

## Temporary Guidance

### Guidance for Protective Medical Goggles and Face Shields – Recognized Standards

Medical Device Sector  
Saudi Food and Drug Authority (SFDA)

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This guidance document will be immediately implemented without prior public comment, SFDA will still review all comments received and revise the guidance document as

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## Introduction

### Purpose

The purpose of this guidance is to specify and clarify the requirements and recognized standards for obtaining Medical Devices Marketing Authorization (MDMA) of protective medical goggles and face shields, in order to place them on the market within the KSA.

### Scope

This guidance applies to Manufacturers, authorized representatives, importers, and distributors of protective medical goggles and face shields.

### Background

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

- Article Three of “The Law of Saudi Food and Drug Authority”
- Requirements specified in “Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5)”.

### Requirements

<b>General</b>	1	<p>Protective medical goggles and face shields specified in the “scope” of this document shall comply with requirements specified in “Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5) which include:</p> <ul style="list-style-type: none"> <li>• Devices and Accessories Information</li> <li>• Design and Manufacturing Information</li> <li>• Manufacturer Quality Management System (ISO 13485:2016)</li> <li>• Essential Principles , Conformance Evidence</li> <li>• Applicable Standards/National Regulations</li> </ul>
<b>Recognized Standards</b>	2	<p>Manufacturers are expected to follow state-of-the-art standards and guidances as required by SFDA essential principles, or evidence of equivalent demonstration of compliance. Compliance with the following standards can be used to demonstrate fulfillments of relevant essential principles:</p> <ul style="list-style-type: none"> <li>• ISO 4007:2018 “Personal protective equipment — Eye and face protection — Vocabulary</li> <li>• ISO 4849:1981 Personal eye-protectors — Specifications</li> <li>• EN 166/2002 “Personal eye protection”</li> <li>• OSHA 1910.133 “Eye and face protection”</li> </ul>

## Annexes

### Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Manufacturer	Means any natural or legal person with responsibility for design and manufacture 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.
Importer	Means any natural or legal person established within the KSA that places a device from a third country on the KSA market.
Distributor	Means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Goggles	Protective device that fully encloses the eyes and fits firmly on the face.
Face Shield	Protective device that is worn directly or indirectly on the head and covers the eyes and all, or a substantial part, of the face.

## Annex (2): Instructions for Reprocessing Goggles and Face Shield

**Note:** SFDA does not recommend the reuse of medical Goggles and Face shield, UNLESS there is a shortage in supply and the health workers supposed to follow the instructions form the manufacturer and the WHO guidance.

### **For reprocessing goggles and face shields used by health workers:**

- Clean goggles and face shields with soap/detergent and water followed by disinfection using either sodium hypochlorite 0.1% (followed by rinsing with clean water) or 70% alcohol wipes.
- Goggles and face shields may be cleaned immediately after appropriate doffing and hand hygiene is performed OR placed in designated closed container for later cleaning and disinfection.
- Ensure cleaning of goggles and face shields takes place on a clean surface by disinfecting the surface before cleaning of goggles and face shields.
- Appropriate contact time with disinfectant (e.g. 10 minutes when using sodium hypochlorite 0.1%) should be adhered before reuse of goggles and face shields. After cleaning and disinfection, they must be stored in a clean area to avoid recontamination.

[https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC\\_PPE\\_use-2020.3-eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf)