

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

RESOLUTION No. 2019026663 of June 28, 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 WITH BASE IN THE VERIFICATION OF THE LEGAL TECHNICAL DOCUMENTATION ALLEGED TO THE ADDRESS OF MEDICAL DEVICES AND OTHER TECHNOLOGIES, ISSUING A FAVORABLE CONCEPT FOR THE EXPEDITION OF THIS HEALTH RECORD
 AS A RESULT OF THE ABOVE, IN COMPLIANCE WITH ARTICLE 57 OF LAW 962 OF 2005, INVIMA PERFORM THE SUBSEQUENT CONTROL WITHIN FIFTEEN (15) DAYS AFTER HIS EXPEDITION.

RESOLVE

ARTICLE ONE.- To grant SANITARY REGISTRY for the term of TEN (10) years to

PRODUCT:	Breathing mask LARINGEA	
BRAND:	LMA	
SANITARY REGISTRY NO.:	INVIMA 2019DM-0020004	
TYPE OF REGISTER:	IMPORT AND SELL	
HEADLINES):	MEDICAL TELEPHONE WITH ADDRESS IN IRELAND	
MANUFACTURER (S):	ARROW MEDICAL LTDA WITH DOMICILE IN THE UNITED KINGDOM	
	CHELLE MEDICAL LIMITED WITH DOMICILE IN SEYCHELLES	
	PARKER MEDICAL SYSTEMS DIVISION WITH DOMICILE IN THE UNITED STATES	
	AMERICA	
	FOREFRONT (XIAMEN) MEDICAL DEVICES CO. LTD. WITH DOMICILE IN CHINA	
	THE LARYNGEAL MASK COMPANY (MALAYSIA) SDN. BHD. RESIDING IN	
	MALAYSIA	
	MEDICAL TELEPHONE WITH ADDRESS IN IRELAND	
IMPORTER (S):	PLAXTRON INDUSTRIAL (M) SDN.BHD WITH DOMICILE IN MALAYSIA	
CONDITIONER (S):	TELEFLEX MEDICAL COLOMBIA SAS WITH ADDRESS IN BOGOTA - DC	
	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, BAR	
	ELEVATOR OF EPIGLOTIS, PIPE OF	POLY CHLORIDE VINYL GRADE
	THE AERIAL ROADS, INFLATION LINE	MEDICINAL, SILICONE DE GRADO
	INFLATING BALL, VALVE	MEDICINAL
	RETENTION	
	CHECK VALVE	POLYPROPYLENE MEDICAL GRADE
	CONNECTOR	MEDICINAL GRADE POLYSULPHONE
APPLICATIONS:	IS INTENDED FOR THE OBTAINING AND MAINTAINING OF CONTROL OF THE AERIAL ROUTE DURING THE ROUTINE ANESTHESIA PROCEDURES AND EMERGENCY IN PATIENTS IN FASTES THAT USE SPONTANEOUS VENTILATION OR FOR POSITIVE PRESSURE (VPP). - ALSO IS INDICATED TO ENSURE THE	

DIFFICULTY IN KNOWING WHEN TO USE IT IN SURGICAL PROCEDURES ELECTIVES IN WHICH TRAQUEAL INTUBATION IS NOT NEEDED. - CAN USED TO ESTABLISH A FREE AND IMMEDIATE AIRWAY DURING THE CARDIOPULMONARY RESUSCITATION (CPR) IN PATIENTS DEEPLY UNCONSCIOUS WITH ABSENCE OF GLOSOFARINGEOS AND LARGE GEOS REFLEXES THAT REQUIRE ARTIFICIAL VENTILATION. IN THESE CASES, IT MUST BE USED ONLY WHEN IT IS NOT POSSIBLE TO PERFORM A TRACHEAL INTUBATION.

COMMERCIAL PRESENTATION: PACKAGED INDIVIDUALLY IN TOTALLY SEALED BAGS TYVEK / POLYESTER / POLYETHYLENE, WHICH ARE INTRODUCED IN PACKAGING CORRUGATED CARDBOARD

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OBSERVATIONS:

THIS HEALTH RECORD COVERS THE FOLLOWING REFERENCES:

CODE, MODEL OR REFERENCE	DESCRIPTION
125010, 125015, 125020, 125025, 125030, 125040, 125050, 128010, 128015, 128020, 128025, 128030, 128040, 128050	LMA UNIQUE
100010, 100015, 100020, 100025, 100030, 100040, 100050, 100060	LMA CLASSIC
110020, 110025, 110030, 110040, 110050, 110060	FLEXIBLE LMA
115020, 115025, 115030, 115040, 115050	FLEXIBLE LMA SU (SINGLE USE)
150010, 150015, 150020, 150025, 150030, 150040, 150050	LMA PROSEAL

USEFUL LIFE: 4.5 YEARS (54 MONTHS)
NO FILES.: 20165432
RADICATION NO.: 20191121259
DATE OF RADICATION: 26 06 2019

SECOND ARTICLE .- AGAINST THE PRESENT RESOLUTION PROCEED ONLY 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 DESCRIBED IN THE CODE OF ADMINISTRATIVE PROCEDURE AND ADMINISTRATIVE CONTENTIOUS.

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

ARTICLE FOUR.- RIGHTS THAT ARE DERIVED FROM THIS RESOLUTION WILL BE SUBJECT TO CONTROL

POSTERIOR TO ACCORDANCE WITH THE PROVISIONS OF ARTICLES 2 OF DECRETE 4725 OF 2004, MUST CARRY OUT

COMMUNICATE, NOTIFY AND COMPLY

Given in Bogotá DC on June 28, 2019

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LUCIA AYALA RODRIGUEZ

Signed: DIRECTOR (A) TECHNICIAN OF MEDICAL DEVICES AND OTHER TECHNOLOGIES
PROJECT: LEGAL: FMOSCOSOM, TECHNICAL: VLARAT, REVISED: CORDINA_VARIOS

Signed digitally by
LUCIA AYALA
RODRIGUEZ
Date: 2019/07/03
11:35:51 COT
Reason: Invima
Location: BOGOTA DC,
Colombia

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