

IVI98 SURGICAL MASK CE 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:

System Progressive: 1963541

Validated on: 12/06/2020

Commercial name and model: SURGICAL MASK IVI98

Code attributed by the manufacturer (catalog identification): IVI98

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

Commercial data

Presence of the bar code: Yes

Attached documentation

Label: ivi98.pdf

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

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

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: 27/06/2020

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE						
TIPOLOGIA	IDENTIFICATIVO		NOME		CLASSE	DATA PRIMA	DATA FINE	RUOLO	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE	
DISPOSITIVO	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	COMMERCIALE									CND
	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	E MODELLO	CE	PUBBLICAZIONE	IN	COMMERCIO					
	BD/RDM												
Dispositivo	1963541	S	IV198	MASCHERINA CHIRURGICA TIPO II	T020601 - MASCHERINE CHIRURGICHE STANDARD	I - Classe I non sterile e senza funzioni di misura	13/06/2020		FABBRICANTE	IVISION S.R.L.	02390970305	02390970305	IT

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