

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (177)

Date: 12 JUL 2021

Subject: Classification of medical devices pertaining to Anesthesiology under the provisions of Medical Devices Rules, 2017-Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.1.2017 which are to be commence from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, Appendix A, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A is subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V.G. Somani)
Drugs Controller General (I)

To,

CDSCO Website

File No. 29/Misc/03/2020-DC(177)
 Drugs Controller General (India)
 Directorate General of Health Services
 FDA Bhawan, Kotla Road, New Delhi.

Date:

NoticeClassification of Medical Devices Pertaining to Anesthesiology

11 2 JUL 2021

Sr. No	Medical Device Name	Intended Use	Risk Class
1	Anesthesia machine	A medical device used to generate and mix a fresh gas flow of medical gases and inhalational anaesthetic agents for the purpose of inducing, monitoring and maintaining anaesthesia.	C
2	Aerosol delivery tubing	A flexible tube used in conjunction with an oxygen mask, endotracheal (ET) tube, humidifier, or nebulizer, intended for the delivery of aerosolized humidification, typically oxygen enriched.	A
3	Aerosol face mask	A flexible, form-shaped device that is placed over the nose and mouth to deliver air, oxygen (O ₂), or a mixture of the two gases, with aerosolized particles, to a patient's airway.	B
4	Aerosol inhalation monitor	It is a device that enables a medical professional to objectively assess in detail how the test subject uses their inhaler.	B
5	Airway device cleaning utensil	A hand-held device intended to be used to clean an in situ and ex situ airway device.	A
6	Airway pressure alarm	A device connected to the breathing circuit that monitors a patient's upper airway pressure during assisted mechanical ventilation.	A
7	Airway pressure/oxygen monitor	It is a device intended to continuously measure and display the breathing circuit pressure and oxygen (O ₂) concentration levels of respiratory gases delivered to a patient through positive pressure ventilation systems.	B
8	Airway protection face mask	A flexible, form-shaped device that is placed over the nose and mouth to provide respiratory protection.	A
9	Airway temperature monitoring system	An assembly of devices used to continuously measure the temperature at a specific point along a ventilation airway.	B
10	Airway tube forceps	A hand-held instrument used for grasping a tube for its insertion and/or extraction into/from the airways, or for grasping obstructive objects for their removal from the airways.	A
11	Anaesthesia breathing circuit	An assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient.	B

12	Anaesthesia catheter Luer connector	It is a device intended to create a mechanical union between an anaesthesia catheter and an external device, via a Luer connection.	A
13	Anaesthesia depth monitor	It is a device intended to be used to detect, process, and display the signals recorded from an unconscious patient (in a state of anaesthesia), showing the degree of consciousness.	B
14	Anaesthesia depth simulator	A device intended to simulate the electroencephalography (EEG) signals of an unconscious patient (in a state of anaesthesia) in order to test and calibrate an anaesthesia depth monitor, check patient cable continuity, or train healthcare providers.	A
15	Anaesthesia instrument table	It is intended as a support for Anaesthesia instruments used during general anaesthesia surgical procedures.	A
16	Anaesthesia mask stabilizer	A device intended to secure an anaesthesia mask on the face of a patient typically by providing anchorage for the fixation of the mask's headstrap.	A
17	Anaesthesia system leakage tester	A device intended to test an anaesthesia system for leakage.	A
18	anaesthesia vaporizer	A device used to vaporize the anaesthetic agent and deliver a controlled amount of the agent to a patient being prepared for surgery.	C
19	Anaesthesia warmer	A device intended to warm the anaesthetic solutions prior to it being administered to a patient for anaesthesia.	A
20	Anaesthesia workstation gas scavenger	A device intended to connect between the expiratory valve/port of a breathing circuit and the extraction system enabling the waste anaesthetic, exhaled, or other trace gases to be removed under controlled conditions from the work environment and channelled to the outside of the building.	B
21	Anaesthetic gas absorption/desorption device	A device intended to, when integrated within the common line of a breathing circuit, absorb and desorb (i.e., recycle) exhaled volatile anaesthetic agents.	B
22	Anaesthetic gas scavenging terminal unit	A device intended to function as an outlet assembly to which the operator can connect/disconnect an anaesthetic gas scavenging system (AGSS).	A
23	Anesthesia Face Mask	A device designed to be placed over a patient's nose and/or mouth to administer anaesthetic gases to the upper airway.	A
24	Artificial airway stylet	A device intended for insertion within the lumen of an artificial airway tube to stiffen and/or maintain the shape of the tube to facilitate intubation.	A
25	Artificial airway washing/disinfection jar	A container intended to hold artificial airway devices to facilitate their washing/disinfection.	B

26	Atomizer	A device that is intended to provide liquid medication in aerosolized form into the air that a patient will breathe.	A
27	Brachial plexus anaesthesia kit	A collection of devices intended to deliver a brachial plexus nerve block through one of several routes that could include supraclavicular, interscalene, infraclavicular, or axillary.	B
28	Breathing circuit bag	A device intended to store breathing gas during the respiratory cycle.	A
29	Breathing circuit condenser	A device intended to be integrated within the expiratory limb of a breathing circuit to remove excess moisture through cooling and condensing, whilst also reheating the dried gases to an appropriate machine-compatible temperature.	A
30	Breathing circuit dryer	A device that is used for the purpose of drying breathing circuit equipment that have been washed in order to prevent bacteria growth and deterioration	A
31	Breathing circuit gas-sampling/monitoring set	A collection of devices intended to be integrated within a breathing circuit to enable interface of gases between the breathing circuit and a respiratory monitoring device for sampling the patient's expired gas for measurements of pressure, flow and/or gas analysis.	B
32	Breathing circuit washer/disinfector	A device intended for the cleaning and high-level disinfection of breathing circuit components used in respiratory therapy and anaesthesia equipment.	B
33	Breathing mouthpiece	A device intended to be inserted into a patient's mouth to facilitate access to the respiratory system.	A
34	Bronchoscope	An endoscope with an inserted portion intended for the visual examination and treatment of the trachea, primary bronchi, and upper regions of the lungs and take biopsies and sample of secretions.	A
35	Capnography oxygen mask	A device intended to be placed over the nose and mouth to deliver oxygen (O ₂) to a patient's airway and to sample exhaled respiratory gases for monitoring the patient's ventilatory status.	A
36	Capnography sampling adaptor	The device is intended for sampling CO ₂ and use with monitors enabled with capnography technology .	A
37	Carbon dioxide monitor	A device intended to continuously measure the concentration of carbon dioxide (CO ₂) in a gas mixture to determine a patient's ventilatory, circulatory, or metabolic status.	C
38	CPAP/BPAP nasal mask	A device designed to be placed over a user's nose to interface with a continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) unit to provide the respiratory tract with direct ambient air, or medical oxygen (O ₂) and air, at a higher pressure than ambient air for noninvasive positive pressure ventilation (NPPV).	B

39	CPAP/BPAP oral mask	A device designed to be fitted to the user's mouth to interface with a continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) unit to provide the respiratory tract with direct ambient air, or medical oxygen (O ₂) and air, at a higher pressure than ambient air for noninvasive positive pressure ventilation (NPPV).	B
40	Electronic epidural space locator control unit	A device intended to be used with an epidural needle and an electronic epidural space locator pressure-sensing set, to aid a user in locating the epidural needle tip within the epidural space for subsequent anaesthesia administration.	D
41	Electronic oesophageal stethoscope	An electronic listening device designed to be inserted into a patient's oesophagus to listen to heart and breathe sounds, typically while the patient is under anaesthesia.	B
42	Endobronchial airway sizing kit	A collection of mechanical devices intended to be used with a balloon catheter for a planned intervention to determine the appropriate endobronchial valve sizes for a patient's lung airways (bronchial lumens).	A
43	Helium/oxygen breathing gas mixer	An independent mechanical device designed for accurate mixing of helium (He) and oxygen (O ₂) with concentrations that are appropriated for breathing in a patient who is indicated to assist flow of O ₂ into the alveoli and to reduce the work of breathing.	B
44	High-frequency ventilator	A device intended to assist or control alveolar ventilation using a frequency that is considerably higher than the physiological breathing rate and a tidal volume less than or equal to the anatomic dead space.	C
45	Inhalational analgesia unit	A device primarily designed to administer analgesic gases to the patient, or produce analgesic vapours for inhalation.	B
46	In-line arterial blood sampling set	A collection of devices designed to obtain an in-line arterial blood specimen while maintaining a closed system.	A
47	In-line backflow valve	A general-purpose device used in medical tubing or pipelines to prevent the backflow of gases or liquids.	A
48	Intracardiac oximeter	A photoelectric device designed to transmit radiation at a known wavelength(s) through blood to measure the concentration of oxygen, or dye, within the heart based on the amount of reflected or scattered radiation.	B
49	Intravascular blood gas/pH monitoring system	An assembly of devices used for the continuous in vivo measurement and display of the values of pH and/or the partial pressure of CO ₂ and/or O ₂ in arterial blood. The system is used for patients with respiratory failure or severe pulmonary hypertension after cardiac surgery.	B

