local Manufacturing		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number (not required In case of annual needs), manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any

4	Country of Origin Certificate	– If any
5	Manufacturer License	– Instead, an industrial license is required in if the applicant is a new local manufacturer that has not started production yet, with a declaration proving that. – Local manufacturer under construction are excluded – For more information, see MDS-REQ9
6	Evidence that the product is classified as a medical device/supply	– Not required for importing raw and non-raw chemicals used in the manufacture of medical devices/supplies which within the production plan – Evidence may be a declaration of conformity (DOC), or a product classification decision issued by the SFDA, see services of products classification
7	Material Safety Data Sheet	– It shall be issued by the manufacturer
8	Chemical details in terms of weight or volume	– Required only if the product contains chemical substances under MOI control – It shall be issued by the manufacturer – Measuring unit shall be in Kilogram or Liter – Quantity shall be for annual needs
9	Application and attestation forms required, for chemicals importation, by MOI that are specified in Article Two of "Regulation for Law of Chemicals Import and Management"	– Required only if the product contains chemical substances under MOI control – The attestation of responsible person for chemical warehouse shall contain his contact information – They shall contain storage warehouse location (Sketch)
(4) Required Documents for License of Importing for Clinical Studies		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number, manufacturer name, product name, model number, lot/serial numbers, quantity, and

		expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any
5	Importer License	– It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
6	SFDA Approval (No Objection Letter) for Conducting the Clinical Trial	–
(5) Required Documents for License of Importing for Research and Education		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any
5	Importer License or Manufacturer License	– The following are excluded: o Healthcare providers o Educational facilities o Research centers o Independent researchers

		– It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
6	Declaration of Beneficiaries of Research Products	– See Annex (4)
7	Beneficiary PO	– Required only if there is no a label, fixed by the manufacturer, include that the device is for educational or research use only
8	Manufacturer letter clarifying the importation purpose	– Required only if the importer is a local manufacturer – It shall include that the medical device/supply is imported for non-clinical research purpose, and that the manufacturer has a research and development unit
(6) Required Documents for License of Importing for Demonstration		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number, manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any
5	Importer License	– The following are excluded: o Facilities organizing exhibitions o Healthcare providers o Educational facilities o Other relevant facilities

		– It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
6	Label of the medical device/supply indicates that it is for demonstration purposes only and not for sale	– It shall include a phrase indicating the use purpose of use, such as: (For Demo Only) and (Not for sale)
7	Labeling of medical device/supply	– It includes: o Label affixed to a medical device/supply or any of its containers or wrappers o Instructions for Use (IFU)
8	Evidence that the product is classified as a medical device/supply	– Evidence may be a declaration of conformity (DOC), or a product classification decision issued by the SFDA, see services of products classification
(7) Required Documents for License of Importing for National Emergency		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number, manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any
5	Importer License	– The exception is made when there is justification – It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9

6	Declaration of Healthcare Provider	– See Annex (5)
7	Declaration of Conformity (DOC)	– Declaration of conformity with the regulatory requirements of one of the following (Australia, Canada, Japan, the USA and the EU/EFTA) – Not required if acceptable justification is provided
8	Material Safety Data Sheet	– It shall be issued by the manufacturer
9	Chemical details in terms of weight or volume	– Required only if the product contains chemical substances under MOI control – It shall be issued by the manufacturer – Measuring unit shall be in Kilogram or Liter – Quantity shall be for annual needs
10	Application and attestation forms required, for chemicals importation, by MOI that are specified in Article Two of "Regulation for Law of Chemicals Import and Management"	– Required only if the product contains chemical substances under MOI control – The attestation of responsible person for chemical warehouse shall contain his contact information – They shall contain storage warehouse location (Sketch)
(8) Required Documents for License of Importing for Humanitarian Purposes (including Custom-Made Medical Devices)		
1	Declaration of Importers	– See Annex (2) – It shall be signed by authorized person identified in GHAD system
2	Purchase Invoice	– If it is not available, provide the Pro Forma – It shall include involve number, manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice, and it shall be stamped by the concerned authority for trade in the country of origin (if applicable)
3	Bill Of Lading	– If any
4	Country of Origin Certificate	– If any

5	Declaration of Health Practitioner	– See Annex (3)
6	Healthcare professional's written prescription	– Required only for importing custom-made medical devices – It means healthcare professional's written prescription which gives specific design characteristics for the sole use of a particular patient at the health professional responsibility
(9) Required Documents for Free Sale Certificate		
1	Application Form of Free Sale Certificate	– See Annex (6)
2	Medical Devices Marketing Authorization (MDMA)	– Automatically verified without the need to provide it in the application – For more information, see MDS-REQ1
3	Manufacturer License	– For more information, see MDS-REQ9
(10) Required Documents for Shipments Clearance		
1	Purchase Invoice	– It shall be authenticated by the chamber of commerce in the country of origin – It shall contain the invoice number, manufacturer's name, products name, quantity, and unit price – Model/part numbers and lot/serial numbers shall be indicating in the invoice or packing list – In case the shipment requires data logger (sensor/reader/indicator) according to manufacturer instructions, the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice or bill of lading)
2	Bill Of Lading	– In case the shipment requires data logger (sensor/reader/indicator) according to manufacturer instructions, the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice or bill of lading)
3	Customs Declaration	–
4	Medical Devices Marketing Authorization (MDMA)	– Required only for importing medical devices/supplies for the purpose of circulation

