

To the Company SEAC Sub S.p.A seabscub@legalmail.it

**Subject: COVID emergency - 19  
Implementation of art.15 paragraph 3 of decree-law 17 March 2020, n.18 Extraordinary validation of personal protective equipment**

THE EXECUTIVE DIRECTOR

In accordance with the decree-law of 17 March 2020, no. 18, converted with modifications by law 24 April 2020, n. 27, containing "Measures to strengthen the National Health Service and economic support for families, workers and businesses connected to the epidemiological emergency from COVID-19";

In accordance with article 15 of the aforementioned decree-law, entitled "Extraordinary provisions for the production of surgical masks and personal protective equipment", which contributes to the management of the COVID-19 emergency and up to the end of the state of emergency of which to the resolution of the Council of Ministers on January 31, 2020, the production, import and placing on the market of surgical masks and personal protective equipment in exemption from the current provisions;

In accordance with paragraph 3 of the same article 15 which provides for individual protection devices a validation procedure carried out by INAIL on the basis of a self-certification of the manufacturing companies and importers, certifying the technical characteristics of the aforementioned devices and compliance by the same of all the safety requirements referred to in current legislation;

In accordance with the notice by the Italian Ministry of Health of 18 March 2020, published on the website [www.salute.gov.it](http://www.salute.gov.it), with which interpretative elements were provided regarding, in particular, the application of the aforementioned article 15;

In accordance with the operating instructions of 19 March 2020 concerning "Emergency COVID - 19 Implementation of art. 15 of decree-law of 17 March 2020, no. 18. Extraordinary validation of personal protective equipment" published on the portal [www.inail.it](http://www.inail.it);

Certified that this is an extraordinary validation, valid for the time strictly necessary and as long as the state of emergency COVID-19 lasts, in the impossibility of carrying out the ordinary procedures for checking the quality and safety standards of the devices in question;

Considering to the pec of 22 April 2020 (prot. n.8252) of 12 May 2020 (prot. nn. 14137 and 14171) and of 19 May 2020 (prot. n.16597), with which SEAC Sub SpA, as manufacturer of the following product:

**Full face masks for the protection of the respiratory tract (deriving from a "large snorkeling facial"), Magica, Libera and Unica models;**

has sent to this Institute the self-certification required by the aforementioned standard in which, under its own exclusive responsibility, it has certified the technical characteristics of the aforementioned product and has declared that it respects all the safety requirements

of the current legislation, and recalled the own notes prot. nn. 11706 of May 7, 2020 and 16743 of May 31, 2020;

having regard to the subsequent pec of June 26, 2020 (prot. n.20865) with which the same manufacturer sent further technical documentation to support the validation practice presented with particular reference to full-face masks derived from masks from the Libera and Unica models;

acquired on 6 July 2020 the technical evaluation made by the Institute's technical-scientific structures on the basis of declarations made in the self-certification and of the documentation produced by the applicant;

considering that the technical evaluation gave the following positive result for both the above-mentioned mask models:

"Considering the documentation in the possession of the Institute and having examined test report no. 200721\_1 issued on 25 June 2020 by an accredited body for the certification of PPE for the protection of the respiratory tract, the proposed devices comply with the UNI EN 136: 2000 standard.

It also highlights the compliance with the requirements of UNI EN 143: 2007 of the new type of filters provided for air treatment.

Therefore, in relation to the technical changes introduced and resulting from the documentary evidence reported in the integration of 26 June 2020, a positive technical opinion is expressed for the Libera and Unica models ",

DECLARES

As indicated in the introduction, compliance with the current regulations of the following individual protection device:

**Full face masks for the protection of the respiratory tract (deriving from a "large snorkeling facial"), Libera and Unica models, produced by SEAC Sub SpA.**

This declaration is valid from the date of this provision until the end of the state of emergency referred to in the resolution of the Council of Ministers on January 31, 2020.

In order to maintain the validity of this declaration during the aforementioned period, it is essential that the technical characteristics of the personal protective equipment remain unchanged and that the product is not modified.

dr. Edoardo Gambacciani  
Rome, date of registration

The document is digitally signed pursuant to Legislative Decree 82/2005 s.m.i. and related standards and replaces the document