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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 one can state, 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.



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 blue ink, appearing to be 'Dr. Lücker', written over the typed name.

(Dr. Lücker)
Attorney at Law



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Sehr geehrter Herr Harrer,

vielen Dank für Ihre E-Mail vom 16.09.2013 und die englische Übersetzung unseres Schreibens vom 23.08.2013.

Wir haben die englische Übersetzung geprüft und in einigen Aspekten noch einmal überarbeitet. In der Anlage überreichen wir die finale englische Stellungnahme auf unserem Briefbogen zu Ihrer gefälligen Kenntnisnahme und Verfügung.

Darüber hinaus haben wir keine Veränderung unserer bisherigen Stellungnahme vom 23.08.2013 vorgenommen. Sie merken an, die Definition in § 3 Nr. 1 MPG sei von uns eine "frühere Definition" gewesen. Hier missverstehen Sie leider unseren Text. Uns ist sehr wohl die aktuelle gesetzliche Fassung der Definition bewusst, allein wir haben ausdrücklich im Text nur die Komponenten aufgenommen, die für die weitere rechtliche Beurteilung Ihres Produktes relevant waren. Da wir eine Beurteilung über "Laufbänder" zu erstellen hatten, sind die Komponenten "Stoffe oder Zubereitung aus Stoffen" und auch "Software" nicht relevant, sodass sie, wie auch sonstige Komponenten, zur besseren Lesbarkeit aus der Definition in unserem Text gekürzt wurden. Wir haben ausdrücklich darauf hingewiesen, dass wir die Definition "mit der hier allein relevanten Alternative" in den Text aufgenommen haben.

Wir hoffen mit dieser Erläuterung unsere bisherige Position klarstellen zu können.

Für Rückfragen stehe ich Ihnen jederzeit gerne zur Verfügung.

Mit freundlichen Grüßen


(Dr. Lücker)
Rechtsanwalt

Anlage:
Schreiben vom 23.09.2013