		– The MDMA shall be valid, noting that it can be renewed 90 days before its expiration – For more information, see MDS-REQ1
5	AR License	– Required only for importing medical devices/supplies for the purpose of circulation, it is automatically verified without the need to provide it in the application – The MDMA shall be valid, noting that it can be renewed 90 days before its expiration – For more information, see MDS-REQ9
6	Importer License	– Required only for importing medical devices/supplies for the purpose of circulation – Automatically verified without the need to provide it in the application – It shall be valid, noting that it can be renewed 60 days before its expiration – For more information, see MDS-REQ9
7	Declaration of Conformity to Medical Devices and Supplies Law and its Implementing Regulation	– Required only for importing medical devices/supplies for the purpose of circulation – See Annex (8) – This declaration is different than the declaration of conformity provided for purpose of obtaining MDMA
8	Importation License/Permission	– Not required for importing medical devices/supplies for the purpose of circulation and contain chemical substances

Annexes

Annex (1): Declaration and Attestation of Medical Devices/Supplies Users

Click here for printable and editable version

Name of Device:	اسم الجهاز/المستلزم الطبي :
Quantity:	الكمية:
Country of Shipment:	بلد الشحن:
Carrier:	الشركة الناقلة:
Justifications:	مسوغ الشراء:
Purchase method: ○ Through Internet: Write the the name of the site …… ○ Other: ……	طريقة الشراء: ○ عبر الانترنت: اكتب اسم الموقع ..... ○ أخرى: .....
أتعهد بأن الأجهزة والمستلزمات الطبية المذكورة في الطلب هي للاستخدام الشخصي فقط وليست للاستخدام لأي غرض آخر. كما اقر بأني على علم أن الهيئة العامة للغذاء والدواء لا تضمن سلامتها أو كفاءتها أو جودتها، لذا أتحمل كامل المسؤولية في حال نتج عن استخدامها أي مخاطر. كما اقر بأن جميع المعلومات المقدمة صحيحة. I declare that mentioned medical device/supply(s) are for personal use only, and not intended to be used for any another purpose. I also understand that the Saudi Food & Drug Authority (SFDA) can give no guarantee as to the safety, effectiveness, or quality of the above medical device/supply(s). Therefore, I will take full responsibility for all hazards or risks due to usage. I also declare all provided information is correct.	
Name of User's Device:	اسم مستخدم الجهاز:
Mobile Number:	رقم الجوال:
ID/Passport No.:	رقم الهوية/الجواز:
E-mail:	البريد الإلكتروني:
National Address:	العنوان الوطني:
Date:	التاريخ:
Signature	التوقيع:

Annex (2): Declaration and Attestation of Importers

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[To be printed on Manufacturer Letterhead]

أ) بيانات المنشأة	
اسم الشركة/المؤسسة/المستودع/المستشفى	
رقم المعرف في نظام غد	

ب) بيانات الأجهزة والمستلزمات الطبية (حسب بيانات الفاتورة)

	اسم البند	رقم الفاتورة	الكمية	تاريخ الفاتورة	الشركة المصنعة	بلد الصنع
١						
٢						
٣						
...						

ج) محتويات الجهاز والمستلزم		
هل يحتوي الجهاز/المستلزم على:	نعم أو لا؟	اسم المادة (عند الإجابة بنعم)
مادة مشعة		
مادة كيميائية خاضعة لرقابة وزارة الداخلية		
مادة مخدرة		

د) الغرض من الاستيراد ومنفذ الدخول	
الغرض من الاستخدام/الاستيراد	
منفذ الدخول الجمركي	

هـ) الإقرار والتعهد:

نتعهد نحن المدونة بياناتنا أعلاه بالآتي:

تعهدات عامة:

الأنظمة واللوائح

١) مطابقة بنود الإرسالية (الشحنة) الواردة في الفاتورة مع الشروط والمعايير الدولية والمتطلبات الواردة في "نظام الأجهزة والمستلزمات الطبية" ولائحته التنفيذية.

٢) الالتزام بـ "نظام الأجهزة والمستلزمات الطبية" ولائحته التنفيذية والمتطلبات ذات العلاقة

٣) جميع البيانات المدخلة في الطلب في نظام غد الالكتروني صحيحة وعلى مسؤولية مقدم الطلب.

