§ 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).

§ 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, and provision for a portable oxygen bottle.

(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).