50	Intravascular membrane oxygenator	A device designed for intravascular diffusion of oxygen into and carbon dioxide from the blood across an implantable (vena cava) gas-permeable membrane, used mainly as a temporary treatment for failing lungs in adults with respiratory distress syndrome.	C
51	Intravascular oximeter	An instrument designed for the continuous in vivo measurement of venous blood oxygen saturation (SvO ₂) using a fibreoptic catheter.	B
52	Intubation laryngoscope	A hand-held device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.	A
53	Intubation teeth protector	A device designed to fit over the upper and lower sets of teeth to protect them from damage during endotracheal (ET) tube intubation procedures.	A
54	Invasive arterial pressure cardiac output/oximetry monitor	A device intended to continuously measure and display arterial pressure cardiac output (APCO) and haemoglobin oxygen saturation (e.g., SpO ₂) when connected to an extravascular blood pressure transducer linked to a peripheral arterial line, and to a pulse oximeter or an oximetry catheter.	B
55	Laryngeal airway introducer	A device intended to aid insertion of a laryngeal airway into the pharyngeal cavity of a patient while reducing or eliminating the need for finger manipulation within the mouth. It is typically in the form of a metal blade with a handle and may be mounted onto the laryngeal airway during insertion. This is a reusable device intended to be sterilized prior to use.	A
56	Laryngectomy tube	A device intended to maintain tracheostoma patency after laryngectomy to provide an airway for the patient and to prevent tracheostomal stenosis in the months following the procedure.	B
57	Laryngotracheal anaesthesia applicator	A non-sterile container that is prefilled with an anaesthetic agent and intended to be used to apply the agent to the oropharynx and upper airway, to relax laryngotracheal reflexes prior to an intervention of an endotracheal (ET) tube or other type of tracheal tube.	B
58	Manual jet ventilation device	A portable, manually-operated, noninvasive device intended to be used in conjunction with a separate compressed oxygen (O ₂) source and airway access device for transtracheal ventilation of a patient in an emergency situation where there is complete or partial obstruction of the airways.	C

59	Mechanical positive pressure airway secretion-clearing device	A hand-held, mechanical device designed to remove excessive mucus or sputum (phlegm) from the lungs and upper airway of a patient typically suffering from acute or chronic lung disease.	A
60	Medical gas flowmeter	A device intended to measure and regulate the flow of a medical gas during various procedures.	A
61	Medical gas flowmeter, Thorpe tube	A device intended to measure and regulate the flow of a medical gas during various procedures.	A
62	Medical gas pipeline system	An assembly of devices designed to supply compressed medical gases from a central source to endpoints throughout a medical facility.	A
63	Medical gas pipeline system automatic outlet analyser	A main component of a medical gas pipeline supply system that monitors the composition of a gas delivered from the supply system.	A
64	Medical gas pipeline system pressure monitor	A component of a medical gas pipeline system designed to continuously monitor and detect changes in the pressure values of the medical gases in the supply pipeline.	A
65	Medical gas terminal unit	A device that is a component of a medical gas pipeline system or a medical gas/vacuum pipeline system that has a gas-specific outlet connection for a single/mixture of gas to which the operator can connect and disconnect a medical device.	A
66	Microbial medical gas filter	A screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anaesthesia and/or endoscopy.	B
67	Negative-pressure ventilator	An automatic cycling machine used to assist or control alveolar respiration that exerts a negative pressure on the external surface of the chest wall, expanding the chest and moving air into the lungs.	C
68	Neonatal chest percussor	A hand-held device (a percussor) intended to be operated by a healthcare professional to provide external vibrations to the chest wall of a neonate to help loosen bronchial mucus for expectoration through suctioning. It is used to help loosen secretion build-up in the lungs of neonates who cannot perform the natural cough mechanism.	B
69	Nerve-block injection manometer	A noninvasive device intended to be connected between a syringe and a nerve-block needle to indicate injection pressure during administration of local or regional anaesthesia to achieve peripheral nerve blockade.	A
70	Nitric oxide delivery unit	A device intended for the delivery of precise amounts of nitric oxide (NO), also known as nitrogen monoxide, to the respiratory tract of neonate, paediatric, and adult patients to treat severe respiratory disorders.	B
71	Non-heated respiratory humidifier	A device designed to prevent the drying of airway passages associated with the inhalation of oxygen (O ₂) by adding water vapour to the dry gas as it is passed through, or more seldom, over water.	B

