

# SURGICAL MASK & P.P.E. PRODUCTION

# **COVID-19 EMERGENCY**

Because of COVID-19, the whole world has been faced with a pandemic that has no equal.

The current Italian need has gone from **130 ML per month** of surgical masks to 950 ML per month and the need for masks is expected to continue even after the coronavirus emergency.

It is precisely for this reason that we, part of the iVision group, immediately wanted to invest in the HFAITH of each person and given the current need for surgical masks, we created the iVision **HEALTH** division.



### **CORRIERE DELLA SERA** / CRONACHE

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

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

### *NIERE 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 in San Dorligo della Valle (TS - Italy) in a space of about 2500 square meters inside which there are machines for the production of surgical masks. Our strengths:

- Production capacity of 200.000 surgical masks per day
- CE Certification and Authorization from the Superior Institute of Health.
- Very high quality Italian fabrics with filtering capacity ≥ 98%
- Raw materials and production MADE in ITALY
- 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 holds all the necessary authorizations to produce surgical masks according to the standards required by law:

- ISO 9001: 2015 certification for the design, production and sale of surgical masks
- Authorization ISS Superior Institute of Health with reference COV1297 and COV1303 www.iss.it
  - CE Certification <u>www.salute.gov.it</u>











#### 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

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**

The surgical masks have the purpose of preventing the wearer from contaminating the environment, as they limit the transmission of infectious agents and fall within the scope of the medical devices referred to in Legislative Decree 24 February 1997, Hen.46 and subsequent amendments. (source: http://www.salute.gov.it)

**iVision Health** produces surgical masks of different types and colors respecting 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. On the minor sides of the mask there are elastic bands to wear it finally on the upper side there is 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 nonwoven 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. \*)** ≥ **98%** and are classified as **Type II** in accordance with **UNI FN 14683**.



# **PRODUCTS**





#### **SURGICAL MASK**







**Type I** high filtering mask

Outer layer: 17 gr. Filter layer: 22 gr. Outer layer: 17 gr.

**B.F.E.** ≥ 95%



#### **iVi98 SURGICAL MASK**

**Type II** high filtering mask

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

**B.F.E.** ≥ 98%



#### **iVi98S SURGICAL MASK**

**Type II** high filtering mask

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

**B.F.E.** ≥ 98%



iVision Health surgical masks are packaged in various ways: 1/5/10/20 pcs. or in boxes of 50 pcs.



# **PRODUCTS (WORK IN PROGRESS)**



### P.P.E. PERSONAL PROTECTIVE EQUIPMENT







**FILTERING M. FFP2** 



FILTERING M. FFP3



**GLASSES AND VISORS** 



**COATS AND PROTECTIONS** 



**GLOVES** 



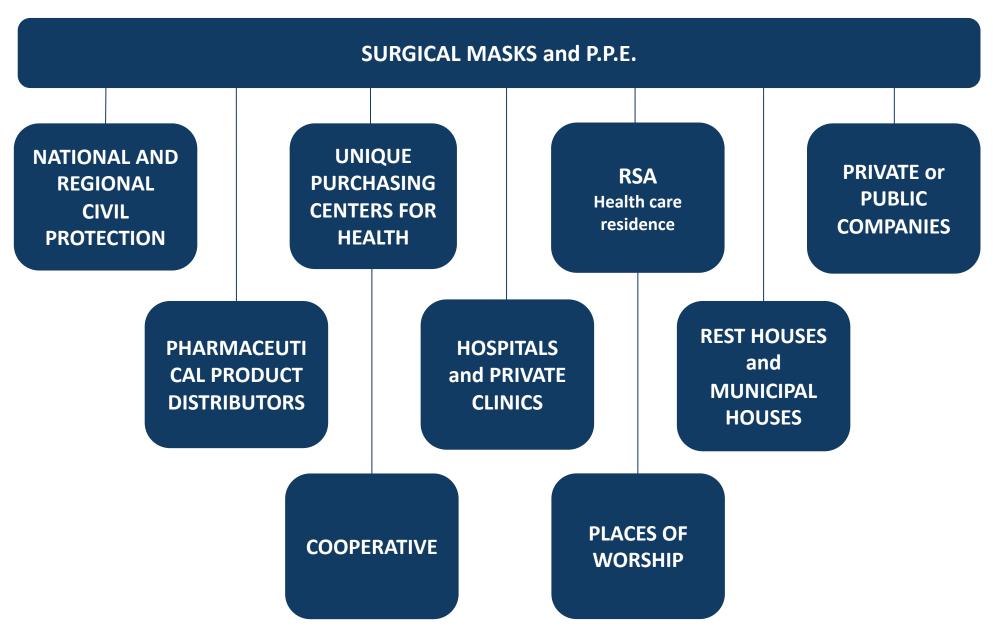
**SANITIZING GEL** 



**PROTECTIVE BARRIERS** 

# **COMMERCIAL MATRIX**





# **GENERAL MASK LEGEND**





#### **SURGICAL MASKS**

The main intended use of **surgical masks** is to **protect the person and those close to them** from infectious agents and, in addition, in certain circumstances, **to protect the wearer** from splashes of potentially contaminated liquids. They can also be destined to be worn by patients and other people 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 means masks with filtering capacity (B.F.E) ≥ 95%.
- For Type II masks with filtering capacity (B.F.E) ≥ 98%.



#### **FILTERING MASKS (FFP1,FFP2,FFP3)**

The main function of the **Filter Masks** is to **protect only the wearer** as they filter inwards but not outwards, therefore if an infected person wears them, they can infect other people. The filter masks are mainly used in the 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"). The **FFP1** have a filtering **capacity of at least 80%**, the **FFP2** have a filtering **capacity of at least 94%** and the **FFP3** have a filtering **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

<u>info@ivisionhealth.it</u> www.ivisionhealth.it