



•ALERT•

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Import of facemasks, medical devices and ppe: administrative and criminal penalties

"Seizures of facemasks, optical thermometers and sanitizers not complying with the law"; "Finance Police raids, facemasks have been seized and wholesalers have been reported"; "Virus, Finance Police in pharmacies: non-compliant facemasks have been seized".

These are the headlines of recent articles published by the most important national newspapers, which reported about raids, in several areas of the country, by the Italian NAS, the Finance Police and the Customs Agency, aimed at the seizure of medical devices ("MD") and personal protective equipment ("PPE") imported from non-EU countries, and distributed within the national territory, with "counterfeit" CE conformity marking or "lacking conformity and safety standards".

From a regulatory perspective, the import and distribution of PPE and MD are regulated by respectively:

- **Council Directive 93/42/EEC** concerning medical devices, implemented in the Italian legal system by **Legislative Decree No. 46 dated 24 February 1997** (as amended by Legislative Decree No. 37 dated 25 January 2010 and by Law No. 37 dated 3 May 2019);
- **EU Regulation** of the European Parliament and of the Council of **9 March 2016 No. 425** on personal protective equipment and **Legislative Decree No. 475 dated 4 December 1992** (as amended by Legislative Decree No. 17 dated 19 February 2019).

The so-called "**Decreto Cura Italia**" (Law Decree No. 18 dated



17 March 2020, converted by Parliament with Law No. 27 dated 24 April 2020) issued in order to face the epidemiological emergency, has been recently released on the subject; Article 15 of the Decree allows the production, import and placing on the market of "*surgical masks and personal protective equipment in **derogation** from the European regulations in force*" regarding CE marking and procedures for assessing compliance with safety standards.

It is an **exceptional** provision, based on the state of health emergency, so that the authorisations issued by the competent authorities - the Italian Institute of Health in case of MD, the Italian INAIL in case of PPE - are valid only in Italy and until the end of the emergency period (31 July 2020).

Moreover, pursuant to Article 16, second paragraph, of the Law Decree "Cura Italia" a special precautionary measure has been introduced: the "facemasks" for common use, which are neither MD nor PPE.

The overlapping of regulatory provisions, during this emergency period, has caused a high-level uncertainty over the interpretation of such legislation; therefore, it cannot be ruled out that non-compliance with requirements may entail liability, even criminal liability, as shown by recent judicial investigations.

Thus, it is appropriate to briefly examine the main consequences – both administrative and criminal – that may occur in case of import and distribution of MD and PPE.



ADMINISTRATIVE PENALTIES

Non-compliance with certification and safety standards provided for MD and PPE

Legislative Decree No. 46, dated 24 February 1997 provides for several administrative fines (from a minimum of € 500 to a maximum of € 128,400) in case of non-compliance with the certification and safety requirements provided for MD.

The following conducts may constitute an administrative offence:

- violation of the provisions concerning the CE marking;
- affixing of markings, signs and inscriptions suitable to deceive third parties on the meaning and/or design of the CE marking;
- marketing, sale or entry into service of MD without CE conformity marking or devices without EU declaration of conformity, unless the fact constitutes a criminal offence;
- improper or unduly affixing of the CE conformity marking, unless the fact constitutes a criminal offence.

Legislative Decree No. 475, dated 4 December 1992, instead, punishes some violation regarding PPE with an administrative fine (from a minimum of € 1,000 to a maximum of € 60,000, depending on the case) in the following cases:

- production and import of first-class PPE that do not fulfil the essential safety standards;
- distribution on the market of PPE under Category I, II, and III that do not fulfil the essential safety standards;
- failure to draw up the EU declaration of conformity;
- placing of PPE on market without the CE marking;
- affixing of markings, signs and inscriptions suitable to deceive third parties on the meaning and/or design of the CE marking.

The import or distribution in accordance with the "Cura Italia" Law Decree do not constitute an administrative offence.

Customs offence referred to in article 303 TULD

The import from non-EU countries of PPE or MD, for their subsequent distribution in Italy, could be relevant from customs point of view.