72	Non-rebreathing oxygen face mask	A flexible, form-shaped device designed with valve to control rebreathing and contamination of gas, placed over the nose and mouth to deliver air of high oxygen (O ₂) concentration to a patient's airway for oxygen therapy.	A
73	Nose clip	A device intended to be used to compress the nose externally, to ensure that airflow is exclusively conducted through the mouth during examinations of the pulmonary function and/or to stop nosebleeds.	A
74	Oxygen administration hood	A device consisting of a rigid transparent plastic shell forming an enclosure over the head of an adult, typically to provide an enriched oxygen (O ₂) environment to increase the patient's O ₂ uptake.	A
75	Oxygen saturation/pulse rate simulator	An electronic instrument designed to simulate arterial oxygen saturation and/or pulse rate for testing and calibrating pulse oximeters, pulse oximeter probes and other related pulse oximetry devices.	A
76	Oxygen/air breathing gas mixer	A portable mechanical device designed to mix air and oxygen (O ₂) for mobile O ₂ administration during first aid or emergency situations.	B
77	Patient physiologic monitoring system	An assembly of devices designed for continuous assessment of several vital physiologic parameters of patient(s).	C
78	Pleural manometer	A noninvasive device intended to convert pressure into electrical signals for the measurement of pressure within the pleural cavity.	B
79	Pneumatic chest percussor	A hand-held pneumatic device designed to provide external vibrations to the chest wall of a patient to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
80	Pressure algometer/aesthesiometer	An instrument designed to measure a patient's sensitivity to pain (pain threshold) and tactile sensibility.	B
81	Pulmonary resuscitator	A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration.	C
82	Pulse Co-oximeter	A device designed to detect hypoxia via the transcutaneous multiwave measurement and display of carboxy-haemoglobin saturation (SpCO) and typically other related parameters such as haemoglobin oxygen saturation (SpO ₂), methaemoglobin saturation (SpMet), and haemoglobin concentration (SpHb).	B
83	Pulse oximeter	A device intended for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO ₂).	C
84	Rebreathing oxygen face mask	A flexible, form-shaped device designed to be placed over the nose and mouth to deliver a proportional mixture of air/oxygen (O ₂) to a patient's airway.	A

85	Respiration monitor	A device designed to measure and display a non-ambulatory patient's respiratory functions. Measurements include concentration of respiratory gas components and/or continuous monitoring of the inspiration/expiration cycle including respiration rate, air volume, and cessation of breathing (apnoea).	B
86	Respiratory oxygen monitor	An instrument designed to continuously measure the concentration of oxygen (O ₂) inspired by a patient in a respiratory maintenance/therapy setting.	B
87	Respiratory oxygen therapy monitor/regulator	An electrically-powered unit designed to be connected to a pulse oximeter sensor and used during the administration of oxygen (O ₂) to a spontaneously breathing patient, for: 1) continuous monitoring of physiologic parameters, especially haemoglobin oxygen saturation (SpO ₂); and 2) dynamic regulation of the amount of O ₂ delivered to the patient based on physiological parameter measurements.	B
88	Rigid non-bladed video intubation laryngoscope	A non-sterile device intended to facilitate the positioning of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.	A
89	Saddle block anaesthesia kit	A collection of devices designed to deliver an analgesic or anaesthetic agent to the lower dural sac in the region corresponding to the buttocks, in the perineum, or to the inner aspects of the thighs.	B
90	Spinal needle bioimpedance navigation unit	A device designed to transmit and receive electrical signals to/from a dedicated spinal needle and to analyse bioimpedance data in real-time, to predict needle tip location.	D
91	Spirometer/pulmonary function analyser syringe	A device consisting of a barrel (cylinder) with plunger/piston intended to be used for injecting small volumes of accurately measured amounts of gas into a spirometer, pulmonary function analyser, or other diagnostic pulmonary measuring/testing device for calibration or reference.	A
92	Tracheal surgery dilator	A hand-held manual surgical instrument intended to be used during surgical intervention of the trachea to dilate tracheal structures/passages, typically during the creation of a tracheostoma and/or for expanding the margins of a tracheostoma to assist in the insertion of a tracheostomy tube.	A
93	Tracheotome	A surgical instrument designed to cut an opening into the trachea (windpipe) through the anterior surface of the neck to create an artificial airway (tracheotomy).	A
94	Ultrasonic cough stimulation system	An assembly of devices designed to stimulate a reflex cough using ultrasound in a patient who cannot cough on command, typically respiratory patients with cortical insufficiency or the very young/elderly, to help clear the lungs of secretions and aspirated materials.	A

