

Republic of Colombia
Ministry of Health and Social Protection
National Institute for Food and Drug Surveillance - INVIMA

RESOLUTION No. 2019027332 of July 3, 2019
By which a Health Registry is granted

The Technical Director of Medical Devices and other Technologies of the National Institute of Surveillance of Medications and Foods INVIMA, in exercise of the Legal Powers conferred in Decree 2078 of 2012, Regulatory Decree 4725 of 2005, Law 1437 of 2011 and Law 962 of 2005

CONSIDERING

WHERE BEFORE THIS INSTITUTE HAS BEEN REQUESTED THE GRANT OF AN AUTOMATIC SANITARY REGISTRY BASED ON THE VERIFICATION OF THE LEGAL TECHNICAL DOCUMENTATION ALLEGED TO THE ADDRESS OF MEDICAL DEVICES AND OTHER TECHNOLOGIES, ISSUING A FAVORABLE CONCEPT FOR ISSUANCE OF THIS HEALTH RECORD.

AS A RESULT OF THE FOREGOING, PURSUANT TO ARTICLE 57 OF LAW 962 OF 2005 INVIMA WILL CARRY OUT THE SUBSEQUENT CONTROL WITHIN FIFTEEN (15) DAYS FOLLOWING ITS EXPEDITION.

RESOLVE

ARTICLE ONE.- GRANT SANITARY REGISTRY FOR THE TERM OF TEN (10) YEARS A

PRODUCT:	Breathing mask LARINGEA
BRAND:	LMA
SANITARY REGISTRY NO .:	INVIMA 2019DM-0020032
TYPE OF REGISTER:	IMPORT AND SELL
HEADLINES):	MEDICAL TELEPHONE WITH ADDRESS IN IRELAND
MANUFACTURER (S):	RESPONSIBLE: TELEFLEX MEDICAL WITH ADDRESS IN IRELAND THE LARYNGEAL MASK COMPANY (MALAYSIA) SDN. BHD. RESIDING IN MALAYSIA
IMPORTER (S):	TELEFLEX MEDICAL COLOMBIA SAS WITH ADDRESS IN BOGOTA - DC
CONDITIONER (S):	BIOMEDICAL DISTRIBUTION COLOMBIA SL LTDA WITH DOMICILE IN COTA - CUNDINAMARCA
TYPE OF DEVICE	INVASIVE
RISK:	IIA
COMPOSITION:	

PARTS THAT COMPOSE THE MEDICAL DEVICE	QUALITATIVE COMPOSITION
SLEEVE, REAR PLATE, TUBE AERIAL ROAD, BITEBLOCK, LINE OF INFLATED, INFLATING BALL, DRAINAGE PIPE, SHORT TUBE DRAINAGE	VINYL POLYLORIDE MEDICAL DEGREE
RETENTION VALVE	POLYVINYLCHLORIDE
CONNECTOR BODY	POLYCARBONATE GRADE MEDICINAL
VENTILATION PART	POLYPROPYLENE (WITH PIGMENT RED)
PRINT INK IN TUBE VIA AEREA	INK MEDICAL GRADE

APPLICATIONS:

OF THE AIRWAY FOR OBSTACLES AND AS AN APPROACH FOR CONTROL AND EMERGENCY IN PATIENTS IN FASTES THAT USE VENTILATION SPONTANEOUS OR POSITIVE PRESSURE. - ALSO IS INDICATED FOR USE AS A DEVICE OF THE AIRWAY OF RESCUE IN PROCEDURES OF CPR. ALSO IS INDICATED AS "DEVICE OF AERIAL ROUTE OF RESCUE "IN DIFFICULT AIRWAY SITUATIONS KNOWN OR UNEXPECTED. CAN BE USED TO ESTABLISH AN AERIAL ROUTE IMMEDIATE AND CLEAR DURING THE RESUSCITATION OF A PATIENT IN STATE OF DEEP UNCONSCIOUSNESS WITHOUT GLOSSOPHARGEAN REFLECTIONS NI LARGE WHICH MAY REQUIRE ARTIFICIAL VENTILATION. AS WELL CAN BE USED TO ENSURE AN IMMEDIATE AIRWAY WHEN THE TRACHEAL INTUBATION IS IMPOSSIBLE DUE TO LACK OF

page 1 of 2

Page 2

**Republic of Colombia
Ministry of Health and Social Protection
National Institute for Food and Drug Surveillance - INVIMA**

**RESOLUTION No. 2019027332 of July 3, 2019
By which a Health Registry is granted**

The Technical Director of Medical Devices and other Technologies of the National Institute of Surveillance of Medications and Foods INVIMA, in exercise of the Legal Powers conferred in Decree 2078 of 2012, Regulatory Decree 4725 of 2005, Law 1437 of 2011 and Law 962 of 2005

SOMEONE WITH EXPERIENCE OR AVAILABLE EQUIPMENT, OR WHEN THEY HAVE FAILED TRACHEAL INTUBATION ATTEMPTS.
COMMERCIAL PRESENTATION: STERILE SUPPLY FOR SINGLE USE, PACKAGED INDIVIDUALLY IN TOTALLY SEALED BAG OF TYVEK / POLYESTER / POLYETHYLENE, THE WHICH ARE INTRODUCED IN CORRUGATED CARTON PACKAGING
OBSERVATIONS: THIS SANITARY REGISTRY FITS THE FOLLOWING REFERENCES:

CODE, MODEL OR REFERENCE	DESCRIPTION
--------------------------	-------------

175010, 175015, 175020, 175025, 175030, 175040, 175050	SUPREME LMA
---	-------------

USEFUL LIFE:	3 YEARS
NO FILES.:	20165519
RADICATION NO .:	20191122223
DATE OF RADICATION:	27 06 2019

ARTICLE TWO.- AGAINST THE PRESENT RESOLUTION PROCEED SOLELY THE RESOURCE OF REFITTING, WHICH MUST BE INTERPOSE BEFORE THE DIRECTOR OF MEDICAL AND OTHER DEVICES TECHNOLOGIES, WITHIN TEN (10) DAYS FOLLOWING YOUR NOTIFICATION, IN THE TERMS INDICATED IN THE CODE OF ADMINISTRATIVE PROCEDURE AND THE CONTENTIOUS ADMINISTRATIVE.

ARTICLE THREE.- THIS RESOLUTION REMAINS FROM THE DATE OF ITS EXPEDITION.

ARTICLE FOUR.- THE RIGHTS THAT ARE DERIVED FROM THIS RESOLUTION WILL BE SUBJECT TO THE POSTERIOR CONTROL TO BE CARRIED OUT BY THE NATIONAL MEDICINES AND SURVEILLANCE INSTITUTE ALIMENTOS INVIMA COMPLIES WITH THE PROVISIONS OF ARTICLE 22 OF DECREE 4725 OF 2005

COMMUNICATE, NOTIFY AND COMPLY

GIVEN IN BOGOTÁ DC ON JULY 3, 2019

THIS SPACE, UNTIL THE SIGNATURE IS CONSIDERED BLANK.

LUCIA AYALA RODRIGUEZ
DIRECTOR (A) TECHNICIAN OF MEDICAL DEVICES AND OTHER TECHNOLOGIES
PROJECT: LEGAL: FMOSCOSOM, TECHNICAL: MSANDOVALC, REVISED: CORDINA_VARIOS

Signature Not
Verified

Signed digitally by
LUCIA AYALA
RODRIGUEZ
Date: 2019/07/08
12:24:12 COT
Reason: Invima
Location: BOGOTA DC,
Colombia

Page 2 of 2