

## IVILIGHT 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: 1982161

Validated on: 28/07/2020

Commercial name and model: SURGICAL MASK IVILIGHT – TYPE II

Code attributed by the manufacturer (catalog identification): IVILIGHT

Role of the user who entered the DM: MANUFACTURER

Manufacturer: IVISION S.R.L.

CND Classification: STANDARD SURGICAL MASKS

Complete GMDN nomenclator: A device placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery or examination is being performed. It is made of a porous material or textile that allows the user to breathe normally through the mask and it is a single-use device.

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: **1982161**  
 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:22/08/2020

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE						
TIPOLOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	NOME		CLASSE	DATA PRIMA	DATA FINE	RUOLO	DENOMINAZIONE	CODICE	PARTITA	NAZIONE
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	COMMERCIALE	CND	CE	PUBBLICAZIONE	IMMISSIONE	AZIENDA		FISCALE	IVA/VAT	
	BD/RDM			E MODELLO				IN	COMMERCIO			NUMBER	
Dispositivo	1982161	S	IVILIGHT	MASCHERINA CHIRURGICA IVILIGHT - TIPO II	T020601 - MASCHERINE CHIRURGICHE STANDARD	I - Classe I non sterile e senza funzioni di misura	29/07/2020		FABBRICANTE	IVISION S.R.L.	02390970305	02390970305	IT

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