



## LIFE SCIENCES & HEALTHCARE

### QUALIFICATION OF PROTECTION MASKS

With the confinement coming being phased out, INFARMED, I.P. (the Portuguese Medicines and Health Products Agency) has been asked about the different types of masks and their uses, having issued [Notice Number 096/CD/100.20.200 dated 13/05/2020](#).

Regarding the applicable, INFARMED, I.P. makes reference to three documents published by the Directorate-General for Health: Rule No. 07/2020 of 29 March 2020 for health professionals, Guideline No. 19/2020 of 3 April 2020 for other professionals, and Information No. 09/2020 of 13 April 2020, for all citizens.

Regarding the type of masks, whether imported or produced nationally, Infarmed, in conjunction with the Directorate-General for Health (DGS), the Food and Economic Security Authority (ASAE) and the Portuguese Institute of Quality (IPQ) issued separate guidelines - the

"Technical Specifications DGS / INFARMED / ASAE / IPQ", which were published on 14 April, 2020, and the INFARMED / ASAE guidelines on "Import and Manufacture of Medical Devices and Personal Protective Equipment in the context COVID-19 Pandemic under the terms of Decree-Law no. 14-E / 2020, of April 13".

Masks must have the CE marking or may be covered by equivalent standards, as stated in the guidelines referred to above or, in accordance with Decree-Law no. 14-E / 2020, of 13 April, published online with Commission [Recommendation \(EU\) 2020/403](#) of 13 March.

In this way, suppliers (manufacturers, importers and wholesale distributors) should provide information that demonstrates the conformity of the mask they market or distribute with the requirements of the applicable legislation, or with that established in Decree-Law No. 14-E / 2020, that allows for the identification of the applied law. This information should accompany each mask supply.

Information about the type of mask, namely surgical mask (medical device), respiratory protection half mask (personal protective equipment) or the so-called social or community masks (textile product) must appear on the label or on the product itself. This information should also appear on the corresponding invoice, in order to allow for a rapid identification of the regulatory framework.

According to what is set down in the document entitled “Masks intended for use within the scope of COVID-19”, social masks must provide, via the labeling or marking of the textile product, information on the composition, the performance characteristics of the product and that it is not a medical device nor personal protective equipment. Any information that is conveyed at points of sale must be consistent therewith, for example, the physical and digital information and promotional media.

Considering who will use them, masks are grouped into three levels of protection by the document entitled “[Masks intended for use within the scope of COVID-19](#)”, namely:

*[Summary Table on the next page](#)*

Level of protection	Recipients	Product type	Competent authority
Level 1	Health professionals and patients	<u>Individual protection equipment:</u> Respiratory protection semi-mask (FFP2, FFP3). Preferably with CE marking. Alternatively, masks in accordance with the equivalent international standardization requirements, recognized at European level.	ASAE
		<u>Medical Device:</u> Type II and IIR surgical masks. Not reusable. Preferably with CE marking. Alternatively masks in accordance with the equivalent international standardization requirements, recognized at European level.	INFARMED, I.P.
Level 2	Professionals in frequent contact with the public	<u>Medical Device:</u> Type I surgical masks Not reusable. Preferably with CE marking. Alternatively masks in accordance with the equivalent international standardization requirements, recognized at European level.	INFARMED, I.P.
		<u>Textile:</u> Alternative masks for frequent contact with the public, single use or reusable <ul style="list-style-type: none"> <li>• Minimum filtration performance of 90%</li> <li>• Breathability of at least 8l / min according to EN ISO 9237: 1995 or at most 40 Pa according to EN 14683: 2019 (Annex C)</li> <li>• Allows 4 h of uninterrupted use without degradation of the particle retention capacity or of the breathability</li> <li>• No performance degradation over its lifetime (maximum number of times that can be reused)</li> <li>• Proper design and construction</li> </ul>	ASAE
Level 3	Professionals who are not telecommuting or the general population for authorized outlets in the context of confinement	<u>Textile:</u> Alternative masks for infrequent contact, single use or reusable. <ul style="list-style-type: none"> <li>• Minimum filtration performance of 70%</li> <li>• Breathability of at least 8l / min according to EN ISO 9237: 1995 or at most 40 Pa according to EN 14683: 2019 (Annex C)</li> <li>• Allows 4 h of uninterrupted use without degradation of the particle retention capacity or of the breathability</li> <li>• No performance degradation over its lifetime (maximum number of times that can be reused)</li> <li>• Proper design and construction</li> </ul>	ASAE

For more information on the different types of masks and their uses, see the published infographics.

All information is available on the INFARMED, I.P. website under COVID-19:

- ▶ Masks intended for use within the scope of COVID-19 Technical Specifications;
- ▶ Import and Manufacture of Medical Devices and Personal Protective Equipment in the context of Pandemic COVID-19 - Decree-Law no. 14-E / 2020, of 13 April.

On the DGS website at:

- ▶ Information on the placing on the market of products without CE marking by national manufacturers who do not usually produce them.

## CONTACTS

César Sá  
Esteves

**PARTNER**

[cesar.esteves@srslegal.pt](mailto:cesar.esteves@srslegal.pt)



Ana Menéres

**PARTNER**

[ana.meneres@srslegal.pt](mailto:ana.meneres@srslegal.pt)



Diana Abegão  
Pinto

**ASSOCIATE**

[diana.pinto@srslegal.pt](mailto:diana.pinto@srslegal.pt)



\*\*\*\*

This Newsletter is intended for distribution to clients and colleagues and the information contained herein may not be used or reproduced, in whole or in part, without the express consent of SRS. If you require further information on this topic, please contact us: [srsglobal@srslegal.pt](mailto:srsglobal@srslegal.pt)