٤) جميع المستندات المرفقة في الطلب متعلقة بالبنود المطلوبة.

المواد الكيميائية

٥) أن الأجهزة والمستلزمات الطبية ذات العلاقة لا تحتوي على أي مادة كيميائية من المواد الموضحة في الجداول الملحقة في اتفاقية حظر الأسلحة الكيميائية ولا تحتوي في تركيبها أياً من تلك المواد.

٦) أن الأجهزة والمستلزمات الطبية ذات العلاقة لا تحتوي على أي مواد مخدرة أو متفجرة أو مشعة أو أي مواد محظورة غير الموضحة أعلاه.

٧) إبلاغ وزارة الداخلية قبل نقل المواد الكيميائية الخطرة.

٨) الاحتفاظ بالمستندات وسجلات بيانات الكميات الواردة والمنصرفة والمستهلكة سنوياً.

النقل والتخزين

٩) مراعاة شروط النقل والتخزين حسب اشتراطات ومتطلبات المصنع والهيئة العامة للغذاء والدواء والجهات الحكومية الأخرى ذات العلاقة مع إيضاح مكان التخزين بعد فسح الإرسالية (الشحنة).

١٠) سحب الأجهزة والمستلزمات الطبية من الجمارك لحظة وصولها دون أي تأخير كما نتحمل أي مسئولية تترتب على هذا التأخير.

الإجراءات الجمركية

١١) إحضار أصل الفاتورة وشهادة المنشأ لدى منفذ الوصول.

العاملين

١٢) الأفراد القائمين بالعمل مؤهلون علمياً وعملياً

المشكلات والحوادث

١٣) ابلاغ المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية (NCMDR) بالهيئة عن أي حوادث أو مشكلات ذات علاقة بالجهاز/المستلزم الطبي ذو العلاقة.

١٤) التعاون مع الهيئة و/أو المصنّع و/أو الممثل المعتمد في أنشطة الرقابة بعد التسويق وتشمل التحقيق في البلاغات ومتابعة الإجراءات التصحيحية على الجهاز/المستلزم الطبي ذو العلاقة.

الدعاية والإعلان

١٥) عدم إصدار أي مادة دعائية أو إعلانية للجهاز أو المستلزم الطبي ذو العلاقة إلا إذا كان حاصلاً على الإذن بالتسويق للأجهزة والمستلزمات الطبية.

الاستخدام

١٦) ألا تستخدم الأجهزة والمستلزمات الطبية ذات العلاقة إلا في الأغراض الموردة من أجلها فقط، وعدم تداولها في غير الأماكن المخصصة لذلك، وتحمل جميع الأضرار الناجمة عن سوء الاستخدام أو استخدامها في غير الغرض الذي وردت من أجله.

تعهدات إضافية:

تعهدات إضافية متعلقة بالإذن بالاستيراد للأجهزة والمستلزمات الطبية المستعملة

عدم تداول الأجهزة والمستلزمات الطبية ذات العلاقة بالمملكة حتى بعد صيانتها أو تجديدها، وإعادة تصديرها بعد صيانتها أو تجديدها وإخطار الهيئة عند تصديرها مع إحضار ما يثبت ذلك، ملاحظة: لا ينطبق ذلك عند الرغبة بتداول الجهاز/المستلزم الطبي المجدد، بشرط الالتزام بالمادتين (٣/٢٠) و(٤/٢٠) من "اللائحة التنفيذية لنظام الأجهزة والمستلزمات الطبية"

تعهدات إضافية متعلقة بالإذن بالاستيراد لغرض العرض

١٧) عدم إصدار أي مادة دعائية أو إعلانية للجهاز أو المستلزم الطبي ذو العلاقة إلا إذا كان حاصلاً على الإذن بالتسويق للأجهزة والمستلزمات الطبية، ويمكن تقديم بعض التفاصيل عنها للمختصين فقط

١٨) ألا يستخدم الجهاز/ المستلزم إلا بعد وجود بطاقة تعريفية (ملصق خارجي) على الجهاز/المستلزم الطبي (أو أحد حاوياته أو أغلفته إن تعذر ذلك) ذو العلاقة، باللغة العربية و/أو الإنجليزية، تتضمن أن الجهاز/المستلزم الطبي مخصص للعرض فقط وليس للبيع.

١٩) إعادة تصدير الأجهزة والمستلزمات الطبية ذات العلاقة بتاريخ ..... (ستة أشهر كحد أقصى) أو إتلافها (وفقا لمتطلبات الإتلاف المشار إليها في "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية (MDS-REQ9)") مع تقديم ما يثبت ذلك للهيئة، وعندما لا يمكن تطبيق ذلك فيجب تقديم مسوغ مقبول لدى الهيئة.

