

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

Notice

File No. 29/Misc./03/2020-DC (197)

Date: 06 AUG 2021

Subject: Classification of Medical Device pertaining to Respiratory 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 with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented 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, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A 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 in nature 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 (India)**

To,

1. CDSCO Website

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Classification of Medical Devices Pertaining to Respiratory

Sr. No.	Medical Device Name	Intended use	Risk Class
1	Activated-oxygen generator	It is a device that makes activated oxygen (singlet oxygen) which is mixed with room air and produces activated water as a by-product.	B
2	Argon gas analyser	An instrument intended to measure the concentration (partial pressure) of argon (Ar) in a gas mixture sample to aid in determining a patient's ventilatory status.	B
3	Artificial airway tube cuff pressure monitor	A device intended to intermittently or continuously measure the internal pressure in the cuff of an endotracheal (ET)/endobronchial/tracheostomy tube when this has been situated into the tracheal passage.	B
4	Bulk oxygen concentration system	An assembly of devices designed to concentrate medical grade oxygen (O ₂) from ambient air and then deliver the concentrated O ₂ , with purity of up to 93%-99.5%, to the hospital medical gas supply system for therapeutic use on patients in Hospital.	A
5	Cardiopulmonary resuscitation mask	A device that intended to be placed over a patient's mouth to administer "mouth-to-mask" exhaled air from the user to the patient during cardiopulmonary resuscitation (CPR).	A
6	Cerebral oximeter	A device used as an adjunct monitor for the regional haemoglobin oxygen saturation of blood in the brain of a patient.	B
7	Chest-oscillation airway secretion-clearing system	Devices designed to provide high frequency chest wall oscillation (HFCWO) for external chest wall manipulation intended to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
8	Chest-percussion airway secretion-clearing system	Devices designed to provide external mechanical percussion (rapid tapping) 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
9	Cold-air diagnostic inhalation system	An assembly of devices intended to be used in the assessment of a pateint suffering from asthma.	B

10	Cough long-term ambulatory recording system	An assembly of devices intended for long-term detection and recording of the number of times a patient coughs during daily activities or sleep.	A
11	Cricothyrotome	A hand-held manual surgical instrument intended to be used to perform a cricothyrotomy providing airway access within seconds for immediate ventilation of the patient and necessary suction procedures.	B
12	Dry powder inhaler	A hand-held device designed to administer powdered medicine through the mouth and into the bronchial airways.	A
13	Dry salt therapy device	A hand-held inhaler prefilled with salt crystals and used to provide an inhalation of salt particles through the mouth and into the bronchial airways to induce natural self-cleansing mechanisms that flush away the impurities from the surface of cells and mechanically clean the airways.	A
14	Electroacoustical airway secretion-clearing system	An assembly of devices designed to provide externally applied vibrations to the chest wall of a patient via an electroacoustical transducer (the applicator) to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
15	Endotracheal tube introducer	A device designed to help with the insertion of an endotracheal (ET) tube into the airways of a patient during intubation	A
16	Exhaled-gas oesophageal intubation detector	A device designed to verify proper endotracheal (ET) tube placement by detecting/assessing escaping levels of exhaled carbon dioxide (CO ₂) during airway management disclosing potential incorrect intubation.	A
17	Foetal pulse oximeter	A photoelectric device designed for the monitoring of intrapartum foetal oxygen saturation (FSpO ₂) in the presence of a non-reassuring foetal heart rate (FHR) pattern during labour.	B
18	Gas pipeline/supply system air compressor	A device designed to create compressed medical grade air, and supply it to a hospital or institution's gas pipeline/supply system for patient use.	B
19	Heated respiratory humidifier	A device designed to heat and humidify air/oxygen inspired by a patient to help maintain the mucous membranes of the respiratory tract typically during periods of prolonged respiratory support/therapy.	B
20	Home-use sleep apnoea recording system	A device intended to continuously measure and record patient physiological parameters during sleep in the home, to facilitate the diagnosis of sleep apnoea.	B

