



## **SURGICAL MASK & P.P.E. PRODUCTION**

# COVID-19 EMERGENCY

Because of COVID-19, the whole world has had to face an unequalled pandemic.

Currently in Italy the need of surgical masks has increased from **130 ML** to **950 ML per month**. Moreover, this need is expected to continue even once the Coronavirus emergency ends.

For this reason, as **iVision Group**, we immediately wanted to invest in the **HEALTH** of each person.

Thanks to the solid experience of our group on digital technologies, and to our cross-cutting skills, we created the **iVision HEALTH** division.



## CORRIERE DELLA SERA / CRONACHE

LE PROTEZIONI

### Coronavirus, la caccia a 130 milioni di mascherine al mese

L'esplosione dei costi per fornirle almeno a chi lavora. Atterrato il Cargo bloccato in Cina con 900 mila pezzi. Il sequestro di farmaci e respiratori destinati all'export

#### CORRIERE DELLA SERA

del 22 Aprile 2020

locali. Il Politecnico di Torino ha fatto una stima del fabbisogno nazionale, a partire dalle riaperture del 4 maggio, depurando il numero del probabile smart working: 953 milioni di mascherine al mese, 35 milioni al giorno. Un numero enorme che difficilmente si riuscirà a reperire.



# COMPANY & PRODUCTION

The production plant is located in **San Dorligo della Valle** (TS - Italy) in a 2500 square meters area, where our **state-of-the-art machines** for the production of surgical masks are situated. These, along with our constantly growing **team**, are able to guarantee high quality products. Our **strengths** include:

- Production capacity of **200.000 surgical masks per day**
- **CE Certification** and ISS Authorization (**Istituto Superiore di Sanità**)
- High quality **Italian fabrics** with **filtering capacity  $\geq 98\%$**
- Raw materials and production **100% MADE in ITALY**
- Production compliant with **UNI EN 14683** and **UNI EN ISO 10993** standards
- **ISO 9001:2015** Certification



# CERTIFICATIONS

iVision Health is not only a certified company but it also holds all the necessary authorizations in order to produce **surgical masks**, according to the standards required by law:

- **ISO 9001: 2015** certification for the design, the production and the marketing of surgical masks
- **Authorization ISS** – Istituto Superiore di Sanità - **COV1297** and **COV1303** reference  
[www.iss.it](http://www.iss.it)
- **CE Certification**, according to 93/42 CEE directive  
[www.salute.gov.it](http://www.salute.gov.it)



*Istituto Superiore di Sanità*



*Istituto Superiore di Sanità*

Gruppo di Lavoro "Dispositivi Medici COVID-19"

Prot. **19921/COV-DM-D42 - 04/06/2020**

Viale Regina Elena, 299  
00161 R O M A  
Telegrammi: ISTISAN ROMA  
Telefono: 0649901

**IVISION S.r.l.**  
**TRENTO**  
Pec: [ivisionweb@pec.it](mailto:ivisionweb@pec.it)

**Oggetto:** Valutazione maschere facciali ad uso medico; richiesta ai sensi dell'articolo 15, comma 2, del Decreto Legge del 17/03/2020 n. 18, convertito nella Legge 24 aprile 2020, n. 27 – Proponente IVISION S.r.l.  
**Rif. COV 1297**

Con riferimento all'istanza presentata ai sensi dell'articolo 15 comma 2 del Decreto Legge del 17/03/2020 n. 18, convertito nella Legge 24 aprile 2020, n. 27, si trasmette l'allegata dichiarazione, parte integrante della presente comunicazione, riportante parere **FAVOREVOLE ALLA PRODUZIONE E COMMERCIALIZZAZIONE\*** del prodotto iVi 98 Monouso Tipo II, per l'utilizzazione dello stesso secondo la destinazione d'uso prevista, fino al termine dello stato di emergenza di cui alla delibera del Consiglio dei ministri

**IVISION S.R.L.**

VIA DEI SOLTERI, 105, 38121 TRENTO, Italy

come riconoscimento del Sistema Gestione Qualità aziendale in conformità alle Norme

**ISO 9001:2015**

Le attività coperte da questo certificato sono

**Progettazione, produzione e commercializzazione di mascherine chirurgiche TIPO II ( escluso DPI )**

# SURGICAL MASK

**Surgical masks** are intended to prevent the contamination of the environment by the wearer, as they limit the transmission of **infectious agents**. According to Legislative Decree 24 February 1997, Hen.46 and subsequent amendments. (source: <http://www.salute.gov.it>), surgical masks are included among medical devices category.

