§ 868.5895 Continuous ventilator.

(a) Identification. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) Classification. Class II (performance standards).

§ 868.5905 Noncontinuous ventilator (IPPB).

(a) Identification. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient’s lungs or to assist a patient’s breathing.

(b) Classification. Class II (performance standards).

§ 868.5915 Manual emergency ventilator.

(a) Identification. A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient’s airway.

(b) Classification. Class II (performance standards).

§ 868.5925 Powered emergency ventilator.

(a) Identification. A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient’s airway.

(b) Classification. Class II (performance standards).

§ 868.5935 External negative pressure ventilator.

(a) Identification. An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient’s ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.


§ 868.5955 Intermittent mandatory ventilation attachment.

(a) Identification. An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

(b) Classification. Class II (performance standards).

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) Identification. A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient’s lungs above atmospheric pressure at the end of exhalation.

(b) Classification. Class II (performance standards).

§ 868.5975 Ventilator tubing.

(a) Identification. Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.


§ 868.5995 Tee drain (water trap).

(a) Identification. A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.