

MEDICAL DEVICES AND P.P.E. PRODUCTION

COMPANY & PRODUCTION

iVision Health is an industry specialized in manufacturing of medical devices and personal protection equipment (P.P.E.)

Our production plants **are located in Italy, in Martignacco (UD) and in San Dorligo della Valle (TS)**, in a **12,000 square meters** space.

Our **strengths**:

- Production capacity of **15,000,000 surgical masks per month** and **1,000,000 filtering facial-half-masks (FFP) per month**
- Latest generation machinery
- Use of the **highest quality Italian fabrics**
- Process and product quality **certifications and authorizations: ISO, CE, ISS**
- A complete **range of products** in response to market needs



Production plant of Martignacco (UD)



Production plant of S. Dorligo della Valle (TS)

MADE IN ITALY PRODUCTION

iVision Health uses latest **CE certificated** machinery generation, characterized by high precision and speed.

Our **production process protocol** provides stringent **hygiene and cleaning standards**, sanification of environment, plants and production lines, **in order to guarantee the quality** of our products.

The **iVision Health** factory consists of:

- Dedicated lines for mask production
- Packaging automation for different formats
- Trained and qualified internal staff



Production plant of Martignacco (UD)



Production plant of S.Dorligo della Valle (TS)

ITALIAN FABRICS

iVision Health products are made with Italian materials of the highest quality. We carry out careful and continuous research in this regard

Our pluses are:

- Very high **bacterial filtration** capacity
- Maximum **comfort and softness** for extended daily usage
- **Soft fabrics** free of irritants
- **Constant security** assured by in-depth periodic laboratory test

The raw materials we use are as follows:

- Soft **spunbond non-woven** fabric
- **Particulate and antibacterial filter** (meltblown / SMS)
- Anti-bacterial, anti-static, breathable, ecological **Air Cotton fabric**



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** (quality certification) for the design, the production and the marketing of surgical masks
- **ISO 13485:2016** (medical device quality certification) for the design, production and marketing of surgical masks
- **ISS Authorization – Istituto Superiore di Sanità - COV1297 and COV1303 reference www.iss.it**
- **CE Certification, according to 93/42 CEE directive www.salute.gov.it**



Istituto Superiore di Sanità



Certificato Di Registrazione

Questo certificato è stato rilasciato a

IVISION S.R.L.

Sede legale: VIA DEI SOLTERI, 105 - 38121 TRENTO, Italy

Sede operativa: VIA J. RESSEL, 2 - 34018 SAN DORLIGO DELLA VALLE DOLINA (TS)

come riconoscimento del Sistema Gestione Qualità aziendale in conformità alle Norme

ISO 13485:2016

Le attività coperte da questo certificato sono

Progettazione, Produzione e Commercializzazione di Mascherine Chirurgiche di Tipo II

Numero Del Certificato:	Data d'emissione (originale):	Data d'emissione:
204926/BU001/JK/TN	16 Ottobre 2020	16 Ottobre 2020
Emissione No:	Data di Scadenza:	
1	16 Ottobre 2023	

Emesso da:  A nome del Scheme Manager



Per la verifica dell'effettiva conformità dell'azienda al sistema di gestione della qualità, il certificato deve essere rinnovato annualmente. La validità del certificato è di 3 anni. Il certificato è valido solo se l'azienda è iscritta al Registro delle Imprese. Il certificato è valido solo se l'azienda è iscritta al Registro delle Imprese. Il certificato è valido solo se l'azienda è iscritta al Registro delle Imprese.

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.

iVision Health masks guarantee:

- **Liquid splash resistance**
- **Breathability**
- **Bacterial filtration efficiency**
- **Cleaning by microbes**



FILTERING FACIAL HALF MASKS

The **filtering facial half masks** (FFP2 and FFP3) are used in hospital and care settings to **protect the user from external agents** (including the transmission of infections by droplets and aerosols), are certified in accordance with the provisions of Legislative Decree n. 475/1992. They are **Individual Protection Devices** (source: <http://www.salute.gov.it>).

iVision Health produces different types of filtering face half masks, guaranteeing respiratory protection in accordance to **UNI EN 149:2009** technical standard:

- **Dust filter**
- **Guarantee on efficiency characteristics**
- **Breathability**
- **Stability of the structure**



CE

SURGICAL MASK

CE



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%



iViLight SURGICAL MASK

Type II high filtering mask

Outer Layer: 25 gr.
Filter Layer: 35 gr.

B.F.E. ≥ 98%





SURGICAL MASK



+Forti SURGICAL MASK

Type II high filtering mask

Outer Layer: 25 gr.
Filter Layer: 35 gr.
Outer Layer: 25 gr.

B.F.E. \geq 98%



iViBlue SURGICAL MASK

Type II high filtering mask

Outer Layer: 20 gr.
Filter Layer: 25 gr.
Outer Layer: 25 gr.

B.F.E. \geq 98%



iViWhite SURGICAL MASK

Type II high filtering mask

Outer Layer: 25 gr.
Filter Layer: 35 gr.