**iVision Health** produces surgical masks of different types, in accordance with the best technical characteristics of the tissues.

**iVi** masks guarantee:

- **liquid splash resistance**
- **breathability**
- **bacterial filtration efficiency**
- **cleaning by microbes**



# ITALIAN FABRICS

iVision Health surgical masks are disposable with **three layers**: two external layers of non-woven fabric and an intermediate layer with **high filtering efficiency**. The masks are equipped with elastic bands on the sides. In addition, on the upper side, they are provided with a conformable **nose clip**.

The **technical characteristics** of the masks are as follows:

- outer layer: **non-woven Italian polypropylene (spunbond) 25 gr.**
- filtering intermediate layer: **Italian non-woven fabric (meltblown) 22 gr.**
- outer layer in contact with the user: **non-woven Italian polypropylene fabric (spunbond) 25 gr.**

iVision Health surgical masks have a **filtering power (B.F.E. \*)  $\geq 98\%$**  and are classified as **Type II** in accordance with **UNI EN 14683**.



\* II B.F.E. *BACTERIAL FILTRATION EFFICACY* it ' the reference parameter that indicates the effectiveness of filtering bacteria

# PRODUCTS

**CE** **SURGICAL MASK** **CE**



**iVilight SURGICAL MASK**

**iVi98 SURGICAL MASK**

**iVi98S SURGICAL MASK**

**Type II high filtering mask**

Outer layer: 25 gr.  
Filter layer: 35 gr.

**B.F.E. ≥ 98%**

**Type II high filtering mask**

Outer layer: 25 gr.  
Filter layer: 22 gr.  
Outer layer: 25 gr.

**B.F.E. ≥ 98%**

**Type II high filtering mask**

Outer layer: 25 gr.  
Filter layer: 35 gr.  
Outer layer: 25 gr.