تعهدات إضافية متعلقة بالإذن بالاستيراد لغرض الدراسات السريرية

٢٠) ألا يستخدم الجهاز/ المستلزم إلا بعد وجود بطاقة تعريفية (ملصق خارجي) على الجهاز/المستلزم الطبي (أو أحد حاوياته أو أغلفته إن تعذر ذلك) ذو العلاقة، باللغة العربية و/أو الإنجليزية، تتضمن أن الجهاز/المستلزم الطبي مخصص للدراسات السريرية فقط.

٢١) إعادة تصدير الأجهزة والمستلزمات الطبية ذات العلاقة بعدما ينتفي الغرض الذي جلب من أجلها أو إتلافها (وفقا لمتطلبات الإتلاف المشار إليها في "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية (MDS-REQ9)") مع تقديم ما يثبت ذلك للهيئة، وعندما لا يمكن تطبيق ذلك فيجب تقديم مسوغ مقبول لدى الهيئة.

تعهدات إضافية متعلقة بالإذن بالاستيراد لغرض التعليم أو الأبحاث غير السريرية

٢٢) ألا يستخدم الجهاز/المستلزم إلا بعد وجود بطاقة تعريفية (ملصق خارجي) على الجهاز/المستلزم الطبي (أو أحد حاوياته أو أغلفته إن تعذر ذلك) ذو العلاقة، باللغة العربية و/أو الإنجليزية، تتضمن أن الجهاز/المستلزم الطبي مخصص للتعليم أو الأبحاث غير السريرية فقط.

٢٣) إعادة تصدير الأجهزة والمستلزمات الطبية ذات العلاقة بعدما ينتفي الغرض الذي جلب من أجلها أو إتلافها (وفقا لمتطلبات الإتلاف المشار إليها في "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية (MDS-REQ9)") مع تقديم ما يثبت ذلك للهيئة، وعندما لا يمكن تطبيق ذلك فيجب تقديم مسوغ مقبول لدى الهيئة.

تعهدات إضافية متعلقة بالإذن بالاستيراد للأجهزة والمستلزمات الطبية لغرض إنساني (وتشمل الأجهزة الطبية المصنعة حسب الطلب)

٢٤) ألا يستخدم الجهاز/ المستلزم إلا بعد وجود بطاقة تعريفية (ملصق خارجي) على الجهاز/المستلزم الطبي (أو أحد حاوياته أو أغلفته إن تعذر ذلك) ذو العلاقة، باللغة العربية و/أو الإنجليزية، تتضمن أن الجهاز/المستلزم الطبي مصنع حسب الطلب، وذلك في حال استيراد الأجهزة الطبية المصنعة حسب الطلب.

٢٥) إعادة تصدير الأجهزة والمستلزمات الطبية ذات العلاقة بعدما ينتفي الغرض الذي جلب من أجلها أو إتلافها (وفقا لمتطلبات الإتلاف المشار إليها في "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية (MDS-REQ9)") مع تقديم ما يثبت ذلك للهيئة، وعندما لا يمكن تطبيق ذلك فيجب تقديم مسوغ مقبول لدى الهيئة.

تعهدات إضافية متعلقة بالإذن بالاستيراد لغرض التصنيع المحلي

٢٦) أن تتوافق الكمية المستوردة مع مخرجات الإنتاج.

٢٧) أن يتم حصول الأجهزة والمستلزمات الطبية ذات العلاقة على الإذن بالتسويق بعد تصنيعها (انظر MDS-REQ1).

تعهدات إضافية متعلقة بالإذن بالاستيراد للأجهزة والمستلزمات الطبية المستعملة المراد استيرادها لغرض صيانتها بالمملكة ثم إعادة تصديرها

٢٨) أن تتم الصيانة في منشأة حاصلة على رخصة صيانة للأجهزة والمستلزمات الطبية.

١) التوقيع	
اسم الشخص المسؤول	
المسمى الوظيفـي	
التاريـــخ	

التوقيـــع	
الختم	

Annex (3): Declaration and Attestation of Health Practitioner

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Medical Device/Supply			الجهاز والمستلزم الطبي	
الكمية Qty	الغرض من الاستخدام Intended Use	الموديل Model	اسم الجهاز/المستلزم الطبي Medical Device/Supply Name	م
				1
				2
				3

Justifications:	مبررات الطلب:	
	أذكر التشخيص أو العلاج أو الوقاية الذي تم من أجله طلب هذا الجهاز/المستلزم Provide the diagnosis, treatment or prevention for which the device is required	1
	اذكر أسباب اختيار هذا الجهاز/المستلزم غير المسجل على الجهاز/المستلزم المسجل بالمملكة أو العلاجات التقليدية لهذا المريض المحدد Provide the reasons why this unregistered device was chosen over a registered device within the KSA or conventional therapies for this particular patient	2
	وضح وعدد المخاطر والفوائد المرتبطة باستخدام هذا الجهاز/المستلزم ووضح كيف أن فوائده المرجوة ستفوق مخاطره Identify and list the risks and benefits associated with the use of the device and indicate how the benefits obtained would outweigh the risks	3
	قارن مخاطر هذا الجهاز/المستلزم غير المسجل بالمملكة بالعلاجات التقليدية Compare the risks of the unregistered device within the KSA with conventional therapies	4

Declaration:	الإقرار:

أقر بالآتي:

١) إني على دراية كاملة بالمخاطر الصحية للجهاز أو المستلزم الطبي المطلوب وفوائده مقارنة بالعلاجات التقليدية أو الأجهزة البديلة المتوفرة في السوق.

