

§ 880.6230

(iv) Instructions to install device in adequately ventilated area and stable area.

[83 FR 19628, May 4, 2018]

§ 880.6230 Tongue depressor.

(a) *Identification.* A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(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 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, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6250 Non-powdered patient examination glove.

(a) *Identification.* A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

(b) *Classification.* Class I (general controls). The device, when it is a finger cot, 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, Oct. 21, 1980, as amended at 54 FR 1604, Jan. 13, 1989; 66 FR 46952, Sept. 10, 2001; 81 FR 91730, Dec. 19, 2016; 84 FR 71815, Dec. 30, 2019]

§ 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

(a) *Identification.* A filtering facepiece respirator for use by the general public in public health medical emergencies is

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a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) *Classification.* Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies." See §880.1(e) for information on obtaining a copy of this guidance document.

[72 FR 36362, July 3, 2007]

§ 880.6265 Examination gown.

(a) *Identification.* An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical examination.

(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 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, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6280 Medical insole.

(a) *Identification.* A medical insole is a device intended for medical purposes