95	Ultrasonic respiratory humidifier	A device designed to agitate water into micro-particles with ultrasound to add moisture to the flow of air/gases administered to a patient via a breathing tube/circuit.	B
96	Vacuum-assisted airway secretion-clearing system	A device assembly designed to remove excessive secretion from the lungs and upper airway of patients with respiratory disease or during cardiac rehabilitation through vacuum technology.	B
97	Venturi oxygen face mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver a mixture of an almost precise ratio of air and oxygen to the patient's airway. The device usually has a replaceable part (Venturi tube) to change the mixture ratio of air and oxygen so that oxygen is delivered at a desired concentration. The device is connected to the oxygen source via a tube. The device has a head strap for fixation. Normally comes with an adapter to connect with humidifier.	B
98	Venturi oxygen face mask	A device designed to be placed over the nose and mouth of a patient to deliver a near-precise mixture of air and oxygen (O ₂) to a patient's airway without the use of a gas mixer.	B
99	Bronchial cannula	A tube-shaped surgical instrument that is inserted into the lumen of the bronchus by means of a trocar blade to provide rigidity.	A
100	Bronchoscopy tube	A device which is inserted orally into the trachea to maintain airway patency and/or to deliver anaesthetic inhalation agents or other medical gases, and secure ventilation during diagnostic or therapeutic bronchoscopy using a flexible bronchoscope.	C
101	Bulk oxygen concentration system	An assembly of devices designed to concentrate oxygen (O ₂) from ambient air and then deliver the concentrated O ₂ , with purity of up to 99.5%, to the hospital medical gas supply system.	B
102	Endotracheal secretion monitoring system	An assembly of devices designed to continuously detect the sound of endotracheal (ET) secretions moving through a ventilation circuit during suctioning of an artificially ventilated and/or spontaneously breathing patient to assess the effectiveness of suctioning.	B
103	Epidural anaesthesia kit	A collection of devices intended to be used to deliver an analgesic or anaesthetic agent to the epidural space for pain management.	C
104	Laryngeal airway	A curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients.	A

105	Medicine chamber spacer	A device intended to be placed between a nebulizer or a metered dose inhaler (MDI) and the patient's mouth, to function as a reservoir into which an aerosol medication is dispensed in order to minimize delivery of large aerosolized particles.	A
106	Nasopharyngeal airway	A rubber or plastic tube that extends into the pharynx from either naris to maintain airway patency.	B
107	Oropharyngeal airway	A curved metal or plastic tube inserted through the mouth to facilitate airway patency for gas exchange or suctioning. The device prevents the tongue from obstructing airflow.	A
108	Oxygen/air/nitrous oxide breathing gas mixer	An device designed for accurate mixing of oxygen (O ₂) and air or O ₂ and nitrous oxide (N ₂ O) in pre-set concentrations appropriated for breathing.	C
109	Peak flow meter	A device designed to measure the maximum rate of expiratory gas flow [peak expiratory flow (PEF) or peak expiratory flow rate (PEFR)] and forced expiratory volume (FEV) from the lungs. The device is typically intended to monitor the respiratory status of a patient suffering from chronic respiratory disease in a clinical setting or the home.	B
110	Pulmonary function analysis system	A device used to measure the function of the respiratory system in adults and compliant children.	B
111	Retrograde endotracheal intubation kit	A collection of devices used to assist in the placement of an endotracheal (ET) tube during difficult/emergency airway access procedures	B
112	Tracheostomy kit	A collection of surgical instruments, dilators, tracheostomy tubes and other items intended to be used to create a percutaneous opening in the trachea (tracheotomy) for the insertion of a tracheostomy tube to relieve upper airway obstruction and to facilitate ventilation.	C

Note: Accessories/components of medical devices imported as a system need not be registered separately. However this does not debar from risk based classification of Accessories/components of medical devices.