٢) أن لدي إلمام بالمعلومات المتاحة عن سلامة وأداء الجهاز/المستلزم الطبي المطلوب.

٣) ابلاغ المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية (NCMDR) بالهيئة عن أي حوادث أو مشكلات ذات علاقة بالجهاز/المستلزم الطبي.

٤) عدم إعادة استخدام الأجهزة والمستلزمات الطبية على مريض أخر غير الذي جلبت من أجله، وإعادة تصديرها بعدما ينتفي الغرض الذي جلب من أجلها أو إتلافها مع تقديم ما يثبت ذلك للهيئة، وعندما لا يمكن تطبيق ذلك فيجب تقديم مسوغ مقبول لدى الهيئة.

٥) التعاون مع الهيئة و/أو المصنّع و/أو الممثل المعتمد و/أو المستورد و/أو الموزع في أنشطة الرقابة بعد التسويق وتشمل التحقيق في البلاغات ومتابعة الإجراءات التصحيحية على الجهاز/المستلزم الطبي.

٦) أن الآتي تم شرحه أو سيتم شرحه للمريض و/أو ذويه:

- أن الهيئة العامة للغذاء والدواء لا تضمن سلامة وكفاءة وجودة الأجهزة والمستلزمات الطبية المذكورة أعلاه وأدائها للغرض الذي صنعت من أجله، وأن هذه الأجهزة والمستلزمات غير مسجلة في المملكة ولكن قد يوافق عليها تحت تدابير خاصة.
- إيضاح المخاطر المحتملة لاستخدام الأجهزة والمستلزمات الطبية المذكورة أعلاه والفوائد المرجوة منها.

I declare with the following:

1) I am fully aware of the health-related risks and benefits of the requested medical device/supply in comparison to conventional therapies or alternative devices available on the market.
2) I have knowledgeable about the available safety and performance information in respect of the requested device.
3) I will report to the SFDA's National Centre for Medical Device Reporting (NCMDR), any relevant adverse event of which it becomes aware, that involves the medical device/supply(s).
4) Not to reuse the device on a patient other than the one for whom the device were imported, and re-export or destroy it immediately upon completion of its use, providing the SFDA a proof. If this cannot be applied, a justification acceptable to the SFDA shall be submitted.
5) I will cooperate with the SFDA, manufacturer, authorized representative, importer and/or distributer on post market surveillance activities.
6) I have explained or I will explain the following to the patient and/or the patient's family:
   - that the Saudi Food & Drug Authority (SFDA) can give no guarantee as to the safety, effectiveness, or quality of the above device(s), and that device(s) is not registered for use in the KSA but that use of the device may be authorized under special provisions.
   - the possible risks and benefits of the above device(s).

رقم هوية المريض:
Patient's ID:

اسم الممارس الصحي:
Healthcare Professional's Name:

جهة عمل الممارس الصحي:
Healthcare Professional's Organization :

توقيع الممارس الصحي:
Healthcare Professional's Signature:

التاريخ:
Date:

Annex (4): Declaration and Attestation of Beneficiaries of Research Products

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نموذج إقرار وتعهد المستفيدين من المنتجات البحثية

(يطبع على الورق الرسمي الخاص بالمستفيد)

اضغط هنا لنسخة قابلة للطباعة والتعديل

التاريخ: .....

سعادة / نائب الرئيس التنفيذي لقطاع العمليات المحترم

بناءً على التعميد رقم ..... والصادر بتاريخ ..... لصالح شركة .....

والمتعلق بتوريد أجهزة ومستلزمات طبية للاستخدام البحثي أو التعليمي أدناه داخل المنشأة المعنية

م	اسم الجهاز/المستلزم	الكمية	الشركة المصنعة
١			
٢			
٣			
...			

نتعهد بعدم استخدام الأجهزة والمستلزمات المذكورة أعلاه في التطبيقات الطبية العلاجية أو التشخيصية وإنما يقتصر استعمالها على المجال البحثي أو التعليمي فقط، بغض النظر عن كفاءتها للاستخدامات العلاجية أو التشخيصية.