B.F.E. \geq 98%





FILTERING MASKS



FFP2

Filtering Facial Half Masks
Outer Layer: 30 gr. (SPUN)
Filter Layer: 25 gr. (MELT)
Inner Layer: 40 gr. (AIR COTTON)
Filter Layer: 25 gr. (MELT)
Outer Layer: 30 gr. (SPUN)

B.F.E. \geq 95%

AVAILABLE IN DECEMBER 2020



FFP3

WORK IN PROGRESS

B.F.E. \geq 98%

AVAILABLE IN FEBRUARY 2021



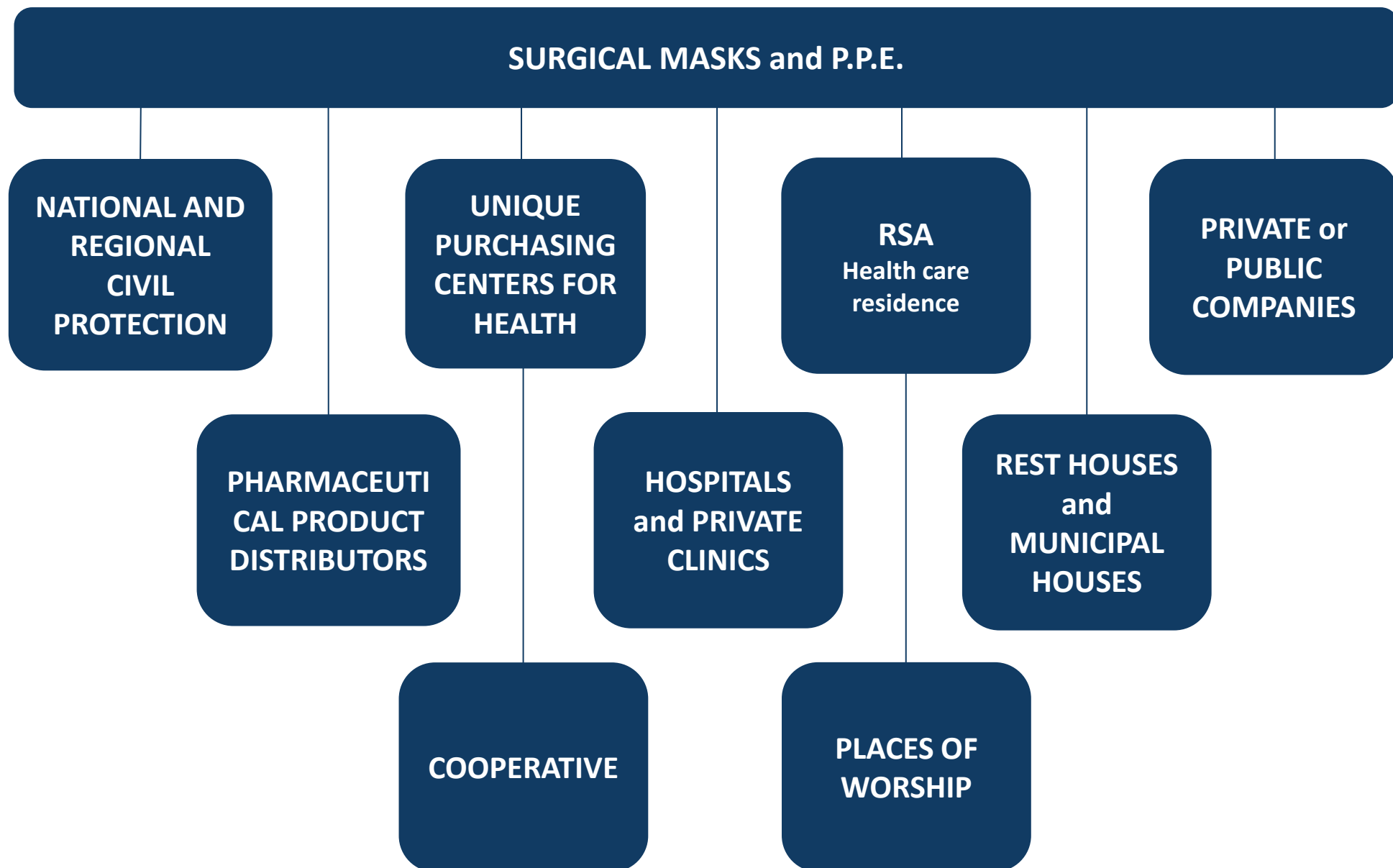
MODELS WITH VALVE

WORK IN PROGRESS

B.F.E. \geq 98%

AVAILABLE IN MARCH 2021

COMMERCIAL MATRIX



SOME OF OUR CLIENTS



MASK GENERAL 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) $\geq 95\%$**
- **Type II** masks have a filtration capacity of **(B.F.E) $\geq 98\%$**

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 Spilimbergo 154, Martignacco (UD)
Tel +39 0432 1482743

Production Plant UD

Via Spilimbergo 154, Martignacco (UD)

Production Plant TS

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

info@ivisionhealth.it

www.ivisionhealth.it

www.ivision-group.it