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2013-09-23

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Is a treadmill ergometer sports equipment or a medical device?

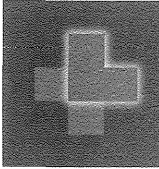
Type of product according to the Medical Device Law (MPG)

Dear Mr. Harrer

You advise that you place "treadmills" on the market. You asked to re-confirm to which category these treadmills are assigned to. To this end we would like to give the short following legal opinion:

1. Basic product class

Basically once can statue, that there is a type of legal gradation for products of the type into which a treadmill could fall. As a basis, the (German) Product Safety Act (ProdSG) applies to all products that are industrially manufactured and placed on the market. A special class then provides for "Commodities" according to section 2 paragraph 6 of the Food and Feed Code (LFGB). Such commodities are products that come in contact in some way with food or cosmetics (packaging), etc., or in any other way into temporary contact with the human body such as toys and decorations.



Another particular type of product are "medical devices" within the meaning of section 3 of the (German) Medical Devices Act (MPG). These are basically all the items which are used in medical, therapeutic, diagnostic or rehabilitative treatment.

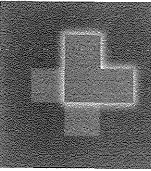
As a crucial demarcation criterion will be seen the intended use (objective purpose) of each product, the special purpose provisions are to be classified with respect to the overall purpose of the product as a priority and classify the total product to an appropriate genre. Thus, a product can only be classified under the Product Safety Act if no intended use (purposes), either in the manufacturers description or the objective expectations of the consumer, for another more specific type of product are met.

The definition of a medical device is in section 3 no. 1 Medical Devices Act with the only relevant alternatives here:

"Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination intended by the manufacturer to be used for human beings for the purpose of:

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, or
- c) investigation of a physiological process."

Accordingly, it is essential for the assignment of a treadmill to a specific product category, whether at least a purpose that makes reference to a disease or the treatment, alleviation of or compensation of injury or handicap, or simply for the medical examination of a physiological process of the body. The term "disease" is not defined in the Act. While the WHO assumes a much wider concept of disease, the German courts have repeatedly discussed different views on the concept of "disease", especially with respect to the social insurance law. Generally, however, the definition of the Federal Supreme Court should be taken, after which a disease is a disorder of the normal condition or the normal activity of the body which can be eliminated or alleviated. In the social insurance law in this regard it is added that disease is an abnormal state of mind or body, that requires medical treatment and/or leads to an incapacity for work. A differentiation needs to be made so that the concept of disease symptoms of a



particular people, corresponding to a normal life process (especially ageing) are excluded. This can not be described as a disease. On the other hand, age-related wear and tear (degenerative joint disease), or presbyopias, age-related diabetes etc. despite being related to the ageing process of the body are to be understood as a disease.

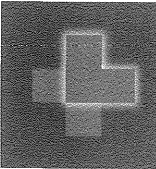
Especially in the field of sport, the concept between sporting exercise, wellness, health promotion, disease prevention and disease treatment is fluid. The crucial factor is always that one of the aspects may be due to disease. Next to it is also the further possibility that the purpose of a medical device, is the compensation of an injury or handicap, whether this handicap can be healed through therapy or not, is one possible purpose.

2. Attributable of a treadmill to product category

Under these guidelines, a treadmill is always a medical device if it (or at least also) is used for medical purposes as mentioned above. Here these medical purposes may initially present themselves in the rehabilitative field. If a treadmill was used for rehabilitation after disease, injury or surgery, this treadmill clearly meets the purpose of a medical device. It does not matter whether this rehabilitation is required after a sports injury or due to a medical operation (e. g. replacement of the hip joint). In both cases the implementation of the measures would only be possible with a medical device. Also included in this field is gait therapy, locomotion or other orthopaedic rehabilitation.

In addition diagnostic functions of a treadmill come into consideration. A medical device is used for detection and monitoring of disease and can be used for examining a physiological process of the body. So treadmills used for stress ECGs, ergometry, movement and gait analysis and sports medicine diagnostics of lactate or heart rate analysis or in a study following any disease related state of the body are also medical devices.

If a treadmill is used for at least also one or more of the above purposes, it is mandatory that the product is categorised as a "medical device" according to section 3 no. 1 of the German Medical Devices Act MPG.



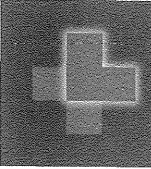
In contrast, treadmills that are to be used only in the area of sport training optimization or general performance enhancement and general fitness of users fall within the meaning of the Product Safety Act. However, it should always be borne in mind that whenever such applications, if only as a side effect during use help in recognizing possible problems (particularly circulatory problems, heart problems or similar pathological conditions) of the athlete/user mean that the treadmill is a medical device. Guiding the way in this case is the recent decision of the European Court from 22.11.2012 (Legal Case C 219/11) indicating that an item that was designed for people to use for the purpose of investigation of a physiological process, except when there is no measurement of the function of human organs in any way meaning that it does not fall under the concept of a medical device, is for medical use.

3. Relevance to user

The correct classification of a product is especially necessary for users of a treadmill because the Medical Devices Act and the Medical Devices Directive (MDD) also apply to products that are not placed on the market as medical devices by the manufacturer, but the users and operators have an appropriate purpose use of a medical device according to section 2, paragraph 2 of the German Medical Devices Act. Therefore, it must first be evaluated by the buyer of a treadmill if the proposed use (intended use) is for (or additional to) a medical, rehabilitative or medical diagnostic purpose. In this case, the only legally correct path is the purchase and use of a product classified as medical device.

4. Consequence of the type of product

Medical devices may be placed on the market only if they have undergone a specific conformity assessment procedure. With the CE marking, the manufacturer confirms that all the essential requirements for the specific medical device have been tested and met. The most diverse harmonised standards for the various types medical devices have been adopted and implemented and should be respected by the manufacturer of the product. In particular, the performance and quality characteristics have to meet very high standards, so that a "treadmill" built and classified as a medical device is in no way comparable to a "treadmill" for the pure sportive training.



Medical devices may only be used in accordance with section 6 paragraph 1 of the German Medical Devices Act if they bear the required CE marking.

We hope to have sufficiently and clearly explained the distinctions.

For further requests, please contact us at any time.

Yours sincerely

A handwritten signature in black ink, appearing to be 'Dr. L.' with a flourish.

(Dr. Lücker)
Attorney at Law