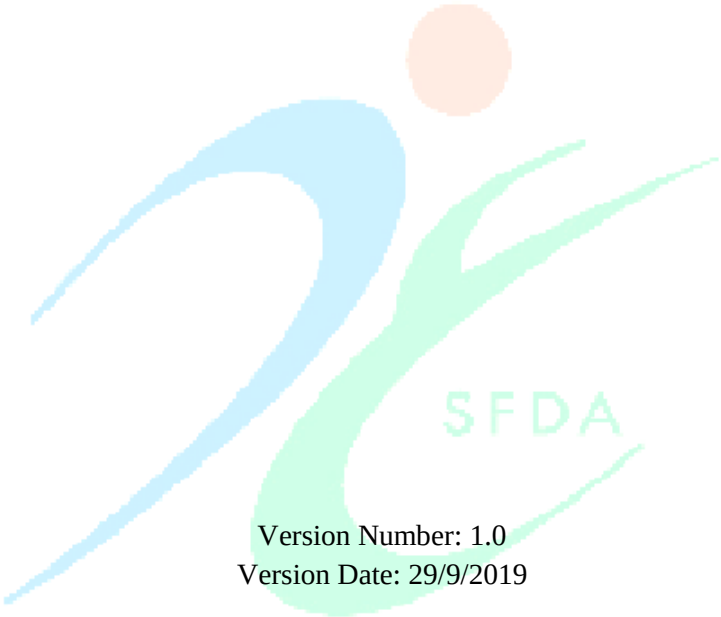
MDS – G41

Guidance on Requirements for Electronic Instructions for Use (e-IFU) of Medical Devices



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Introduction

Purpose

The purpose of this guidance is to clarify requirements for electronic instructions for use (e-IFU) of medical devices.

Scope

This guidance applies to medical devices (including IVD medical devices) that:

- will be supplied to the KSA market,
- have IFU in electronic form, and
- are intended for professional users

Excluded are:

- Medical devices (including IVD medical devices) intended for layperson use, and
- IVD medical devices intended for near patient testing (i.e. at point of care)

Background

SFDA/MDS has issued this guidance document in reference to the Essential Principles specified in "Guidance on Requirements for Medical Device Listing and Marketing Authorization (MDS-G5)" that indicate that the instructions for use may be provided to the user in non-paper format (e.g. electronic).

Requirements

Indication that IFU is supplied in electronic form	1	The physical information provided with the device shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form; and where relevant, the URL (Uniform Resource Locator) indicating the web address with clear navigation to where the e-IFU is located on the internet should be provided to users.
	2	For medical devices fitted with a built-in system visually displaying the instructions for use, the display of the instructions for use shall not impede the safe use of the device, in particular life-monitoring or life-supporting functions.
Risk Assessment	3	Manufacturers of devices that want to provide instructions for use in electronic form instead of in paper form shall undertake a documented risk assessment which shall cover at least the following elements: a) knowledge and experience of the intended users in particular regarding the use of the device and user needs b) characteristics of the environment in which the device will be used; c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form; d) access of the user to the reasonably foreseeable electronic resources needed at the time of use; e) performance of safeguards to ensure that the electronic data and content are protected from tampering; f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device; g) foreseeable medical emergency situations requiring the provision of information in paper form; h) impact caused by the temporary unavailability of the specific website or of the Internet in general, or of their access in the healthcare facility as well as the safety measures available to cope with such a situation; i) evaluation of the time period within which the instructions for use shall be provided in paper form at the users request.
	4	The risk assessment shall also be updated in view of the experience gained in the post-marketing phase.
	5	The e-IFU shall clearly state the date of release, and target regulatory jurisdiction and should be version controlled. For online

Information in e-IFU		IFU, obsolete versions of the IFU shall remain accessible to the public where appropriate.
	6	Information in the e-IFU shall include all items specified in essential principles of the "Guidance on Requirements for Medical Device Listing and Marketing Authorization (MDS-G5)".
	7	For devices with a defined expiry date, except implantable devices, they shall keep the instructions for use available for the users in electronic form for at least 2 years after the end of the expiry date of the last produced device.
	8	For devices without a defined expiry date and for implantable devices, they shall keep the instructions for use available for the users in electronic form for a period of 15 years after the last device has been manufactured.
Website	9	Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements: a) the instructions for use shall be provided in a commonly used format that can be read with freely available software; b) it shall be protected against hardware and software intrusion; c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible; d) all previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website e) The IFU should be readily accessible and should not require the creation of an online account or password. f) The IFU approved for Saudi market should be readily identified as such.

Annexes

Annex (1): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Lay person	individual that does not have formal training in a relevant field or discipline.
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 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	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.
Labelling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. Information accompanying a medical device, related to its use, but excluding shipping documents.

Instructions For Use (IFU)	information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.
Electronic IFU (e-IFU)	refers to the electronic version of the IFU.