MDS-G16

Guidance on Importation Requirements of Non-Medical In-Vitro Diagnostics

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Introduction

Purpose

The purpose of this guidance is to clarify the requirements for obtaining an importation license and a clearance for non-medical IVDs.

Scope

This guidance applies to importers of non-medical IVDs excluding the following:

- Radioactive materials
- Chemicals
- Non-medical IVDs containing any of the components identified in "Chemical Weapons Convention"

Background

In accordance with "The Law of Saudi Food and Drug Authority" issued by the Royal Decree No.(M/6) issued on 25/1/1428 H, stipulating that SFDA shall regulate the IVDs, and in accordance with "The Law of Chemical Materials Importing and its Management" issued by the Royal Decree No. (M/38) dated 16/6/1427H, stipulating that an authorization shall be obtained for importation and clearance of non-medical IVDs; SFDA/MDS undertakes the responsibility of issuing an importation license and a clearance for non-medical IVDs in collaboration with the MOI to ensure that they are imported for the intended purpose.

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Requirements

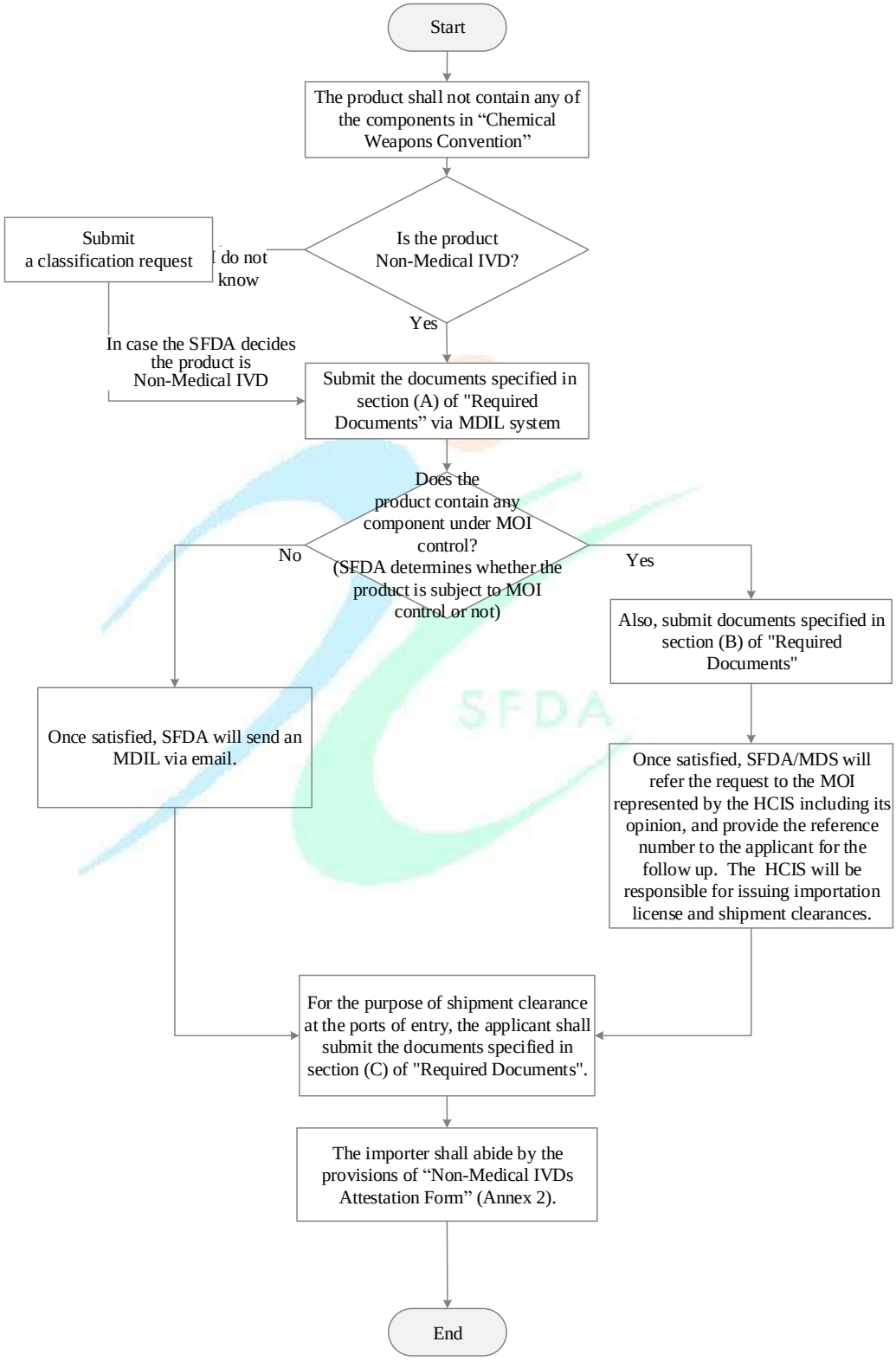
General	1	Non-medical IVDs shall NOT be imported unless MDIL is obtained from SFDA/MDS.
Submitting to SFDA	2	Applicant shall submit the "Non-Medical IVDs Application Form (Annex1)" electronically via MDIL portion on the SFDA's website, and provide "Required Documents" specified in section (A) , in addition to (B) if the product contains chemical substances under MOI control.
MDIL Approval Process	3	A. For products do not contain chemical substances under MOI control; once satisfied, SFDA issues an MDIL then send it via email. B. If the product contains chemical substances under MOI control, SFDA/MDS will refer the request to the MOI represented by the HCIS (Central Licensing Unit) including its opinion, and provide the reference number to the applicant for the follow up. The HCIS will be responsible for issuing importation license and shipment clearances.
Clearance at the Ports of Entry	4	A. For the purpose of shipment clearance at the ports of entry, applicant shall submit documents specified in section (C) of "Required Documents" according to "Guidance on Requirements of Shipments Clearance (MDS-G21)". If the product contains chemical substances under MOI control, the shipment clearance requires approval from the SFDA and HCIS. B. The labeling of the product shall include manufacturer's name and address, county of origin and product name. C. Each shipment that requires specific temperature for transportation and/or storage, according to the manufacturer instructions, shall contain temperature indicator activated from the time of shipping.
Importers' Responsibility	5	The importer shall abide by the provisions of "Non-Medical IVDs Attestation Form" (Annex 2).

Required Documents

	Required Documents	Sample	Notes
A. Required Documents for MDIL			
1	Copy of the Business Registration Certificate		– It shall be valid – Governmental establishments are exempt
2	Conformity Letter that indicates that the product is classified as a non-medical IVD		– If the Conformity Letter is unavailable, the applicant shall provide a document that proves that the product is non-medical IVD, such as: o user manual o catalog o clarification letter issued by the manufacturer Note: If not proved, the applicant shall submit a classification request. For more information, refer to the SFDA's website.
3	Copy of the Material Safety Data Sheet		– It shall be issued by the manufacturer
4	Copy of the Country of Origin Certificate		– If any
5	Copy of the PO from the beneficiary or Civil Defense License for the warehouse		-
6	Non-Medical IVDs Attestation Form		– See Annex (2), click here for printable and editable version – It shall be on the importer's official letter
7	Copy of Purchase Invoice		– It shall be issued by the manufacturer, and if not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice – It shall include expiry date and lot number (if available) – In case of annual needs, the Pro Forma shall be provided. The Pro Forma shall issued by the manufacturer and shall include product name, model number, quantity and, if the product contains chemical substances subject to the control of the MOI, net weight.
8	Copy of the Bill Of Lading (B/L) or the Air Waybill (AWB)		– If any

B. Additional Required Document if the Product Contains Chemical Substances Subject to the Control of the MOI (SFDA determines whether the product is subject to the control of the MOI or not)		
9	Chemical details in terms of weight or volume	– It shall be issued by the manufacturer – Measuring unit shall be in Kilogram or Liter
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"	– The attestion of responsible person for chemical warehouse shall contain his contact information – They shall contain storage warehouse location (Sketch)
C. Required Documents for Shipment Clearance (For Products that do NOT Contain Chemical Substances Subject to the Control of the MOI)		
11	Copy of MDIL	– It shall be valid
12	Copy of 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
13	Bill Of Lading (B/L) or the Air Waybill (AWB)	–