**B.F.E. ≥ 98%**



# PRODUCTS (WORK IN PROGRESS)

## P.P.E. PERSONAL PROTECTIVE EQUIPMENT



**FILTERING M. FFP1**



**FILTERING M. FFP2**



**FILTERING M. FFP3**



**GLASSES AND VISORS**



**COATS AND PROTECTIONS**



**GLOVES**



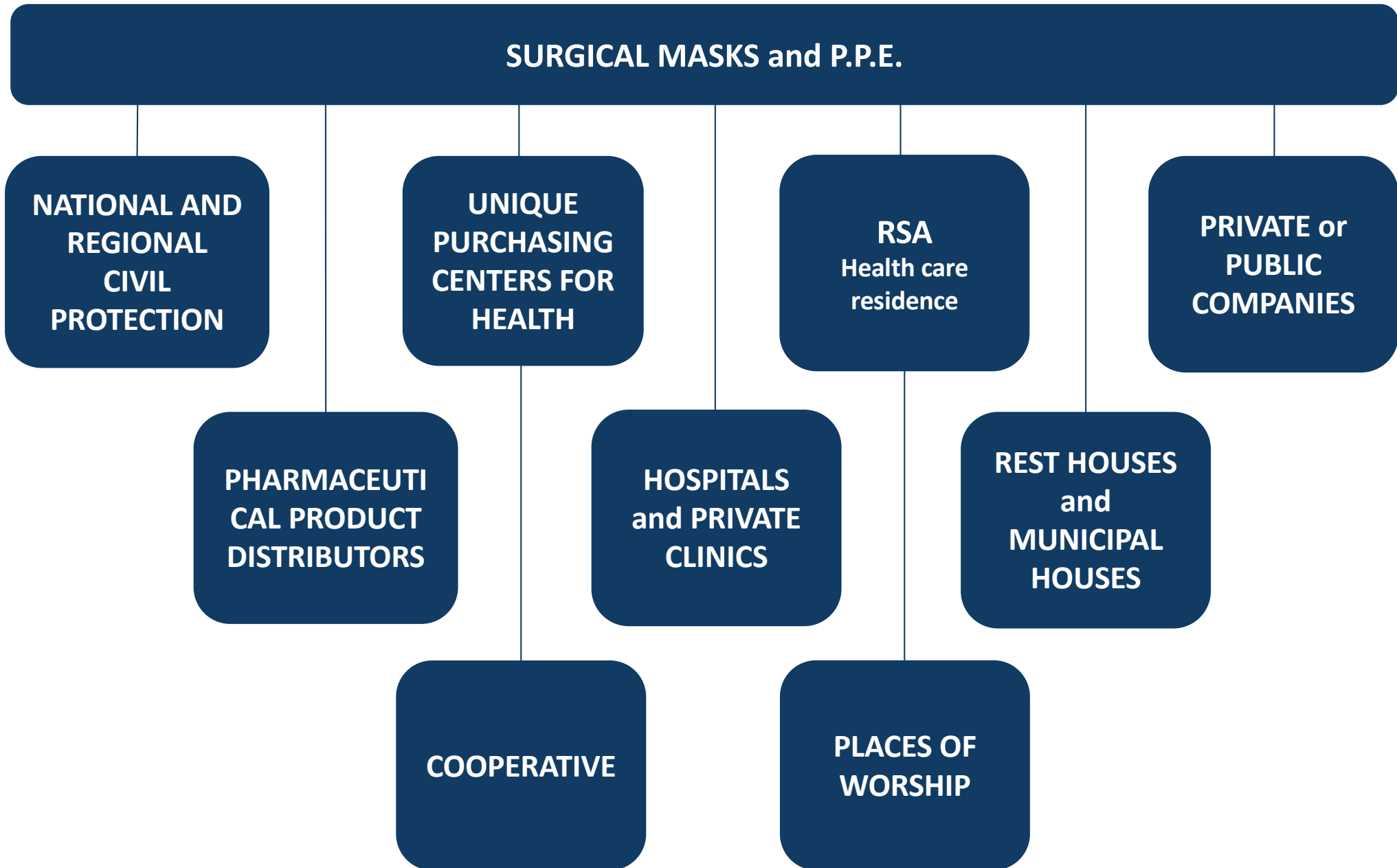
**SANITIZING GEL**



**PROTECTIVE BARRIERS**



# COMMERCIAL MATRIX



# GENERAL MASK LEGEND

## SURGICAL MASKS



The main intended use of **surgical masks** is to **protect people around us** from infectious agents. They can also be worn by patients and other people in order to reduce the risk of spreading infections, particularly in epidemic or pandemic situations.

**Surgical masks** are classified worldwide as **Type I and II**:

- **Type I** masks have a filtration capacity of **(B.F.E) ≥ 95%**
- **Type II** masks have a filtration capacity of **(B.F.E) ≥ 98%**

## FILTERING MASKS (FFP1,FFP2,FFP3)



The main function of **Filtering Masks** with valve is to **protect only the wearer** as they filter inwards but not outwards, therefore, an infected person can infect the others. Filter masks are mainly used in professional field (doctors in infectious wards, etc.). They are divided into **three classes of FFP** protection (the acronym stands for filtering face piece, in Italian "particle filtering facepiece")

- **FFP1** have a **filtration capacity** of at least **80%**
- **FFP2** have a **filtration capacity** of at least **94%**
- **FFP3** have a **filtration capacity** of at least **99%**



## **IVISION HEALTH by IVISION GROUP**

### **Office**

Via Caiselli, 19 – 33100 Udine - Italy

Tel +39 0432 519401

### **Production Plant**

Via J. Ressel 2, San Dorligo della Valle (TS) - Italy

[info@ivisionhealth.it](mailto:info@ivisionhealth.it)

[www.ivisionhealth.it](http://www.ivisionhealth.it)