



## Responses to Medical Device Shortage: An Italian Perspective

### Background

The aim of this contribution is to develop a first analysis of the Italian Government main responses to COVID-19 epidemic and, in particular, to the shortage of medical devices. In such a scenario, I would like to draw attention to the provisions concerning the manufacture and marketing of surgical masks.

Italy has been the first European country to witness the spread of COVID-19 and to face a healthcare system crisis characterized by a severe shortage of medical devices. After the first case was recorded, the Italian National Health Service (SSN) rapidly experienced a shortage of essential medical devices to treat or contain the outbreak of the virus.

The healthcare structures have been struggling in acquiring diagnostic tests, sanitising products, oxygenation masks, surgical masks and, more generally, personal protective equipment (PPE). In particular, surgical masks and PPE are essential for COVID-19 patient care, and the absence of such equipment has resulted in, especially in Lombardy, high rates of infections also among medical staff.

The Italian medical devices shortage has certainly various causes, including the high rate at which the virus is spreading and the structure of medical device supply chain. Those causes are common to all countries affected by Covid-19. Yet certain aspects are exclusively attributable to circumstances in Italy.

### The Italian National Health Service Organisation

The SSN offers healthcare access to all Italian citizens and residents free of charge. The medical device shortage and the consequent exponential COVID-19 growth put severe pressure on the SSN. However, an analysis of the Italian healthcare system crisis cannot be limited to the shortage of medical devices, but needs to take into account the more complex context of SSN organisation and resources allocation: it is essential to understand that healthcare in Italy is regionally organised.

This means that the legislative and administrative powers, as far as healthcare is concerned, lie with the Italian regions, leaving limited authority to the central government.

In particular, the central government is entitled to determine the "essential levels of care" (the minimum standard healthcare service and benefits that the Italian regions are expected to cover; so-called "LEA") and the aggregate amount of financial resources for granting the healthcare services and their allocations among regions. Each region is fully in control of the budget allocated and therefore singularly reacts to the healthcare structures deficiencies and needs.

### Financial Resources and Supply Chain

In order to support the Italian regions in handling the COVID-19 emergency, the Italian Government has taken several legislative initiatives. As an immediate response to the COVID-19 outbreak, the Italian Government has assigned financial resources to strengthen the SSN and guarantee both medical device supply and medical staff hiring. However, the allocation of such resources remains to be clearly defined. Meanwhile, with immediate effect, the Italian Government has implemented protective measures including the suspension of all the productive and commercial activities with the sole exception of those considered essential (e.g. food and healthcare industries). Among the protective measures, the Italian Government has introduced certain derogations to the current Italian legal framework designed to encourage the companies, affected by the above-mentioned suspension, to shift their production (where practicable) and overcome the shortage in manufacturing the needed devices. Such derogations especially concern the manufacture and marketing of PPE and surgical masks.

### Surgical Masks

As it is widely known, the use of surgical masks reduces the chance of infection. Both from an EU and Italian perspective, surgical masks are considered medical devices and fall within the class I risk (low-risk devices). This means that they do not need a Notified Body assessment to be marketed. Indeed, under the Italian legislative framework, the manufacturer must simply formulate an EC declaration of conformity by which it declares the compliance with the medical device regulation and the fulfilment of the related administrative procedures. The administrative procedures substantially consist in registering the manufactured medical device on the Italian Minister of Health databank for medical devices. The registration on the databank ensures the traceability of the registered medical device and access to data relating its main characteristics.

Given that, the most recent and representative legislative initiatives, the Italian Law Decree 2 March 2020, n. 9 ("D.L. 9/2020") and Italian Law Decree 17 March 2020, n. 18 ("Cura Italia" or simpler "D.L. 18/2020") provisions, have drastically simplified market access of medical devices. In accordance with article 34, paragraph 3 of D.L. 9/2020, after an evaluation carried out by the Italian Institute of Health (ISS), it is permitted the use of surgical masks free of the CE mark. The same provision establishes that surgical masks shall be considered personal protective equipment for healthcare professionals.

This provision is complemented by article 15, paragraph 1 of D.L. 18/2020 allowing for the manufacturing, import and marketing of surgical masks by way of derogation to the Italian medical device regulation. The article 15 derogation is limited to the CE certificate affixation and the medical device registration on the Italian Minister of Health databank. Thus, the provision must not be understood in terms of quality and safety standard exceptions. Indeed, the second paragraph of article 15 outlines a specific procedure for those who intend to benefit from the derogation and therefore manufacture, import and market surgical masks. Such exceptional procedure requires that the manufacturer and/or importer shall submit to ISS a self-certification according to which they certify the medical device technical standards and therefore that such product complies with the medical device safety standards. Thereby safety and quality standards are still guaranteed.

Both articles 34 of D.L. 9/2020 and 15 of D.L. 18/2020 derogations are in line with the EU Directive 93/42/EEC concerning medical devices which allows a Member State, on a duly justified request and in the interest of protection of health, to authorize the placing on the market (within the Member State's territory) of individual devices for which the conformity assessment procedures have not been carried out yet.

### Filtering Masks and Requisitions

Although the derogations allow for a speedier market access process for medical devices, they do not sufficiently guarantee a consistent and continuous supply of surgical masks meeting not only the medical staff or workers but also the collective need. And for that reason, the Italian Government has established further exceptional provisions, including the authorisation of the use of filtering masks (so-called "*mascherine filtranti*"), via article 16, paragraph 2, of D.L. 18/2020.

Actually, the "filtering masks" are a new type of category and do not fall within the medical device nor PPE categories. They are not intended for medical staff or workers but for the community.

The manufacturer of filtering masks does not need to comply with specific technical provisions and quality and safety standards; the only requirement is that such masks must not be harmful or pose any extra safety or security risks for the users.

To be more precise, filtering masks could be regarded as comparable to apparel items, and that is the reason why several Italian fashion companies are breaking into filtering masks business. However, filtering masks are not apparel items to the extent that they provide a minimum standard of protection from COVID-19 infection. Indeed, by means of such legislative innovation, the Italian Executive is seeking to guarantee the use of filtering masks for the community letting the workers and the medical staff use respectively the PPE and surgical masks currently available on the market.

Secondly, with the same purpose of differentiating the use of masks (surgical masks, filtering masks and PPE masks), in accordance with article 6, paragraph 1 of the Cura Italia Decree, the Head of the Civil Protection Department and the new Special Commissioner (through the Italian Customs and Monopoly Agency) can request the requisition of healthcare and medical-surgical devices from any private or public entity, as well as any movable goods designed to implement and support the measures to contain the COVID-19 emergency. This means that any kind of mask (surgical mask, PPE face mask and filtering mask) can be subject to requisition and therefore addressed to the neediest healthcare structure (granting an indemnity to the owner of such masks).

### Conclusions

All the described provisions are part of the Italian Government's COVID-19 emergency plan and apply until the end of the state of emergency, currently set for the 31 July 2020. They have been enacted through law-decrees, which means that each of the legislative initiatives carried out by the Italian Government may be amended when the Italian houses of parliament convert them into laws.

Therefore, though the effects and the related evaluations on the legislative initiatives adopted by the Government are still to come, it is clear that the derogations to the Italian medical device regulation represent a short-term crisis response, while more effective coordination between the Italian central government and the regions could guarantee an adequate and prompt intervention in addressing the shortage of medical devices on a systematic basis.