21	Hyperbaric chamber	The intended use of the Hyperbaric Chamber is to administer 100% oxygen at pressure greater than ambient.	C
22	Hypopnea sensor/alarm	An electronic device intended to be used to indicate patient hypopnea by monitoring the movement of the thorax and abdomen with each breath and provides a signal, according to predetermined settings.	B
23	Impedance pneumography recording/analysis system	An assembly of electronic devices intended for continuous recording of a patient's pulmonary function parameters using impedance pneumography (IP).	B
24	Implantable sleep apnoea treatment system	An assembly of devices intended for home management of obstructive sleep apnoea (OSA) using an implanted stimulator to provide electrical stimulation to the hypoglossal nerve.	C
25	Infant apnoea monitor	A device that is used to register the respiratory rate of an infant and which gives an alarm signal (e.g., audible/visual) when the pre-set limits are exceeded caused by an extended interruption or cessation (apnoea) of the infants breathing pattern; a condition known as sudden infant death syndrome (SIDS).	B
26	Manual chest percussor	A hand-held device designed to facilitate manual percussion (rapid tapping) 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
27	Nitrogen monoxide analyser	A device intended to measure nitric oxide (NO), in exhaled air to facilitate diagnosis and management of asthma.	B
28	Nitrous oxide analyser	An instrument used to measure the concentration of nitrous oxide (N ₂ O) in a sample of a gas mixture taken from an enclosed environment such as a healthcare facility, a compressed medical air or gas system, and/or devices used for anaesthesia administration or respiratory therapy.	B
29	Pulse oximetry telemetric monitoring system	An assembly of devices designed to continuously measure and wirelessly transmit haemoglobin oxygen saturation (SpO ₂) signals from a patient to a receiving location for viewing.	B
30	Respiratory apnoea monitoring system	An assembly of devices designed to detect the cessation of breathing (apnoea) in patient who are at risk of respiratory failure to alert a parent or attendant of the life-threatening episode(s).	B

31	Steam inhaler	An electrically-powered, hand-held device designed for the inhalation of steam for the relief of the symptoms (congestion and pressure) associated with upper respiratory disorders.	A
32	Stress test treadmill	A device used as a component of a stress test system that permits the evaluation of a patient's physiologic response to physical stress.	A
33	Therapeutic air ionizer	A device that produces small, biologically-active, negatively-charged ions of oxygen (O ₂), pulsed at various selected frequencies, that are emitted into the ambient air and absorbed into the bloodstream via the lungs to potentially produce a therapeutic effect.	A
34	Therapeutic positive pressure breathing ventilator	A device used for therapeutic rehabilitation of patients with chronic respiratory diseases, and for the distribution of aerosolized pharmacological agents to the patient's airways and lungs.	C
35	Thoracic bioconductance measurement system	An assembly of devices designed to measure and store bioconductance measurements, analyse the stored data and provide information that can aid a clinician in their evaluation of lesions suspicious of lung cancer.	B
36	Thoracic electrical impedance segmentography system	An assembly of devices designed to perform thoracic bio-impedance measurements to continuously record the distribution of air across 4 quadrants of the lungs, commonly of a neonatal/infant patient to detect changes in lung ventilation at a regional level, to assist in the diagnosis of lung conditions.	B
37	Thoracic electrical impedance tomography system	An assembly of devices designed to perform continuous bio-impedance measurements throughout a cross-section of the thorax, to provide real-time feedback of lung function of a ventilated patient.	C
38	Thoracic suction pump	A device intended to generate negative pressure specifically for aspiration, to remove fluids, secretions and air to allow for the normal expansion/function of the lungs and/or mediastinum.	B
39	Tongue-adjustment sleep apnoea treatment system	An assembly of devices intended for home management of obstructive sleep apnoea (OSA) by monitoring breathing parameters during sleep to detect the onset of an apnoea event and reducing pharyngeal obstruction by the tongue.	B
40	Tracheostoma protective filter	A device designed as a filter for protecting a stomal opening in the windpipe against harmful external influences.	A

41	Tracheostoma protector	A patient-worn device in the form of a patch, collar, or cloth designed to be fastened around the neck to protect a tracheostoma orifice against harmful external influences. It is not intended to be used as a shower shield.	A
42	Tracheostomy tube lubricant	A substance made of oil designed to be applied by healthcare staff or a patient to the outer surface of a tracheostomy tube inner cannula to facilitate its easy sliding into the outer cannula.	A
43	Transcutaneous blood gas monitoring system	An assembly of devices designed for the continuous and transcutaneous measurement of a patient's blood gas parameters detected through the jugular vein (SjvO ₂).	B
44	Valsalva manoeuvre mouthpiece	A device intended to be inserted into a patient's mouth to facilitate performance of the Valsalva manoeuvre.	A
45	Video intubation laryngoscope handle/monitor	A component of a bladed video intubation laryngoscope intended to enable the positioning of the blade into the oral cavity 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
46	Whole-body plethysmograph	A graphic recorder designed for determining and registering airway resistance and thoracic gas volume to assess pulmonary function.	B
47	Diagnostic Spirometer	A device designed to measure several or all respiratory-gas volume and flow parameters needed to evaluate basic pulmonary function.	B
48	Monitoring Spirometer	A device designed to measure continuously a patient's tidal volume or minute volume for the evaluation of the patient's ventilatory status.	B
49	Oxygen Concentrator	A device designed to concentrate oxygen (O ₂) from ambient air and deliver the concentrated O ₂ to patient.	B
50	Pulmonary function analysis system	A device used to measure the function of the respiratory system in adults and compliant children.	B
51	Public respirator (2 ply, 3 ply face mask)	A filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency.	A