



Position Statement

CPSC 16 CFR Part 1633

Flammability Standard

Executive Summary

On July 1, 2007, the Consumer Product Safety Commission (CPSC) implemented a new safety standard for mattresses and mattress sets entitled Standard for the Flammability (Open Flame) of Mattresses and Mattress/Foundation Sets.

All Joerns Healthcare products are designed and manufactured in compliance with applicable U.S. Food and Drug Administration (FDA) Regulations and Guidelines. As such, our products are packaged and labeled in accordance with the requirements set forth in the Labeling regulations pertaining to medical devices as found in Title 21 Part 801 Medical Device Labeling of the Code of Federal Regulations (CFR).

Under the Consumer Product Safety Act, CPSC does not have authority over products regulated by the FDA. These include such Class 1 and Class 2 Medical Devices as therapeutic foam mattresses, air mattresses, and air mattress systems used in the prevention and treatment of pressure ulcers.

It is our position, confirmed by the CPSC, that therapeutic foam and air mattress products regulated by the United States FDA, do not fall within the scope of CPSC 16 CFR Part 1633: Standard for the Flammability (Open Flame) of Mattresses and Mattress/Foundation Sets, and are therefore not expected or required to meet this new national flammability standard.

While our therapeutic support surfaces are not required to comply with 16 CFR Part 1633, we have expanded our foam mattress product offering to include mattresses that meet this new standard for those customers looking for mattresses compliant with 16 CFR Part 1633. At this time, we do not offer therapeutic air mattresses and air mattress systems that are compliant with 16 CFR Part 1633.

The following information is intended to provide background information on the flammability standard and requirements applicable to mattresses.

Joerns Healthcare Background

The US FDA develops and administers regulations under authority granted by laws passed by Congress that apply to food, drugs, cosmetics, biologics, radiation-emitting electronic products, and medical devices.

Joerns Healthcare is one of the world's premium manufacturers and providers of post-acute, acute, and home care medical device products and services, which include therapeutic support surfaces used in the prevention and treatment of pressure ulcers. Support surface products include powered and non-powered therapy mattresses. As a medical device manufacturer, Joerns Healthcare complies with all applicable FDA requirements and guidelines, as well as many other national and international regulatory standards, requirements, and guidelines. As such, our products are packaged and labeled in accordance with the requirements set forth in the Labeling regulations pertaining to medical devices as found in Title 21 Part 801 Medical Device Labeling of the Code of Federal Regulations (CFR).

Understanding 16 CFR Part 1633

Effective July 1, 2007, all mattresses manufactured, imported or renovated for sale or introduction into commerce must meet new the new federal regulations regarding flammability. This new standard, 16 CFR Part 1633, is similar to California Technical Bulletin (TB) 603 but with a few differences. For example, to pass the new standard, the federal regulation requires tested mattresses to energy release levels that are more stringent than TB 603. Low energy release levels from a burning mattress are desirable, in part, to prevent a mattress that has become ignited from turning into a "flashpoint" for the entire room, leading to a broader fire. Manufacturers must submit mattresses to testing against this new standard in order to pass the standard and have the mattresses certified to 16 CFR Part 1633.



California currently has a tough flammability regulation in place, California Technical Bulletin 603, which went into effect January 1, 2005. With the optional fire barrier, our therapeutic foam mattresses meet this standard. Coinciding with the effective date of the Federal 16 CFR Part 1633, California's Technical Bulletin 603 expires July 1, 2007.

Under 16 CFR Part 1633, there are two criteria to limit the growth of fire in a mattress or mattress set:

- The mattress sets must not exceed a 200 kilowatts (kW) peak heat release rate within the 30 minutes of the test.
- The total energy released must be no more than 15 megajoules (MJ) for the first 10 minutes of the test.

Like TB 603, there is a requirement that mattresses have a label that states the mattress is compliant with 16 CFR Part 1633.

Does 16 CFR Part 1633 Apply To Joerns Healthcare Mattresses?

No. Because Joerns Healthcare mattress products are considered medical devices by the FDA, they are exempt from the 16 CFR Part 1633 requirements. **The Joerns®, BioClinic and private label mattress products fall within the statutory definition of a medical device.** Section 201(h) of the Federal Food Drug and Cosmetic Act defines a medical device as:

(A)n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

As noted above, Joerns therapeutic mattresses have a specialized purpose. In determining whether a product is a medical device, the FDA asks whether the manufacturer makes specific medical claims for the product in promotional or other materials. This, in fact, is the case with Joerns mattresses, as their intended use is to serve as a device to treat or prevent pressure ulcers. This is consistent with FDA requirements as specified in 21 CFR 880 § 5150 and 5550.

In addition, under the Consumer Product Safety Act, 15 U.S.C. 2052(a)(1)(H), the CPSC has stated that they do not have jurisdiction over medical devices as that term is defined in the Federal Food, Drug and Cosmetic Act. Instead, medical devices are regulated by the Food and Drug Administration. Thus, since a mattress is a medical device, it would not be subject to 16 C.F.R Part 1633, but would instead be regulated by FDA as a medical device.

As such, even though not required under the Federal regulation, Joerns Healthcare does offer therapeutic foam mattresses that are certified to CPSC 16 CFR Part 1633. Customers who wish to have a therapeutic foam mattress that meets the Federal standard may order a foam mattress with the optional fire barrier.

Helpful Links

- CPSC 16 CFR Part 1633: New Federal regulations
<http://www.cpsc.gov/businfo/frnotices/fr05/openflame.pdf>
- TB 603: State of California regulations
<http://www.bhfti.ca.gov/laws/ab603.htm>
- US FDA information concerning medical devices
<http://www.fda.gov/cdrh/devadvice/>
- Joerns Healthcare
www.joerns.com