The Italian Consolidated Law on Customs (D.P.R. dated 23 January 1973, n. 43 – called "TULD") provides that "*every customs operation must be preceded by a customs declaration*", according to the provisions of the Union Customs Code (EU Regulation dated 9 October 2013, n. 952).

The mismatch between the declaration and the findings of the customs authorities - whether intentional or negligent - is punished by article 303 of the TULD: "*if the declarations concerning the quality, quantity and value of the goods intended for permanent import [...] do not correspond to the findings, the declarant is punished with an administrative penalty from € 103 to € 516*".

CRIMINAL PENALTIES

Fraud in trade and sale of industrial products with mendacious signs under Articles 515 and 517 of the Italian Criminal Code

The import or distribution in Italy of PPE and/or MD without CE conformity marking or with counterfeit CE marking could constitute fraud in trade (Article 515 of the Italian Criminal Code), which punishes "*with imprisonment of up to two years or a fine of up to € 2,065 anyone who, in the exercise of a commercial activity [...] supplies the purchaser with a movable good at the place of another, or a movable good which differ from the one declared or agreed as to origin, provenance, quality or quantity*".

Moreover, the placing on market of PPE or MD bearing mendacious distinctive signs that could deceive the purchaser regarding the quality of the product may also amount to the sale of industrial products with mendacious signs (Article 517 of the Italian Criminal Code), which punishes

"with imprisonment for up to two years and a fine of up to € 20.000, anyone who sells or otherwise puts into service intellectual properties or industrial products, with national or foreign names, trademarks or distinctive signs, suitable to deceive the purchaser regarding the origin, provenance or quality of the work or product".

As clarified by the Supreme Court, the punished conduct ("otherwise puts into service") may be carried out by any handling of goods and, in particular, any activity aimed at getting out the product from the holder's availability for any reason, including its presentation to customs for customs clearance.

These crimes cannot be committed, however, if a MD or PPE has been authorized under article 15 of the "Cura Italia" Law Decree; in this case, during the entire emergency period, the absence or non-conformity of the CE marking will not be deemed as means of "fraud" or "mendacious sign".

The administrative liability of legal entities under Legislative Decree No. 231/2001

Fraud in trade (Article 515 of the Italian Criminal Code) and the sale of industrial products with mendacious signs (Article 517 of the Italian Criminal Code), are included among the offences which might cause the administrative liability of legal entities under the **Legislative Decree No. 231 of 8 June 2001**.

Consequently, a company may be held liable for such crimes, if committed in the interest or to the advantage of the company itself; and pursuant to article 25 bis1 of Legislative Decree No. 231/2001 the company may be punished with an **administrative fine** from a minimum of € 25,800 to a maximum of € 774,500.

The disqualification sanctions provided for by article 9 of the Legislative Decree, instead, will not be applied.

Speculative manoeuvres referred to in article 501 bis of the Italian Criminal Code

With the spread of the epidemiological emergency from Covid-19, many PPE and MD have become a "basic necessities", both in the protection of the individual in the private sphere and in the protection of health in the performance of work activities. The increased demand for such devices could cause an unreasonable increase in consumer prices, given their limited availability on the market.

The **speculative manoeuvres** on the prices of such "basic necessities" may constitute a criminal offence pursuant to **Article 501 bis of the Italian Criminal Code**, which punishes *"with imprisonment from six months to three years and a fine from € 516 to € 25,822 anyone who, in the exercise of any productive or commercial activity, carries out speculative manoeuvres or conceals, hoards or incurs raw materials, consumer food products or **basic necessities**, in order to cause their shortage or the increase in price on the domestic market"*.

Such a case may become more relevant in view of the issuance of the **Order No. 11 dated 26 April 2020**, by which the Extraordinary Commissioner for the emergency from Covid-19, has set at € 0.50 per unit (net of VAT) *"the final consumer price of face masks (standard UNI EN 14683), practised by final retailers"*. Although the boundaries within which this order may apply (by type of product and by subject) are not very clear, it is certain that the "surgical" masks are now expressly declared "basic necessities".

CONTACTS

Dario Covucci

dario.covucci@lcalex.it

Nicolò Pelanda

nicolo.pelanda@lcalex.it

Giovanni Morgese

giovanni.morgese@lcalex.it

