MDS – G9

GUIDANCE ON
INTERNATIONAL QUALITY AND EFFICIENCY SAMPLES

Version Number :1.1
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TABLE OF CONTENTS

DEFINITIONS & ABBREVIATIONS

Definitions

Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - Diagnosis, prevention, monitoring, treatment or alleviation of disease, - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - Investigation, replacement, modification, or support of the anatomy or of a physiological process, - Supporting or sustaining life, - Control of conception, - Disinfection of medical devices, - Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro Medical Device	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Advertising of medical devices	means any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.
Medical Devices National Registry	is the database of both registered establishments and medical devices the SFDA has authorized to be placed on the KSA market.
National Establishment	the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.[1]

1 MDS-IR6 Implementing Rule on Marketing Authorization/ Article Three

Registry Number	
International Quality and Efficiency Samples	international quality and efficiency samples ,that used for external quality assessment that used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory.

Abbreviations

SFDA	Saudi Food and Drug Authority
AR	Authorized Representative
MDMA	Medical Devices Marketing Authorization
MDNR	Medical Devices National Registry
MDIL	Medical Devices Importing License

INTRODUCTION

Purpose

The purpose of this document is to provide guidance on obtaining an importation license for international quality and efficiency samples.

Scope

This document is applicable to any medical devices establishment, health care facility or mediacl laboratory wishes to import international quality and efficiency samples.

Background

Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Medical Devices Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization.

Devices that may access KSA for purposes rather than marketing, such as international quality and efficiency samples ,that used for external quality assessment that used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory, are **exempt** from marketing authorization requirements. This document describes the requirements for obtaining an importation license for international quality and efficiency samples.

