Food and Drug Administration, HHS

§ 868.5795 Tracheal tube cleaning brush.

(a) Identification. A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.

(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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[51 FR 40389, Nov. 6, 1986]

§ 868.5800 Tracheostomy tube and tube cuff.

(a) Identification. A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient’s aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) Classification. Class II.

[51 FR 40389, Nov. 6, 1986]

§ 868.5810 Airway connector.

(a) Identification. An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.

(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.


§ 868.5820 Dental protector.

(a) Identification. A dental protector is a device intended to protect a patient’s teeth during manipulative procedures within a patient’s oral cavity.

(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.


§ 868.5830 Autotransfusion apparatus.

(a) Identification. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

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

§ 868.5860 Pressure tubing and accessories.

(a) Identification. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(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.


§ 868.5870 Nonrebreathing valve.

(a) Identification. A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

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

§ 868.5880 Anesthetic vaporizer.

(a) Identification. An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.
§ 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 II (performance standards).

§ 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.