AGENZIA ADM

Operator's guide for surgical mask import clearance

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THE EQUIPMENT IS DISTINGUISHED INTO THREE CATEGORIES:

1. Medical Devices (the so-called "surgical masks") or MD
2. Personal Protective Equipment or PPE (FFP2 and FFP3)
3. Generic (or "filtering") masks that apparently look like MD "surgical masks" but in reality are neither tested nor certified

CERTIFICATION FOR THE DIFFERENT CATEGORIES

Distinguiamo diversi casi in base alle categorie di cui al primo paragrafo:

Medical Devices: (*surgical masks)*

1) If the CE ademark is present and valid, the device can be cleared immediately through customs

2) If the CE trademark is not present or not valid, , a special self-certification must be sent to the Italian Institute of Health (ISS) as per art. 15, paragraph 2 of the D.L. 17 March 2020, n. 18 and wait for the latter to decide to place the products on the market. In this case the product can only be "conditionally cleared through customs", with requirements, traceability obligation and with the commitment not to place it on the market before the release of the authorization.

Istituto Superiore Sanità - Procedure per richiesta produzione mascherine

If the product does not obtain certification, it is downgraded to a "generic mask" and, if it cannot be re-labeled as generic (because for example the fake Œ mark is imprinted on the fabric and not on the packaging), it will be destroyed.

For this type of device, the direct release procedure can apply if the final recipient falls within those provided for by the Ordinance 6/2020 of the Special Commissioner.

PPE: *(FFP2 and FFP3)*

A) where the CE mark is present and valid, the device can be immediately cleared through customs

B) if the CE trademark is not present or not valid, a special self-certification must be sent to INAIL (National Insurance Institute for Industrial Accidents) as per art. 15, paragraph 3 of the D.L. March 17, 2020, n. 18 and wait for the latter to be granted before releasing the products on the market. In this case the product can only be "conditionally customs cleared", with requirements, traceability obligation and with the commitment not to place it on the market before the release of the authorization (#CuraItalia - Inail istruzioni operative validazione dpi).

If the product does not obtain certification, it is downgraded to a "generic mask" and, if it cannot be re-labeled as generic (because for example the fake Œ mark is imprinted on the fabric and not on the packaging), it will be destroyed.

For this type of device, the direct release procedure can be used if the final recipient falls within those provided for by Ordinance 6/2020 of the Special Commissioner.

Generic Masks:

Generic (or filtering) masks can be cleared through customs only if they meet the production and marketing conditions referred to, lastly, in the MISE Circular no. 107886 of 23 April 2020:

a) must not bear the marking CE ,
b) the packages must expressly indicate that it is not a Medical Device (MD) or Personal Protective Equipment (PPE),
c) must be accompanied by a warning that clearly states that they do not in any way guarantee the protection of the wearer's respiratory tract, which cannot be used when the use of Medical Devices or Personal Protective Equipment is prescribed (for healthcare or in the workplace) but, only by way of example, when the covering of the nose and mouth is considered useful for environmental hygiene purposes and for use by the community,
d) the Manufacturer MUST declare that the Generic Devices do not cause damage and do not cause additional risks for users, according to the destination of the product.

In the event that these conditions are not met, the product, if it is possible to re-label it, can only be "conditionally cleared" with prescriptions, traceability obligation and with the commitment not to market it before replacing the non-compliant labels with those according to law.

Neither the direct release nor the rapid release procedure can be used for this type of device and the same cannot be imported in derogation of the current regulations on production and marketing.
Art. 16 paragraph 2 of the D.L. 18/2020 allows the use (and not the import) of generic masks produced in derogation of the regulations in force for placing on the market, only while the state of emergency continues.
Consequently, based on the aforementioned provision, it will be possible to downgrade and use as generic masks the products imported as PPE that do not obtain the required authorisation, if they still meet the requirements referred to in letters a, b, c and d, referred to in this paragraph. Instead, it will not be possible to import generic masks produced in derogation of the current marketing rules referred to in letters a, b, c and d, invoking the aforementioned rule.

Single sale of masks is allowed provided that such information is clearly intelligible in the place of sale, and buyers are aware of it at the time of purchase.

Customs must confirm (note MISE 107886 of 23 April 2020) that the above conditions apply at the time of import. If the response is negative, it will monitor the conformation, also by suspending the release, with contextual information to the MISE and release of the goods with the A20 invoice (only in the cases provided for).

Where it is not possible to conform, the products as described in the aforementioned provisions, will be destroyed.

NB Generic terms such as "Qualified Certificate", "Protective Mask" or "Fight against COVID-19" cannot replace the CE trademark or INAIL or ISS's authorisation, on the contrary they can represent an element capable of confusing final consumers, and therefore removal may be required as a condition for customs clearance if the product does not obtain the authorisation provided for by art. 15 D.L. 18/2020.

WHAT IS THE FISCAL TREATMENT OF THE SUPPLIES?

1. The supplies imported, for **free distribution**, by entitled parties such as:

    a. Public organizations, state bodies and bodies governed by public law
    b. Philanthropic and charitable organizations authorized by national authorities, subjects operating on behalf of the entities referred to in letter a.
    c. Members of trade associations signing Memoranda of Understanding with ADM

    ARE NOT SUBJECT TO CUSTOMS TAXES (VAT and DUTIES)

2. The supplies **imported for its employees** (therefore not intended for sale), by subjects other than those referred to in point 1, but included in Annex 3 of the Dpcm 10/4/2020

    ARE SUBJECT TO TAXES BUT NOT TO REQUISITION EVALUATION

3. The supplies imported **for sale** without using the direct release and rapid release procedures

    ARE SUBJECT TO TAXES AND REQUISITION EVALUATION

A VAT rate of 5% is applied to the supplies subject to tax upon importation. Until 31 December 2020, imports and subsequent transfers of goods useful for combating COVID-19 (as identified by paragraph 1 of art.124 of Law Decree no.34 of 19 May 2020), are exempt from VAT with the right to deduction of the tax (if it had been paid) pursuant to art. 19, paragraph 1 of Presidential Decree no. 633/1972.

