

## ISAFE SURGICAL MASK CE SELF-CERTIFICATION



The undersigned with FLCVEA89C62H816P Tax Code, on behalf of IVISION S.R.L., having the right to delegate from the Manufacturer or the Agent for the insertion of the data - through the website of the Italian Ministry of Health - of the medical devices listed below, has validated the following information:

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System Progressive: 1971177

Validated on: 04/07/2020

Commercial name and model: SURGICAL MASK ISAFE

Code attributed by the manufacturer (catalog identification): ISAFE

Role of the user who entered the DM: MANUFACTURER

Manufacturer: IVISION S.R.L.

CND Classification: STANDARD SURGICAL MASKS

Complete GMDN nomenclator: GMDN not declared

CE Classification: Class I non sterile and without measuring functions Attachments according to which the device has been marked: Annex VII

Link with other DMs: No

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Commercial data

Presence of the bar code: Yes

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Attached documentation

Label: ivi98.pdf

It is declared that the manufacturer has not accompanied the medical device with instructions for use

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Technical data

Textile / Substance Presence: No

Medicinal Presence: No

The prevailing materials making up the primary packaging of the DM require special disposal conditions: No

Sterile: No

Disposable: Yes

Latex - during the manufacturing process the product came into contact with latex molecules: No



Latex - the product and its packaging are latex-free: Yes  
DM constituent materials in direct contact with the patient  
Material: POLYPROPYLENE  
Special disposal conditions: No

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These information was correctly acquired by the Italian Ministry of Health which issued the following notification identifier to be used for subsequent communications:

The undersigned declares to be aware of the penalties provided for in the event of false or false declarations (art.76 of the Italian Consolidated Law, Presidential Decree 28.12.2000, n. 445).



**Elenco dei dispositivi medici**

**Criteri di ricerca:**

Denominazione fabbricante:  
 Codice fiscale fabbricante:  
 Partita IVA / VAT number fabbricante: **02390970305**  
 Codice nazione fabbricante:  
 Denominazione mandatario:  
 Codice fiscale mandatario:  
 Partita IVA / VAT number mandatario:  
 Codice nazione mandatario:  
 Tipologia dispositivo:  
 Identificativo di registrazione attribuito dal sistema BD/RDM:  
 Codice attribuito dal fabbricante:  
 Nome commerciale e modello:  
 Classificazione CND:  
 Descrizione CND:  
 Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

**Elenco dispositivi individuati**

Dati aggiornati al:11/07/2020

| DISPOSITIVO MEDICO/ASSEMBLATO |               |             |                          |                                   |  |  | FABBRICANTE/ASSEMBLATORE |            |             |                |             |             |         |
|-------------------------------|---------------|-------------|--------------------------|-----------------------------------|--|--|--------------------------|------------|-------------|----------------|-------------|-------------|---------|
| IDENTIFICATIVO                |               | ISCRITTO AL |                          | NOME                              |  | DATA FINE  |                          | RUOLO      |             | PARTITA        |             | NAZIONE     |         |
| TIPOLOGIA                     | DI            | REPERTORIO  | CODICE ATTRIBUITO DAL    | COMMERCIALE                       | CND  | CLASSE   | DATA PRIMA               | IMMISSIONE | RUOLO       | DENOMINAZIONE  | CODICE      | IVA/VAT     | NAZIONE |
| DISPOSITIVO                   | REGISTRAZIONE | BD/RDM      | FABBRICANTE/ASSEMBLATORE | E MODELLO                         |  | CE   | PUBBLICAZIONE            | IN         | AZIENDA     | FISCALE        | NUMBER      |             |         |
| Dispositivo                   | 1971177       | S           | ISAFE                    | MASCHERINA<br>CHIRURGICA<br>ISAFE | T020601 -<br>MASCHERINE<br>CHIRURGICHE<br>STANDARD | I -<br>Classe I<br>non<br>sterile<br>e senza<br>funzioni<br>di<br>misura | 05/07/2020               |            | FABBRICANTE | IVISION S.R.L. | 02390970305 | 02390970305 | IT      |