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Reference: Categorization/Classification of treadmills; liability risks for economic operators

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Dear Mr. Harrer,

in the past, we have discussed in detail the legal categorization of treadmills and the possible responsibility- and liability aspects for economic operator in the event of incorrect categorization or classification of such products.

As requested, we are happy to summarize the key legal aspects for you again below.

I. Categorization of treadmills as medical devices

The specific intended purpose of treadmills is particularly decisive for the initial question of whether electrically powered treadmills must be classified in the legal category of 'medical devices' and thus fall within the scope of European Regulation 2017/745 on medical devices (Medical Device Regulation – MDR). Therefore, the intended purpose is not only based on the manufacturer's direct statements in the product labelling and instructions for use, but is also influenced, for example, by claims made in advertising and sales materials.

According to Article 2 No. 1 MDR, a medical device is defined in the relevant alternatives as an instrument or article

> *´intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> - *diagnosis, monitoring, prognosis, treatment or alleviation of disease,*
> - *diagnosis, monitoring, treatment, alleviation of an injury or disability,*
> - *investigation of a physiological or pathological process or state.´*

1. Decisive feature: Intended purpose

Accordingly, when classifying a treadmill as a medical device, the decisive factor is whether the product has at least one intended purpose in relation to the aforementioned aspects. If this is the case, the specific treadmill must be classified as a medical device, with the result that all MDR requirements must be observed. In this context, it is important to note that the MDR is not only aimed at manufacturers of medical devices, but also addresses separate obligations that must be observed by distributors, importers or authorised representatives.

When deciding whether a treadmill has a medical purpose in the aforementioned sense, it must be taken into account that the term 'disease' is not defined independently in the Regulation. While the World Health Organization (WHO) uses a very broad definition of ´disease´, different interpretations of this term are repeatedly discussed in German case law, particularly in the context of social security law. In general, the definition of the Federal Court of Justice (Bundesgerichtshof, BGH) is used as a basis, according to which disease is a disturbance or abnormal condition or normal activity of the body that can be cured, i.e. eliminated or alleviated. In the context of social security law, it is further specified that disease is an abnormal physical or mental condition that requires medical treatment and/or results in incapacity to work.

This definition of disease must be distinguished in particular from those complaints that are part of the normal life process, such as the ageing process. These complaints are not generally considered to be pathological. On the other hand, age-related degeneration, such as joint degeneration or osteoarthritis, is considered to be a disease despite its cause being the ageing process of the body.

Particularly in a sporting context, the aspects of athletic training for health promotion or health maintenance sometimes merge seamlessly with aspects of disease prevention or treatment.

The decisive factor for the legal classification of a treadmill is therefore always whether its intended purpose refers at least in part to a medical condition. This is always the case if the treadmill is marketed for use in rehabilitation or exercise therapy. It is irrelevant whether rehabilitation or diagnostics are carried out after a sports accident or due to a medically indicated operation (e.g. hip replacement). In both cases, the implementation of such measures requires the use of a medical device. The same applies to the use of treadmills in the context of gait or locomotion therapy or other orthopedic rehabilitation measures.

Treadmills are also used in medical diagnostics. These treadmills, which are used to perform stress ECGs, ergometry, running/gait analyses, sports medicine lactate diagnostics or heart rate analysis for the diagnosis or monitoring of possible pathological conditions, are also considered as medical devices.

Only treadmills that are used exclusively for training purposes in the field of sports or for maintaining/achieving general fitness (especially in gyms) are not considered as medical devices.

2. Content of the conformity assessment procedure

If, based on the above aspects and with regard to the specific intended purpose of a treadmill, it is determined that it is to be classified as a medical device within the meaning of Article 2 No. 1 MDR, the responsible manufacturer must carry out a conformity assessment procedure in accordance with medical device law and the legal requirements of the MDR before the product can be affixed with the necessary CE marking and placed on the market.

Which of the possible conformity assessment procedures under the MDR is applicable depends, among other things, on the risk classification of the specific treadmill (see further details below in Section II).

It is also important to note that, as part of the required conformity assessment of their treadmill, manufacturers must not only comply with the regulations of the MDR, but also with all other legal requirements applicable to the product. By issuing the required declaration of conformity and affixing the CE marking, the manufacturer or its authorised representative declares that it assumes responsibility for ensuring that all EU

harmonization regulations relevant to the specific device have been taken into account and are fulfilled.

For all electrically powered treadmills, regardless of whether they are medical devices according to the MDR or not, the European requirements for machinery or electromagnetic compatibility must therefore always be taken into account.

