Guidance for Electronic Instruction for use

Ministry of Health

Document Title	**Guideline for Electronic Instruction for Use (E-IFU)**
Document Type	Guidance
Directorate/Institution	**Medical Device Control Department**
Targeted Group	**All Medical Device Establishments**
Document Author	**In Vitro Diagnostic Registration Section**
Designation	**In Vitro Diagnostic Registration Section**
Document Reviewer	Director of Medical Device Control Department
Designation	Director of Medical Device Control Department
Release Date	00/00/0000
Review Frequency	

Validated by		**Approved by**	
Name	Eng. Amani ALGhielani Eng.Badria Alwahibi	Name	Ph. Ibrahim Nasser Al Rashdi
Designation	In vitro diagnostics device registration section	Designation	DG of Drug Safety Center
Signature		Signature	
Date	2-4-2023	Date	00/00/0000

Acknowledgement:

We would like to acknowledge the importance of E-IFU guideline in ensuring the safe and effective use of medical devices and the team that has written the first version of this document. We have received query from applicant to know the requirement of E-IFU.

This task force comprised of:

- Eng. Amani AlGhielani , In Vitro Diagnostics devices
- Eng. Badria Alwahibi , In Vitro Diagnostics devices

Table Of Contents:

Acronyms:

E- IFU	**Electronic – Instruction for Use**
IVD	**In Vitro Diagnostics devices**
MOH	**Ministry of Health**
IVD	In Vitro Diagnostic
DSC	Drag safety center
Vers	**Version Number**
URL	**Uniform Resource Locator**

Definitions:

Medical devices: 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 Diagnostics Devices : 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.

Instruction for use: information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken.

Electronic instruction for use: refer to the electronic of the IFU.

Professional users': means person using the medical device in the course of their work and in the framework of a professional healthcare activity.

Label: label is written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.
Labelling: labelling includes the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.
Electronic Labelling refers to any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.

Lay User: lay user refers to individual who does not have formal training in a relevant field or discipline.

CHAPTER ONE:

Introduction:

Label and instruction for use is important for each medical device and each in-vitro diagnostic device. Clear information enables the device to be used safely and correctly and that is appropriate to the education and knowledge of the potential user

Purpose:

This guideline done by medical device control department to provide instruction for e-instruction for use (e- IFU) of medical devices including (IVD).

Scope:

This guideline for companies, it's covered the medical devices, and IVD devices that market in Sultanate of Oman, have electronic format IFU and intended for professional use.

Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

- Active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device
- Implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device
- Fixed installed medical devices covered by Directive 93/42/EEC
- Medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use
- Stand-alone software covered by Directive 93/42/EEC.

Excluded:

- 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)

Structure:

This is the first version of this guideline and it consists of two chapter. Chapter one covers a brief introduction to the guideline as well as the purpose, scope and structure, chapter two consists information about E-IFU, website, risk assessment and recommendation

CHAPTER TWO:

Requirements:

Information in e-IFU

1. All previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website
2. The physical information provided with the device shall clearly indicate that the instructions for use of the device provided in an electronic form and how to access the electronic IFU /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
3. E-IFU entirely the same as would be provided in paper form comply with the regulation in target regulatory instruction
4. Video and audio files maybe offered, and paper IFU shall be provided upon user request without undue delay or cost.
5. 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.
6. Language should be available in Arabic and English.
7. 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.
8. 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.
9. Version should be controlled by the quality management system. Change history should be documented and provided to the regulatory authority upon request.

Website

1. It should be commonly used format software which can be read, freely available, not be editable
2. Protected against hardware and software intrusion.
3. Must be free of charge and should be readily accessible and should not require the creation of an online account or password.
4. It shall be provided in such a way that the server downtime and display errors are reduced as far as possible

Risk Assessment

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:

1. Knowledge and experience of the intended users.
2. Characteristics of the environment in which the device will be used.
3. Knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form.
4. Access of the user to the reasonably foreseeable electronic resources.
5. Performance of safeguards to ensure that the electronic data and content are protected from tampering.
6. 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.
7. Foreseeable medical emergency situations requiring the information in paper format.
8. 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.
9. Evaluation of the time period within which the instructions for use shall be provided in paper form at the user's request.
10. Suitable measure are in place to ensure that the electronic instructions for use reach the professional user.

The risk assessment should be updated in view of the experience gained in the post-marketing phase.

Recommendation

1. Study availability of IT infrastructure in our country.
2. Study cost benefit.
3. Train user.
4. Give suggestion to the manufacture to provide small tablet which have E-IFU without network.

References:

- MHRA
  https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/404784/Electronic_IFU__2_.pdf

- Australian government Department of health
  https://www.tga.gov.au/sites/default/files/electronic-instructions-use-eifu.pdf

- SFDA guideline

  file:///C:/Users/moh76699/Downloads/MDe-IFU-Env1MDS-G(Draft)%20(1).pdf

- AHWP Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)

  http://www.ahwp.info/sites/default/files/03%20AHWP-WG1-WG2-WG3-F002-2019.pdf

- Guidance on Requirements for Electronic Instructions for Use (e-IFU) of Medical Devices (SFDA)
  file:///C:/Users/moh76699/Downloads/MDe-IFU-Env1MDS-G(Draft).pdf

- GHTF
  GHTF /SG1/N70:2011
- ISO
  ISO 13485:2016
- IMDRF
  IMDRF/GRRP WG/N52 FINAL:2019

  -EU
  https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:072:0028:0031:EN:PDF