

§ 895.104

powder for purposes other than manufacturing.

(b) [Reserved]

[81 FR 91731, Dec. 19, 2016]

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

[81 FR 91731, Dec. 19, 2016]

§ 895.105 Electrical stimulation devices for self-injurious or aggressive behavior.

Electrical stimulation devices for self-injurious or aggressive behavior are aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease self-injurious or aggressive behavior.

[85 FR 13354, Mar. 6, 2020]

PART 898—PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec.

898.11 Applicability.

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898.14 Exemptions and variances.

21 CFR Ch. I (4–1–23 Edition)

AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 62 FR 25497, May 9, 1997, unless otherwise noted.

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601–1: Medical Electrical Equipment

601–1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.
1	74 DRT	870.2300	II	Monitor, Cardiac (including Cardiotachometer and Rate Alarm).
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.