

Annex ii directive 93 42 eec without section 4

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Is 93/42 EEC still valid? Regulation (EU) 2017/745 (see summary) originally repealed Directive 93/42/EEC, from 26 May 2020.

What is Council directive 93 42 EEC classification? Annex IX of the Directive stipulates the classification of devices – according to the hazard potential – in Classes I (low), IIa, IIb, and III (high). Depending on the classification of the product, different conformity assessment procedures apply. The Directive includes 18 classification rules.

What is the European Council directive 93 42 EEC known as? Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

What is the rule 15 of Annex IX of the directive 93 42 EEC? Rule 15. All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb. All devices intended specifically to be used for disinfecting medical devices are in Class IIa.

What is the expiration date on a medical device? Expiration date means the date by which the label of a device states the device must or should be used. FDA, we, or us means the Food and Drug Administration. Finished device means any device or accessory to any device that is suitable for use or capable of functioning.

What are the requirements for MDR? The Medical Device Reporting (MDR) Regulation requires medical device manufacturers, device user facilities and importers to establish a system that ensures the prompt identification, timely

investigation, reporting, documentation, and filing of device-related death, serious injury, and malfunction information.

What is 92 42 EEC Directive? Directive 92/42/EEC concerns efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels. The Directive refers to standard boilers, low-temperature boilers and gas-fired condensing boilers with rated output 400 kW.

What are medical device essential requirements? The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be ...

What are the grades of medical devices? The FDA medical device classes are based primarily on the risk the device poses. Class I medical devices are generally deemed low risk. Class II medical devices are associated with a higher risk level than class I devices, but less than that of class III devices. Class III medical devices are seen as the highest risk.

What is the EEC now called? Upon the formation of the European Union (EU) in 1993, the EEC was incorporated and renamed the European Community (EC).

What is the directive 93 44 EEC? Directive 93/44/EEC, which expanded the scope of the Machinery Directive to : safety components, machinery for lifting, the movement of people.

What is the difference between MDD and MDR? While the MDD focused on getting a product to market, the MDR expands to consider the full product lifecycle: development, testing, manufacturing, commercialization, efficacy, safety, and long-term use.

What is the medical device directive 93 42 EEC classification? Medical Device Directive 93/42/EEC alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: Diagnosis, prevention, monitoring, treatment or alleviation of disease.

What is Directive 93/13/EEC on unfair terms? Directive 93/13/EEC protects consumers in the EU from unfair terms and conditions which might be included in a standard contract for goods and services they purchase. It introduces the notion of 'good faith' to avoid any significant imbalance in mutual rights and obligations.

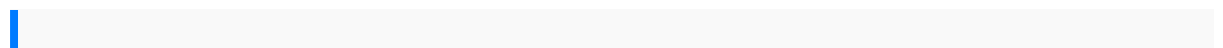
What is the Council Directive EC 93/104 concerning certain aspects of the organization of working time? Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organisation of working time(4) lays down minimum safety and health requirements for the organisation of working time, in respect of periods of daily rest, breaks, weekly rest, maximum weekly working time, annual leave and aspects of ...

What is boiler efficiency directive 92/42/EEC? Directive 92/42/EEC concerns efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels. The Directive refers to standard boilers, low-temperature boilers and gas-fired condensing boilers with rated output 400 kW.

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What is the EEC regulation 95/93? Council Regulation (EEC) No 95/93 of 18 January 1993 on common rules for the allocation of slots at Community airports.



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