GLOVES AND FACE MASKS
DUAL-USE PRODUCTS

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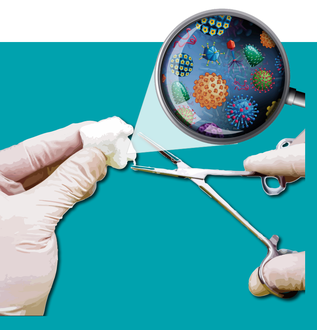
In some cases, **personal protective equipment** (PPE) and **medical devices** (MD), although similar in appearance, have different purposes and must comply with different legislative provisions.

There are important differences that need to be well understood.

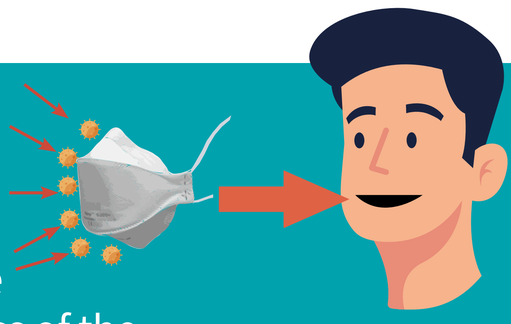
In addition, for certain situations, it may be necessary to combine the requirements of both types of equipment, so we speak about dual-use gloves or masks.

What is a protective glove against micro-organisms?



It is a Personal Protective Equipment (PPE) whose purpose is to protect worker´s hand from contact with patients, their biological fluids, or instruments contaminated with biological agents that may entail a risk to worker´s health.

What is a filtering mask to protect against particles?



It is a personal protective equipment (PPE) covering nose, mouth and chin, designed to ensure protection against solid and liquid aerosols. It must ensure a tight fit to the wearer´s face, regardless of the state of the wearer´s skin and head movements.

What is a medical glove?

It is a Medical Device (MD) whose specific medical purpose is to prevent the appearance of a disease in the patient due to the transmission of biological agents through contact with the hands of the healthcare professional. They can be examination gloves (sterile or not) or surgical gloves (sterile).

What is a medical mask?

A medical device (MD) that covers at least the nose and mouth, providing a barrier to minimise the transmission of infectious agents from the wearer. Additionally, this mask can provide the wearer with protection against splashes of potentially contaminated fluids.

What is a dual-use glove?

It is a glove designed to simultaneously protect the worker and the patient. It must comply with both PPE and MD legislation.

What is a dual-use mask?

Half-mask that provides protection from bioaerosols to the wearer and at the same time reduces the transmission of infectious agents from the wearer to the work area. It must comply with both PPE and MD legislations.

TECHNICAL ASPECTS TO BE CONSIDERED

DUAL-USE GLOVE	AS PROTECTIVE GLOVE (PPE)	AS MEDICAL GLOVE (MD)
DURATION OF USE	Disposable after use in a specific task or after contact with a patient	
CERTIFICATION	According to PPE Regulation[1]	According to MD Regulation[2]
CATEGORY/ CLASS[3]	Category III if biological agents are harmful	Class I if the glove is an examination glove, sterile or not. Class IIa if the glove is a surgical glove
CE MARKING	It must indicate conformity with the two pieces of legislation. The CE marking shall be followed by: - No. of the Notified Body involved in the conformity to type procedure for the PPE (YYYY) in case the glove is category III PPE and class I MD - No. of the Notified Body involved in the conformity assessment for the MD (XXXX) in case the glove is MD, class I sterile or a surgical glove, class IIa - Without Notified Body No. in case the glove is category II PPE and class I MD	
REFERENCE TO STANDARDS	Harmonised product standards with regard to PPE Regulation: EN 420 (General requirements) EN ISO 374-5 (Gloves against micro-organisms) EN ISO 374-1 (Only if the glove is also a chemical protective glove)	Standards (MD Regulation) Examples: EN 455-1 (Absence of holes and AQL) EN 455-2 (Physical properties) EN 455-3 (Biological evaluation) EN 455-4 (Determination of shelf life)
REFERENCE TO TEST METHOD STANDARDS	Optionally, reference can be made to the test method standards applied according to the product standard Some examples are: EN ISO 374-2 (Absence of holes) ISO 16604 (Resistance to virus penetration, optional) EN16523 (Resistance to permeation, chemical glove)	

TECHNICAL ASPECTS TO BE CONSIDERED

DUAL-USE MASK	AS FILTERING MASK (PPE)	AS MEDICAL MASK (MD)
DURATION OF USE	Disposable after use in a specific task or after a stay in a contaminated area	
CERTIFICATION	According to PPE Regulation[1]	According to MD Regulation[2]
CATEGORY/ CLASS[3]	Category III	Class I
CE MARKING	It must indicate conformity with the two pieces of legislation. The CE marking shall be followed by: - No. of the Notified Body involved in the conformity to type procedure (XXXX) as the mask is a category III PPE	
REFERENCE TO STANDARDS	Harmonised product standard with regard to PPE Regulation: EN 149:2001 (Filtering masks to protect against particles)	Standard (MD Regulation). EN 14683:2019 (Medical masks)

(1) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.
(2) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices will apply from 26 May 2020.
(3) The classification as PPE and MD is made by the manufacturer according to the intended use.

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