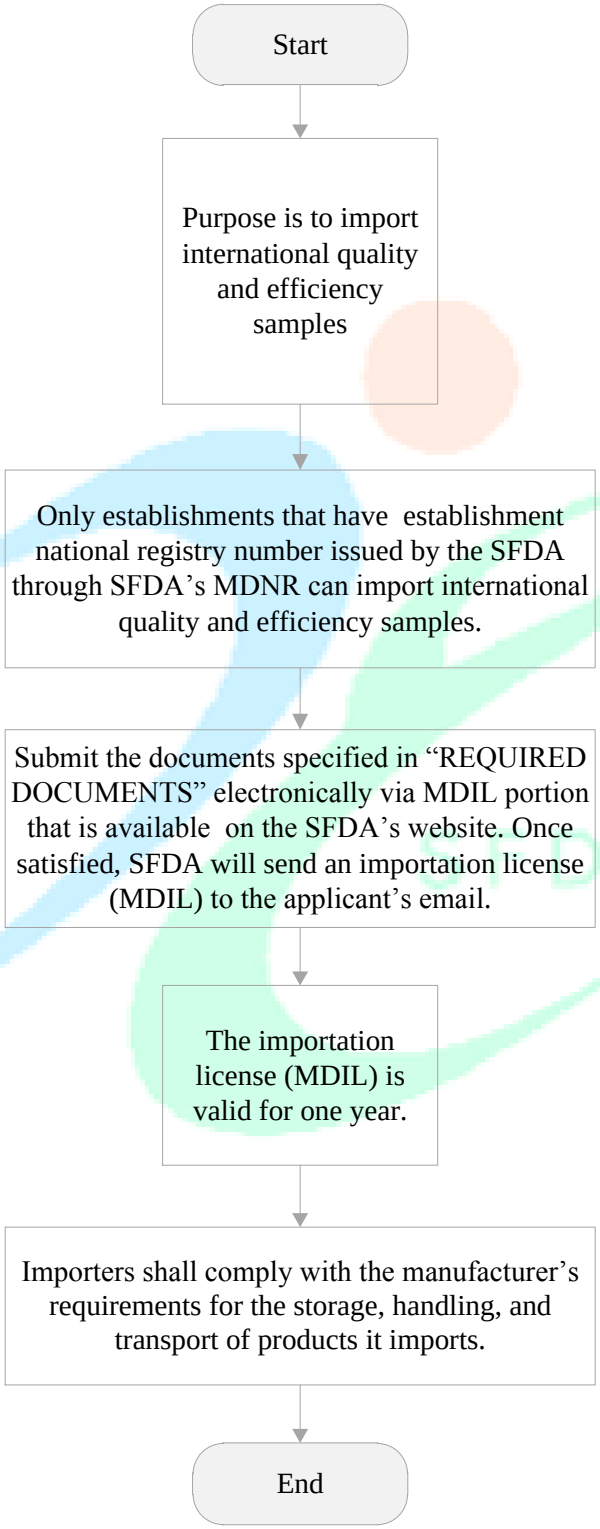
REQUIREMENTS

General	1	International quality and efficiency samples are exempt from marketing authorization requirements.
	2	No person shall import international quality and efficiency samples unless the SFDA has issued an importation license.
Pre-requisite	3	Only medical devices establishments, health care facilities or mediacl laboratories that have national establishment registry number issued by the SFDA through SFDA's MDNR can import international quality and efficiency samples.
Submitting to SFDA	4	Importers shall submit the documents specified in "REQUIRED DOCUMENTS" electronically via MDIL portion that is available on the SFDA's website. Once satisfied, SFDA will send an importation license (MDIL) to the applicant's email.
Validity of the importation license	5	The importation license (MDIL) is valid for one year.
Responsibility	6	Importers shall comply with the manufacturer's requirements for the storage, handling, and transport of products it imports.

REQUIRED DOCUMENTS

S/N	Name of documents	Template / Sample	Note
1	Application form (of international quality and efficiency samples).	See Annex 1	• The electronic form is available on the MDIL portion of the SFDA website. • Before applying for MDIL, establishment must be in possession of an establishment national registry number, assigned to it by the SFDA through MDNR
2	Copy of the invoice.	N/A	N/A
3	Confirmation letter from the manufacturer that confirms that the samples will not be used in any therapeutic or diagnostic applications and will be only limited to Proficiency testing purposes.	N/A	N/A

FLOWCHART


Start
Purpose is to import international quality and efficiency samples
Only establishments that have establishment national registry number issued by the SFDA through SFDA's MDNR can import international quality and efficiency samples.
Submit the documents specified in "REQUIRED DOCUMENTS" electronically via MDIL portion that is available on the SFDA's website. Once satisfied, SFDA will send an importation license (MDIL) to the applicant's email.
The importation license (MDIL) is valid for one year.
Importers shall comply with the manufacturer's requirements for the storage, handling, and transport of products it imports.
End

SFDA

ANNEXES

Annex 1

Application form of international quality and efficiency samples
(electronic form)

نموذج طلب استيراد عينات عالمية للجودة والكفاءة

أ- بيانات المستورد	
التاريخ	
رقم السجل الوطني للمنشأة MDNR	
المستورد	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
رقم السجل التجاري	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
هاتف	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
فاكس	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
البريد الاليكتروني	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
العنوان	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
صندوق البريد	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
اسم الشخص المفوض	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
صفة الشخص المفوض	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
رقم هوية الشخص المفوض	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
وسيلة اتصال بالشخص المفوض	(تستخرج تلقائياً من نظام السجل الوطني للأجهزة والمنتجات الطبية)
ب- بيانات الشحنة	
عدد البنود	
مكان التخزين	
مكان تركيب الجهاز	
دولة المنشأ	
الشركة الصانعة	
الجهة المستفيدة	
تاريخ دخول الجهاز	
تاريخ خروج الجهاز	
شركة الشحن	
رقم البوليصة	
منفذ الوصول	
ج- بيانات المنتجات	
رقم الفاتورة	
التاريخ	
اسم البند	
رقم التشغيلة/الرقم التسلسلي Batch/Lot No/Serial No.	

تاريخ انتهاء الصلاحية	
الكمية	
وحدة الكمية	
تسلسل الفاتورة	

د. المرفقات

١.	وثيقة مطابقة أو خطاب إقرار من الشركة المصنعة	
٢.	نسخة من فاتورة الشراء	
٣.	مرفقات أخرى	