CHECKLIST FOR MEDICAL FACE MASKS WITHOUT CE MARKING

The technical data sheet is the result of the collaboration between Confindustria Dispositivi Medici and the Italian National Institute of Health (ISS) to identify the fundamental requirements for the placing on the market of medical masks without CE marking

Article 15 of Italian Legislative Decree no. 18 of 17 March 2020 on measures to strengthen the Italian healthcare service and economic support for families, workers and businesses related to the COVID-19 epidemiological emergency provides for the placing on the market of medical face masks without CE marking. Below is the procedure with the verification notes by the ISS and the checklist of the minimum required information.

PROCEDURE as provided for by art. 15 of Italian Legislative Decree no. 18 of 17 March 2020

1. Manufacturers wishing to avail themselves of the exemption must send a self-certification to the ISS in which, under their own exclusive responsibility, they indicate the technical characteristics of the masks and their compliance with all the safety requirements set out in the current regulations.
2. No later than three days from the abovementioned self-certification, Manufacturers must also send to the ISS any information useful for the certification of the masks covered by it.
3. The ISS, within three days of receipt of the above, shall rule on the compliance of the masks with the standards in force.
4. If, as a result of the assessment referred to in point 3, the masks do not comply with the rules in force, without prejudice to the application of the provisions on self-certification, the Manufacturer shall immediately cease production.

Notes to be considered for assessment by the ISS

The ISS shall check compliance with the requirements of Directive 93/42/EEC and subsequent amendments and integrations, or, in the absence thereof, compliance with three minimum requirements with regard to the quality, safety and performance of the product and production also in relation to what is defined in the circular of the Italian Ministry of Health of 13 March 2020 "Nonwoven fabric masks - Circular on the COVID-19 epidemiological emergency". Manufacturers/suppliers preparing to manufacture and/or market medical face masks must ensure that at least the following three basic requirements are met:

1. the product must comply with the manufacturing, design and performance requirements and test methods for medical face masks intended to limit the transmission of infectious agents among patients and clinical staff during surgery and other medical contexts with similar requirements, as indicated in technical standard UNI EN 14683:2019 " Medical face masks - Requirements and test methods", with particular regard to the conduction of tests on the filtering capacity of the product. Compliance with performance requirements may entail two different approval options depending on whether the mask is intended for (A) healthcare workers or similar (law enforcement/public contact persons) or (B) employees of companies/citizens. Indeed, in the case of (A) healthcare workers or similar, the Manufacturer shall declare all four of the following requirements for the performance of the face mask:

a) filtering capacity;
b) bioburden;
c) splash protection capacity;
d) differential pressure (breathability).

2. the product must meet the biocompatibility requirements applied to medical devices as specified in technical standard UNI EN ISO 10993-1:2010 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (harmonised). The biological evaluation, carried out on the product in its final form, should be confirmed by tests in order to verify cytotoxicity, sensitisation and skin irritation. The biological evaluation can also be carried out on a bibliographic basis.

3. the manufacturer of face masks shall establish and implement a quality management system to ensure, regulate, maintain and control the basic requirements for the production activity. The information provided to users by means of the label and/or instructions for use, which is important to identify the product, its technical characteristics and methods of use, as well as any markings/certifications, shall also be verified. The documentation supporting points 1-2 of the procedure should be sent to Dr. Marcoaldi roberta.marcoaldi@iss.it, Coordinator of the Working Group "COVID-19 Medical Devices". Below is a short checklist to identify the requirements and minimum information to be verified before contacting the ISS.

MINIMUM INFORMATION REQUIRED

1	Device code and name
2	Brief description (including device dimensions)
3	Indications of use
4	Specify whether the device is disposable
5	Specify whether the device is sterile, and if so, the sterilisation method.
6	Number of layers
7	Specify the materials of which it is made and the chemical composition of the fabric
8	Specify whether the device contains latex
9	Specify the filtering power of the device
10	Specify whether the mask complies with technical standards (e.g. ISO 14683, ISO 10993}.
11	Describe the packaging (packaging material and whether it contains latex)
12	Specify which of the following elements are listed on the label:
	• name or business name and address of the manufacturer
	• name and address of the authorised representative (if the manufacturer is established outside Europe)
	• information strictly necessary to identify the device and the contents of the package
	• the word "STERILE" in the case of a sterile device
	• the lot code number preceded by the word "LOT", or the serial number
	• an indication of the date by which the device should be used safely, expressed in year/month;
	• an indication that the device is disposable (in the case of a disposable device)
	• specific storage and/or handling conditions
	• specific instructions for use

	• warnings and / or precautions to be taken
	• the sterilization method (in the case of a sterile device)
13	Specify contraindications and/or warnings
14	Specify method of disposal
15	Specify the presence and implementation of a company Quality System
16	Specify whether production takes place in controlled contamination environments certified by an external body, and if so, state the class of the environment, the frequency of particle and microbiological validation and attach the latest certification/revalidation reports
17	If the product is not sterile, declare the bioburden provided for in the finished prototype and provide evidence of it
18	Specify any biocompatibility tests performed on the finished product in accordance with technical standard UNI EN ISO 10993-1:2010 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Alternatively, provide the results of the literature evaluation
20	Attach evidence of the application of technical standard UNI EN 14683:2019 "Medical face masks - Requirements and test methods", with particular regard to the performance of tests on the filtering capacity of the product. Attach any supporting certifications and/or test evidence