ولكم جزيل الشكر والتقدير ،،،

التوقيع	
اسم الشخص المسؤول	
المسمى الوظيفي	
التاريخ	
التوقيع	
الختم	

Annex (5): Declaration and Attestation for Healthcare Provider for Importing in National Emergency

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[To be printed on Healthcare Provider Letterhead]

نموذج إقرار وتعهد مقدم الرعاية الصحية للاستيراد في حالات الطوارئ العامة

اضغط هنا لنسخة قابلة للطباعة والتعديل

يطبع على الورق الرسمي الخاص بمقدم الرعاية الصحية

بالرجوع الى التعميد رقم ..... والصادر بتاريخ ..... لصالح شركة ..... نرغب باستيراد الآتي لغرض خاص وطارئ لمنشأتنا فقط:

م	اسم الجهاز/المستلزم الطبي	الكمية	اسم المصنع	المسوغات*
١				
٢				
٣				

* يجب ذكر المسوغات التي توضح بأن الاستيراد طارئ. في حال استيراد أجهزة أو مستلزمات طبية غير حاصلة على الإذن بالتسويق، يجب ذكر مسوغات عدم تأمينه من البديل الحاصل على الإذن بالتسويق. وفي حال أن المستورد غير حاصل على رخصة مستورد للأجهزة والمستلزمات الطبية، يجب ذكر مسوغات ذلك.

نقر نحن ..... أننا على علم بأن الهيئة العامة للغذاء والدواء لا تضمن سلامة وكفاءة وجودة الأجهزة والمستلزمات الطبية المذكورة أعلاه وأدائها للغرض الذي صنعت من أجله. وسيكون استيرادها تحت مسئوليتنا، ونتعهد بأنها لن تستخدم إلا في منشأتنا فقط ولن نقوم باستخدامها في أي مكان أخر أو إعارتها إلا بموافقة الهيئة. ونتعهد بإبلاغ المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية بالهيئة العامة للغذاء والدواء عن أي إشعار إنذار السلامة أو استدعاءات أو أي أحداث سلبية ذات علاقة بالأجهزة والمستلزمات الطبية المذكورة اعلاه فور العلم بها سواءً وقعت داخل المملكة، أو وقعت خارجها ولها عواقب على الأجهزة والمستلزمات الطبية في المملكة، وذلك عبر الرابط التالي: (http://ncmdr.sfda.gov.sa).

ولكم جزيل الشكر والتقدير،،،

التوقيع	
اسم الشخص المسؤول	
المسمى الوظيفـي	
التاريـــخ	
التوقيـــع	
الختم	

Annex (6): Application Form of Free Sale Certificate

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General Information	معلومات عامة
Invoice No.:	رقم الفاتورة:
Customs Ports:	المنفذ الجمركي:
Destination Country:	الدولة المصدر لها:
Establishment Information	**معلومات المنشأة**
Establishment Name (in Arabic):	اسم المنشأة (باللغة العربية):
Commercial Registration No.:	رقم السجل التجاري:
Establishment Account of GHAD system	رقم المعرف/حساب المنشأة في "نظام غد"
National Address:	العنوان الوطني:

Medical Devices/Supplies Information							معلومات الأجهزة والمستلزمات الطبية
الوحدة Unit	الكمية Qty.	التعرفة الجمركة HS Code	رقم القيد الوطني للجهاز أو المستلزم الطبي عندما ينطبق ذلك Medical Device/Supply National Listing Number if applicable	الرقم التسلسلي/ التشغيلة/ المجموعة فقط للأجهزة والمستلزمات التي ستعاد إلى المملكة Serial/Batch Number Only for devices/supplies that will return to KSA	طراز الجهاز أو المستلزم الطبي Medical Device/Supply Model Number	الاسم التجاري للجهاز أو المستلزم الطبي Medical Device//Supply Brand Name	
							1
							2
							3
							4
							5
							6
							7
							8
							..

Attestations	التعهدات
- I confirm that the information given in this form is true, complete and accurate.	- أتعهد بأن جميع البيانات المقدمة بهذا النموذج صحيحة.

- I certify that I will inform the SFDA of any change in the submitted information, within (10) calendar days of the change occurring. - I certify that all attached documents are stamped by company's stamp and considered as an official copy. I take the extreme responsibility for any forgery or incorrect information on these documents. - I certify to comply with the "Law of Medical Devices and Supplies" and its executive regulations, and relevant requirements, circulars and decisions. - I certify to keep the relevant documents, records, and records of production lines outcomes and provide them to the SFDA upon request.	- أتعهد بإبلاغ الهيئة بأي تغيير في المعلومات المقدمة في غضون (١٠) أيام من حدوث التغيير. - أتعهد بأن جميع الوثائق المرفقة والمختومة بختم المنشأة هي نسخ طبق الأصل، وإذا ظهر خلاف ذلك فإني أقر بارتكاب التزوير في الوثائق وأتحمل ما يترتب على ذلك من الجزاء النظامي. - أتعهد بالالتزام بمقتضي "نظام الأجهزة والمستلزمات الطبية" ولائحته التنفيذية والمتطلبات والتعاميم والقرارات ذات العلاقة - أتعهد بالاحتفاظ بالوثائق والسجلات ذات العلاقة وسجلات مخرجات خطوط الإنتاج وتقديمها للهيئة عند طلبها.
Signature	التوقيع
Name of authorized person:	اسم الشخص المفوض:
National ID:	رقم الهوية الوطنية:
Mobile No.:	رقم الجوال:
Signature:	التوقيع:
Establishment Stamp:	ختم المنشأة:

Annex (7): Medical Devices/Supplies Shipments Procedures

Prohibited Medical Devices/Supplies	The following products are prohibited from importation: A. Used medical devices, unless where the purpose of importing them is: • Maintaining or renewing them within the KSA and then re-exporting them. • Return them to the KSA after they have been maintained, calibrated, displayed as marketing samples, corrected according to a field safety notice (FSN) that requires it, or tested outside the KSA. B. Surgical gloves containing powder, patient examination gloves containing powder, and absorbable powder used to facilitate the wearing of medical gloves. C. Products bearing phrases indicating that they are intended for other than the KSA (e.g., For sale only in US) D. Following electrical medical devices: – intended to be operated to an a.c. power supply other than (230) or (400) volts, – intended to be operated with frequency other than (60) hertz, or – fitted with a/c power connector not compatible with part 401 of SBC or the Saudi standard entitled "Plugs and socket-outlets for household and similar purposes-safety requirements and test methods 250 V/13 A (SASO-2203)". E. Any medical device appears to the SFDA that may endanger the health or safety of patients and users, even if it has a MDMA from the SFDA.
Storage, Transportation, Product Shelf Life and Labeling	A. Storage and Transportation of Product: Manufacturer's instructions for the storage, handling, and transport of products they import shall be complied, and when transportation or storage requires specific temperatures or humidity, an electronic data logger (sensor/reader/indicator) for temperature and humidity shall be available in each parcel for each shipment, and: • the data logger shall be activated from the time of shipment. • the data logger shall be readable, in detail without the need for a program to run it, at the POE.

	• the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice or bill of lading). B. Product Shelf Life: If the shelf life of the product is: • less than (1) year, the remaining shelf life, at the POE, shall not be less than 40%. • more than (1) year, the remaining shelf life, at the POE, shall not be less than (7) months. C. Labeling: Labeling of imported products shall be complied with the requirements of SFDA and correspond to the labeling previously submitted to the SFDA, if applicable.
Samples Withdrawal	SFDA withdraws random samples of imported shipments at POEs in order of assessment or examination according to risk-based studies and for testing and scientific evaluation purposes or suspension cases (e.g. misleading medical claims, sterilization and labeling malfunctioning, inappropriate environment conditions, or counterfeit… etc.). However, SFDA bear neither any costs of those samples nor costs of their testing in labs.
Relevant POEs	1. King Khaled International Airport – Riyadh (RAP) 2. Riyadh Dry Port (RDP) 3. King Abdulaziz International Airport – Jeddah (JAP) 4. Jeddah Islamic Seaport – (JSP) 5. King Abdullah Seaport – Rabigh (RSP) 6. King Fahd International Airport – Dammam (DAP) 7. King Abdulaziz Seaport – Dammam (DSP) 8. King Fahd Causeway – Khobar (DBP) 9. Batha Port - Al Ahsa (BBP) 10. Haditha Port - Al Qurayyat (HBP).
Document Retention	The originals of documents submitted to the SFDA shall be kept for five years from the date of shipment clearance, and shall be submitted to the SFDA when requested.
Approval Procedure	The SFDA takes one of the following actions: • Release of the shipment, when the requirements are met. • Conditional release of the shipment and notify the importer of the notes to be corrected. • Rejection of the shipment, and the importer has the right to object within (60) days from the date of shipment rejection by

	submitting an objection letter according to the "objection procedure to the refusal of releasing the shipment" published on the SFDA website.

Annex (8): Declaration of Conformity for the Shipment to Medical Devices and Supplies Law and its Executive Regulation

Click here for printable and editable version
[To be printed Manufacturer on Letterhead]

Manufacturer Name: ……
Manufacturer Identification Number Assigned by the SFDA: ……
Manufacturer Address: ……
Invoice Number (optional): ……

I hereby declare that the medical device(s) identified below complies with the Medical Devices Law and its Executive Regulation and has been authorized by the SFDA to be placed on the KSA market.

Authorized Representative Name: ……
(Note: Not applicable for low-risk medical devices that are non-sterile and not having measuring function)

Importer Name: ……

#	Medical Device Trade Name[1]	Quantity	Serial Number/ Batch Number	Medical Device Listing National Registry Number (mentioned on the MDMA certificate)
1				
2				
…				

[1] Medical device trade name shall match the names mentioned in the invoice and the "SFDA E-Services (Ghad)".
Note: Additional devices may be attached as a list.

