

§ 880.5180

21 CFR Ch. I (4–1–11 Edition)

§ 880.5180 Burn sheet.

(a) *Identification.* A burn sheet is a device made of a porous material that is wrapped around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants.

(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 § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38804, July 25, 2001]

§ 880.5200 Intravascular catheter.

(a) *Identification.* An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.

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

§ 880.5210 Intravascular catheter securement device.

(a) *Identification.* An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin.

(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 § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38804, July 25, 2001]

§ 880.5240 Medical adhesive tape and adhesive bandage.

(a) *Identification.* A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant.

The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.

(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 § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38804, July 25, 2001]

§ 880.5270 Neonatal eye pad.

(a) *Identification.* A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.

(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 § 880.9. 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

§ 880.5300 Medical absorbent fiber.

(a) *Identification.* A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient's body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.

(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 § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing

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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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.5400 Neonatal incubator.

(a) *Identification.* A neonatal incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care.

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

§ 880.5410 Neonatal transport incubator.

(a) *Identification.* A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with insulated walls in which an infant may be kept in a controlled environment while being transported for medical care. The device may include straps to secure the infant, a battery-operated heater, an AC-powered battery charger, a fan to circulate the warmed air, a container for water to add humidity, and provision for a portable oxygen bottle.

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

§ 880.5420 Pressure infusor for an I.V. bag.

(a) *Identification.* A pressure infusor for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.

(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 § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

§ 880.5430 Nonelectrically powered fluid injector.

(a) *Identification.* A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

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

§ 880.5440 Intravascular administration set.

(a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

(b) *Classification.* Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers." Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 15798, Mar. 21, 2001]

§ 880.5450 Patient care reverse isolation chamber.

(a) *Identification.* A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment