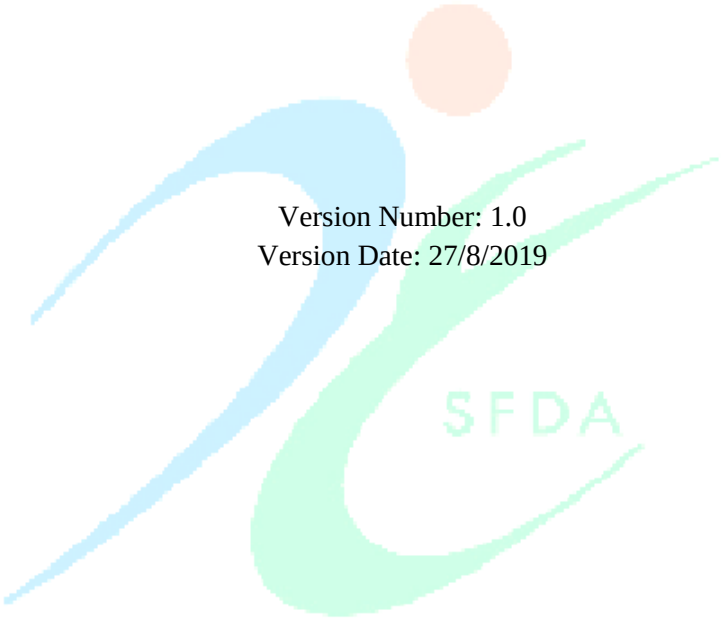
MDS-G40

Guidance on Content of Labeling of Soft Contact Lenses and Contact Lenses Solutions



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Introduction

Purpose

The purpose of this guidance is to provide a checklist for the labeling of contact lenses and contact lenses solutions that shall be provided within MDMA application.

Scope

This guidance is applicable to manufacturers and authorized representatives of soft contact lenses (e.g. cosmetic lenses, corrective lenses…etc) and contact lenses solutions that will be supplied to the KSA market.

Background

SFDA/MDS has issued this guidance document in reference to:

- Requirements specified in "Guidance on Requirements for Medical Devices Labeling (MDS-G10)".
- Saudi standard "Ophthalmic optics -- Contact lenses and contact lenses care products – Labeling (SFDA.MD/GSO ISO 11978:2017)".

Checklist for Labeling of Soft Contact Lenses and Contact Lenses Solutions

	Requirement	Soft Contact Lens		Contact Lens Solution	
		Label	IFU	Label	IFU
1.	Indication of the purpose of contact lenses (e.g. correction, cosmetic…etc)	✓	✓		
2.	Indication of the purpose of solution (e.g. rinse, clean, disinfect, store, or multipurpose ...etc.)			✓	✓
3.	Indication of contact lenses type (soft or hard)	✓	✓		
4.	Indication of schedule for wear (e.g. daily wear and/or extended wear), as applicable		✓		
5.	Indication of replacement frequency (e.g. daily disposable, weekly disposable, or monthly disposable) as applicable	✓	✓		
6.	Indication of materials properties of the contact lenses/solution		✓	✓	✓
7.	Information on contact lenses parameters: contact lenses power/sphere, base curve, diameter, (cylinder and axis for astigmatism / and additional spherical power for presbyopia), if applicable	✓			
8.	Indication of the statement “custom-made device”, if applicable	✓	✓		
9.	Indication if that the product is single use, if applicable	✓	✓		
10.	Name of product (trade Name/brand Name) in English, and in Arabic as it is pronounced in English	✓	✓	✓	✓
11.	Model and/or ID of the product	✓		✓	
12.	Name and address of the legal manufacturer	✓	✓	✓	✓
13.	Name and address of the EU authorized representative, if applicable	✓	✓	✓	✓
14.	Place an indication of traceability method	✓		✓	
15.	Indication of expiry date	✓		✓	
16.	Indication of maximum period of use after the container has first been opened, if applicable			✓	
17.	Information on instructions for use, cleaning, if applicable		✓		✓
18.	Information on any caution, precaution and warnings, and contraindications		✓		✓

19.	Information on circumstances when a lay person should consult with a healthcare professional, if applicable		✓		✓
20.	Any special storage and/or handling conditions	✓	✓	✓	✓
21.	Information about sterilization method	✓	✓	✓	✓
22.	Physical appearance details,(optional)	✓			
23.	Arabic translation for the label of soft contact lenses (at least the purpose of lenses, type of lenses, schedule for wear and replacement frequency)	✓			
24.	Arabic translation for the label of solution			✓	
25.	Full and clear Arabic translation of the IFU		✓		✓
26.	Presence of machine-readable forms, such as radio-frequency identification (RFID) or bar codes	✓		✓	

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia.
SFDA	Saudi Food and Drug Authority.
MDMA	Medical Devices Marketing Authorization.
Party	Any natural or legal person.
Manufacturer	Means any natural or legal person with responsibility for design and manufacturing of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorised Representative (AR)	Means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Labeling	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. c. Information accompanying a medical device, related to its use, but excluding shipping documents.
Instruction for Use (IFU)	Means 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.
Lay Person	Individual that does not have formal training in a specific field or discipline.
Contact Lens	Ophthalmic lens designed to be worn on the front surface of the eye. (ref: ISO 18369-1:2017)
Correction Lens	Contact lens intended to improve vision.
Cosmetic Lens	Contact lens specifically designed to change or mask the appearance of the eye Note 1 to entry: Cosmetic contact lenses are devices which can also be used for therapeutic purposes. (ref: ISO 18369-1:2017)
Soft Contact Lens	Contact lens made of a hydrogel material or non-hydrogel material which, in its hydrated final state and under normal conditions, contains a known water content, is easily deformable and may not retain its form without support. (ref: ISO 18369-1:2017)

Contact Lens Solution	A solution designed to be used for cleaning, disinfecting, rinsing, and/or storing contact lens.
Contact Lens Wear Modality	Prescribed form or manner in which a contact lens is worn. (ref: ISO 18369-1:2017)
Daily Wear	Contact lens wear modality in which a contact lens is worn only during waking periods. (ref: ISO 18369-1:2017)
Extended Wear	Contact lens wear modality in which a contact lens is worn continuously during successive waking and sleeping periods Note 1 to entry: Extended wear is designed for use overnight (ref: ISO 18369-1:2017)
Disposable Contact Lens	Contact lens intended for a single use (wearing period) (ref: ISO 18369-1:2017)