Authorised Signatory (on behalf of the manufacturer)
Name:
Position:
Email:
Date:
Signature:

Annex (9): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MOI	Ministry of Interior
POE	Port of Entry
Law	Medical Devices and Supplies Law issued by the Royal Decree No. (M/54) dated 6/7/1442 H.
Implementing Regulation	Implementing Regulation of Medical Devices and Supplies Law issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H.
Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.
Medical Device	Any instrument, apparatus, implement, implant device, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices and supplies; providing information for medical or personal purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Supply	A medical substance or product used in diagnosis, treatment, prosthetics, or orthotics; or in disability cases or other medical uses for humans, including medical gases.
Accessories of Medical Devices and Supplies	Any substance or product intended specifically to be used with a medical device or supply to enable it to achieve its purpose.
Home-Use Medical Device/Supply	A medical device intended for use in any environment outside a healthcare facility.
Lay Person (Non-Professional User)	A person who does not have formal education or training in a relevant field of healthcare or medical discipline.

Custom-Made Medical Device	a medical device that, at least, meets the following requirements: 1. Intended to a particular person (a patient or a healthcare professional); 2. Manufactured in accordance to a written request by an authorized professional specialist who, under his responsibility, gives specific design characteristics; and 3. It is intended to address the anatomo-physiological characteristics or pathological condition of the person for whom it is intended.
Patient-Specific Medical Device	a medical device produced based on a specified design envelope of the device (e.g., minimum and maximum dimensions, mechanical performance limits, and other relevant factors) that matched to a patient's anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging. It is typically produced in through a process that is capable of being validated. It is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.
Adaptable Medical Device	A medical device that is mass-produced and adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.
Free Sale Certificate	A document issued by the SFDA stating that a manufacturer is registered in the Kingdom and that the medical devices and supplies to be exported have obtained marketing authorization.
MDMA	Medical Devices Marketing Authorization
Identifying Information (Labelling)	Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.
Circulation of Medical Devices and Supplies	The provision of medical devices and supplies at no cost or for a fee, whether for distribution or use.

Annex (10): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 17/9/2017	- Changing in the text of sections (6), (7) and (8) of "Requirements". - Changing in the text of section (3) of "Required Documents". - Adding sections (4) and (5) to "Notes" of "Required Documents". - Changing in Annex (1).
2.0 6/2/2018	- Changing in the text of section (7) of “Requirements”.
3.0 26/7/2018	- Changing in the text of sections “Product Shelf Life” - Reformatting some sections
4.0 20/10/2020	- Genertal changing in the text of sections “Introduction” and Annex (1) for complying with Medical Devices Law and its regulation - Changing from “Guidance on Requirements of Shipments Clearance at Ports of Entry (MDS-G21) to “Requirements for Shipments Clearance Medical Devices and Other Relevant Products (MDS-REQ5)” - Changing on points (3-A) and (3-B) - Adding Annex (2)
5.0 23/3/2022	- Combing the following documents with amendments to comply with the the “Law of Medical Devices and Supplies” and its Executive Regulations: 1. Requirements for Shipments Clearance of Medical Devices at Ports of Entries (MDS-REQ5), v5 dated 23/3/2022 (Update). 2. Guidance for Medical Device Importers and Distributors, v2 dated 26/11/2011. 3. Guidance on Importation Requirements of Medical Devices Intended for Demonstration or Training Purposes Only (MDS-G8), v3 dated 27/12/2020. 4. Relevant requirements of “Guidance on Importation Requirements for Chemicals Used in Medical Devices Applications (MDS-G12)”, v2 dated 23/5/2018.

	5. Guidance on Importation Requirements of Medical Devices in National Emergency Situation (MDS-G14), v2 dated 28/7/2019. 6. Guidance on Importation Requirements for Personal Use and Custom-Made Medical Devices (MDS-G15), v1 dated 31/10/2016. 7. Relevant requirements of "Guidance on Importation Requirements for Medical Devices and Non-Medical IVDs Intended for Educational or Non-Clinical Research Purposes (MDS-G18)", v2 dated 23/5/2018. 8. Guidance of Requirements for Preliminary Products Importation for the Purpose of Local Manufacturing of Medical Devices (MDS-G26), v1 dated 9/7/2018. 9. Requirements for Issuance of Saudi Free Sale Certificate (FAQ), dated 29/9/2015. 10. Requirements of Importation Permit for IVD Medical Devices, dated 26/9/2015. - Developing following requirements: 1. Requirements of Importation for Circulation of Medical Devices/Supplies. 2. Requirements of Importation of Used Medical Devices/Supplies. 3. Requirements of Importation for Humanitarian Purposes. 4. Requirements of Importation for Clinical Studies.