WHO ARE THE SUPPLIES INTENDED FOR?

1. **Direct release** - for IPD and movable property of any kind needed to deal with Covid-19 intended for:
    - Regions and autonomous provinces
    - Local territorial bodies
    - Public administrations
    - Public or private structures accredited and/or included in the regional emergency network (including first aid units for their own needs)
    - Subjects carrying out essential public services of public utility and/or public interest identified by the Dpcm, 26/4/2020

Self-certification must be produced, signed by the actual recipient of the goods or by a person with powers of representation and/or a delegated person, filling in the [FS1] direct release form.

If the requirements for exemption from taxes (VAT and DUTIES) are also met, it must be specified in the lower part of the form for direct release and the importer must also fill in and sign the appropriate form (Self-certification of third party).

2. Fast-release - non-dpi movable assets useful for combating COVID-19 intended for subjects other than those referred to in the above list (Fast-release form) [FS2] .
   Also in this case, if the requirements for exemption from taxes (VAT and DUTIES) are met, it must be specified in the lower part of the form for rapid-release and the importer must also fill in and sign the appropriate form (Self-certification).

Self-certification must be produced by the actual recipient of the goods signed by a person with powers of representation and/or a delegated person, in which it is certified that the goods are used to deal with the Covid-19 emergency. The self-certification must be accompanied by a copy of the identity document of the signatory.

Following the Commissioner's Ordinance no. 13 of 9 May 2020, the PPE, FFP2, FFP3, N95 and KN95, indicated in the circular of the Ministry of Health prot. 4373[1] of 12 February 2020 or other movable assets useful for the fight against COVID-19, as well as surgical masks and their "similar" products if imported by the Associates/Adherents of the signatory associations of the Memorandum of Understanding signed on 1 and 3 May 2020 by the Special Commissioner with some trade associations, are admitted to the direct release. Such operations are subject to VAT and customs duties.

ADM has signed Memoranda of Understanding [FS3] with Regions, Territorial Bodies and Trade Associations, in order to admit PPE and masks imported to be distributed free of charge to employees of companies and businesses belonging to individual associations, to a special direct release procedure, free of VAT and customs duties. In this case must be used the specific Direct release form (called MSDPI) [FS4] and the relative Summary Prospectus [FS5].

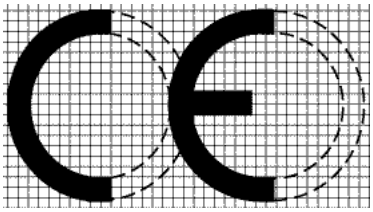
WHERE DO I CHECK THE CE CERTIFICATE?

EUROPEAN COMMISSION Internal Market, Industry, Entrepreneurship and SMEs ITALY

ACCREDIA Coronavirus emergency management

NB the notified body must be authorized to issue certification for the relevant legislation: personal protective equipment (EU Reg. 425/2016); medical devices (93/42/etc).

By way of example only, the graphics of a compliant certificate CE are shown compared with that of a non-compliant one:



[1] Ministry of Health circular prot. 4373 of 12 February 2020

COMPULSORY DAU CODES

In field 44:

1) To report the number of templates [(2)]:
   - 24yy generic non-DM and non-DPI masks, FFP1 masks with or without filter
   - 19yy DM surgical masks
   - 20yy FFP2 and FFP3 masks with or without filter, KN95 masks

2) 07AO + tax code Final recipient of the goods falling within the exemption in combination with code C26 of field 37 and in combination with field 8 c.f. In the case of importation carried out directly by the public body or by the beneficiary of the exemption
3) 08AO direct release self-certification
4) 09AO quick release self-certification
5) 10AO self-certification by the importer, if different from the final recipient, for goods intended entirely for subjects entitled to the exemption on their mandate (this code is mandatory if box 8 is different from the 07AO case)
6) To report imports made exempt from VAT and Duties, by virtue of Memoranda of Understanding signed by ADM with Local Authorities and Trade Associations, aimed at the free distribution of masks to employees of associated companies
7) 11AO, is the protocol number of the Memorandum of Understanding referred to
8) 12AO, is the VAT number/Fiscal Code of the person in charge of the free distribution of the masks (in case of cumulative import of masks on behalf of several companies belonging to a trade association, the document code 12AO must be repeated for each of the companies that will provide free distribution of masks).

In field 37 to invoke application of the deductible: code C26.

In field 33: table of sa codes and taric codes of products and medical supplies intended for the most commonly used emergency (COVID-19 - INDICATIVE LIST OF PRODUCTS TO BE IMPORTED DUTY - VAT FREE) + cadd.

T001 (for CE branded dpi masks with appropriate certification)

T028 (for dm masks with brand CE with suitable certification)

T041 (for masks without CE brand or with CE brand not with suitable certification, notwithstanding article 15 dl 18/2020).

This guide does not in any way replace the legislative and sector provisions but constitutes a collection for practical purposes of the existing requirements and cases, drawn up in order to facilitate the obligations to be implemented.

(2.0 version updated on June 19 2020)

(2) Also in field 44, the code 21yy is used for goggles, visors and protective screens; code 22yy for overalls and gowns and code 23yy for ventilation devices.