

French Published New Mask Decree No 2021-76

French government published a Decree No. 2021-76 on January 27, 2021 which prescribing the general measures necessary to deal with the epidemic of Covid-19 and also updated in the Interministerial Note on 28th, January 2021.

Decree No. 2021-76 of January 27, 2021 prescribing the general measures necessary to deal with the epidemic of Covid-19 as part of the health emergency, is defining new rules relative to the use and sale of masks

Four types of masks are available on the market:

1. Respiratory protection masks (FFP),
2. Surgical-type masks,
3. Non sanitary use masks
4. Other types of masks.

Only masks mentioned under point 1 to 3 are considered as protection masks whose use is recommended by Health authorities.

A notice published in the Official Journal on 10 February 2021 is specifying some rules for the importation of 'general public masks' intended for non-sanitary use.

Non sanitary use masks are defined as masks with filtration greater than 90% of 3 μm particles, tested and compliant with the Interministerial Note of March 29, 2020, amended on January 28, 2021.

In addition, specific masks were designed for deaf and hard of hearing people: they include a transparent window in the middle of the mask.

At point of sale, compliant masks (id est protection masks) must be separated from non-compliant masks and distributors must inform when masks comply or not with sanitary authorities' recommendations. It is important to note that reusable textile masks can still be used if they comply with the updated requirement.

Any manufacturer or importer placing these masks on the market must first:

1. Make sure that **the product meets all the specifications set by the interministerial note of March 29, 2020, updated on January 28, 2021.**
 - Surgical masks defined as Medical devices complying with EN 14683+AC:2019 (or equivalent)
 - Imported masks, with surgical shape, excluding textile fabric masks, whose performance is at least equal to masks mentioned at the 4th bullet point
 - Mask FFP2 or FFP3 (EN 149 or equivalent) without expiratory valve
 - Masks for Non-Sanitary Use (UNS) complying with:
 - Particles filtration efficiency > 90% (3 microns)
 - Breathability allowing wearing the mask for 4 hours
 - Air permeability > 96L/m²/s (differential pressure 100Pa)
 - Good fit of the mask on the face, no sagittal seam
 - If reusable, > 5 washes

It is recalled that the marketing of masks "general public filtration greater than 90%" is not subject to authorization or approval. The name "consumer mask filtration greater than 90%" may not be used and the logo may not be affixed to products other than masks meeting the specifications required for masks "general public filtration greater than 90%".

2. Have tests carried out, under its responsibility, conducted by one of the competent third parties, listed on <https://www.entreprises.gouv.fr/fr/covid-19/entreprises-comment-faire-tester-masques> which demonstrating the performance of its masks with regard to the State specifications appearing in the interministerial information note of March 29, updated January 28, 2021, in new condition and after washing. It must be able to present the results of the tests to the inspection services which so request.

If the material (same supplier, same reference) has already been tested for another manufacturer, the manufacturer is not obliged to re-test it. However, it must be able to present the test report on the material he uses to the inspection services.

3. **Request**, via the platform of simplified procedures, to appear in the test results
<https://www.demarches-simplifiees.fr/commencer/formulaire-fabricants-de-masques-grand-public>
<https://www.demarches-simplifiees.fr/commencer/complexes-deja-testes-attestation>
<https://www.demarches-simplifiees.fr/commencer/formulaire-pour-les-fabricants-masques-a-fenetre>

4. Affix the logo on the product or its packaging to identify masks for the general public.

For “general public filtration greater than 90%” masks, the logo used is that mentioned in appendix V of the interministerial note of March 29, 2020, updated on January 28, 2021.

EXAMPLE OF NEW LOGO



This new logo must be affixed on new masks for the general public with filtration greater than 90% manufactured or on the leaflet or packaging accompanying them no later than March 1, 2021

By derogation, masks “general public superior filtration 90% ”produced or imported before March 1, 2021, meeting the specifications of Annex I, bearing the logo mentioned in Annex III and for which information on filtration performance is provided in a manner that can be read by all alternative means, can be marketed until December 31, 2021.

5. Indicate the filtration performance on the packaging.

In addition, companies must provide the public with a notice indicating how to use, wash and maintain the mask. Download an example of a standard notice (version of February 1, 2021)

French decree n° 2021-76: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043070201>

Notice to importers of “general public” masks reserved for non-sanitary uses:

<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043110523>

COVID 19: Information relating to masks for the general public:

<https://www.entreprises.gouv.fr/fr/covid-19/covid-19-informations-relatives-aux-masques-grand-public>

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