Flowchart


Start
The product shall not contain any of the components in “Chemical Weapons Convention”
Is the product Non-Medical IVD?
I do not know
Submit a classification request
In case the SFDA decides the product is Non-Medical IVD
Yes
Submit the documents specified in section (A) of "Required Documents” via MDIL system
Does the product contain any component under MOI control? (SFDA determines whether the product is subject to MOI control or not)
No
Yes
Once satisfied, SFDA will send an MDIL via email.
Also, submit documents specified in section (B) of "Required Documents"
Once satisfied, SFDA/MDS will refer the request to the MOI represented by the HCIS including its opinion, and provide the reference number to the applicant for the follow up. The HCIS will be responsible for issuing importation license and shipment clearances.
For the purpose of shipment clearance at the ports of entry, the applicant shall submit the documents specified in section (C) of "Required Documents".
The importer shall abide by the provisions of “Non-Medical IVDs Attestation Form” (Annex 2).
End

Annexes

Annex (1): Non-Medical IVDs Application Form

نموذج طلب إذن استيراد الكواشف المخبرية غير الطبية

(Electronic submission through SFDA website)

أ. بيانات المستورد	
التاريخ	
المستورد	
رقم السجل التجاري	
هاتف	
فاكس	
البريد الالكتروني	
العنوان	
صندوق البريد	
اسم الشخص المفوض	
صفة الشخص المفوض	
رقم هوية الشخص المفوض	
وسيلة اتصال بالشخص المفوض	
ب. بيانات الشحنة	
عدد البنود	
دولة المنشأ	
مكان التخزين	
مكان تركيب الجهاز	
الغرض من الاستخدام	
الجهة المستفيدة	
الشركة الصانعة	
شركة الشحن	
رقم البوليصة	
منفذ الوصول	
ج. الكواشف المخبرية	
اسم البند	
رقم التشغيلة	
تاريخ انتهاء الصلاحية	
الكمية	
وحدة الكمية	
تسلسل الفاتورة	

Annex (2): Non-Medical IVDs Attestation Form

نموذج تعهد طلب إذن استيراد كواشف مخبرية غير الطبية

Click here for printable and editable version

سعادة / نائب الرئيس لقطاع الأجهزة والمنتجات الطبية المحترم
الهيئة العامة للغذاء والدواء

إشارةً إلى خطابنا رقم ..... بتاريخ ..... والمتضمن طلب إذن استيراد كواشف مخبرية غير طبية الواردة في الفاتورة / الفواتير أدناه:

م	رقم الفاتورة	تاريخ الفاتورة	عدد البنود	الشركة المصنعة	بلد الصنع
١					
٢					
٣					
٤					

والقادمة عن طريق منفذ ..... نتعهد نحن شركة / مؤسسة / مستودع ..... و سجل تجاري رقم ..... وتاريخ ..... فرع ..... بالآتي:

١. أن بنود الشحنة الوارد في الفاتورة / الفواتير مطابقة للشروط والمعايير الدولية.
٢. مراعاة شروط النقل والتخزين حسب توصيات الشركة الصانعة والهيئة العامة للغذاء والدواء.
٣. بأن البنود الواردة الشحنة لا تحتوي على أي مواد مخدرة أو مواد متفجرة أو مواد مشعة أو أي مواد محظورة.
٤. إحضار أصل الفاتورة وشهادة المنشأ لدى منفذ الوصول.
٥. عدم احتواء الكواشف على العامل المسبب لمرض الايدز (HIV).
٦. استخدام المواد المطلوب استيرادها في الأغراض المجلوبة من أجلها بالإضافة إلى عدم تداولها في غير الأماكن المخصصة لذلك وتحمل جميع الأضرار الناجمة عن سوء استخدام المواد المذكورة في طلب إذن الاستيراد أو استخدامها في غير الغرض الذي جلبت من أجله.
٧. الأفراد القائمين بالعمل مؤهلين علمياً وعملياً.
٨. الاحتفاظ بالمستندات وسجلات بيانات الكميات الواردة والمنصرفة والمستهلكة سنوياً

الختم **مدير عام المنشأة / المفوض :**

التوقيـــــع :

التاريـــــخ :

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
MOI	Ministry Of Interior
SFDA	Saudi Food and Drug Authority
HCIS	High Commission for Industrial Security
MDS	Medical Devices Sector
IVD	In-Vitro Diagnostic
MDIL	Medical Devices Importation Licence