3. Legal basis for non-medical treadmills

This means that the distribution and use of treadmills as non-medical devices is also covered by legal regulation. Rather, such sports equipment is also subject to extensive safety requirements, which may arise, for example, from the provisions of the applicable Directive 2006/42/EC on machinery or the Directive 2014/35/EU on the market of electrical equipment designed for use within certain voltage limits and their national implementation through the Product Safety Act (Produktsicherheitsgesetz - ProdSG) and the associated regulations. Once the Regulation (EU) 2023/1230 on machinery, which replaces the Directive, comes into force in January 2027, the requirements therein must be met.

Given that a conformity assessment procedure is also mandatory for machines before the product can be CE marked and placed on the market or put into service, the following legal considerations can in part be applied to pure 'sports treadmills'.

It should be noted that the Regulation on machinery is not only aimed at the manufacturers of these treadmills, but also imposes extensive legal obligations on authorised representatives, importers and distributors of these treadmills, among others, who in turn are responsible for ensuring that only legally compliant products are placed on the EU market.

II. Classification of a medical treadmill

In order to decide which conformity assessment procedure is required under the annexes to the MDR to obtain marketability for the medical device, the risk classification of the specific treadmill in accordance with the classification rules in Annex VIII to the MDR is mandatory.

According to the rules there, each medical device is classified into one of the possible risk classes I, Im, Ir, Is, IIa, IIb or III.

The correct classification of a device has far-reaching consequences, because a treadmill, for example, that has been incorrectly classified by the manufacturer in risk class I but actually belongs to a higher risk class, is not tradeable and may not be marketed.

Only for medical devices in the lowest risk class I can the manufacturer carry out the necessary conformity assessment procedure on its own responsibility; for all other devices in classes Im/r/s, IIa, IIb or III, a notified body must be consulted, which must carry out its own tests as part of the conformity assessment and issue a certificate of conformity upon successful completion. This certificate from the notified body is in turn a prerequisite for the CE marking to be affixed by the manufacturer and, consequently, for the treadmill to be marketable. Whether a notified body was involved in the conformity assessment in a specific case can be determined by the fact that the device labeling must include not only the CE marking but also the four-digit identification number of the specific notified body.

Treadmills are usually electrically powered and therefore depend on a source of energy. The power supplied is used to drive the motor, which then moves the treadmill on which the patient is standing. According to the definition in Article 2 No. 4 MDR, an electrically powered treadmill is an active device, meaning that rules 9 to 13 in Annex VIII to the MDR, which apply specifically to active devices, are decisive for the further specific classification of the treadmill.

For electrically powered medical treadmills, the application of Rule 9 of Annex VIII to the MDR is particularly relevant. According to this rule, all active therapeutic products intended to administer or exchange energy are classified at least in Class IIa.

In individual cases, classification in risk class IIb according to Rule 9 may even be considered if the characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the destiny and the site of application of the energy. This may be the case, for example, if the treadmill has a so-called perturbation function, whereby the running belt – unexpectedly for the patient – performs strong sideways movements in addition to forward movement. This function, which deliberately throws the patient off balance in order to provoke countermovements, can lead to a classification in risk class IIb due to the increased risk of falling. The possibility of connecting a treadmill to gait orthoses or robotics, or a treadmill with very high speeds, e.g. for exercise tests or sprint tests in sports medicine/ergometry, may also be assessed by the manufacturer in such a way that the exchange of mechanical kinetic energy between the running belt and the patient is considered potentially dangerous, making classification in risk class IIb likely.

In the event that the treadmill is connected to other medical components and is used for diagnostic or monitoring purposes (e.g. performing a stress ECG using a treadmill with a stress test system for exercise ergometry), Rule 10 of Annex VIII to the MDR may also apply if the specific system is intended to allow direct diagnosis or monitoring of vital physiological

processes. In this case, too, such a treadmill is classified in risk class IIa, but may also be classified in risk class IIb if there is a particular risk potential.

It can therefore be concluded that even a 'normal' motor-driven treadmill used for therapeutic purposes is regularly classified as a class IIa device in accordance with Rule 9 of Annex VIII to the MDR.

This classification based on the applicability of Rule 9 in Annex VIII to the MDR is unanimously agreed upon in Germany by responsible manufacturers, experts from the field of biomechanics research, notified bodies and authorities.

In particular, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) recently confirmed the applicability of Rule 9 for a motorised treadmill in a classification decision based on Section 6 (2) of the German Medical Devices Implementation Act (Medizinprodukterecht-Durchführungsgesetz -MPDG). The competent authorities in market surveillance also follow this classification in class IIa or IIb.

This risk classification means that the manufacturer must involve a notified body in its conformity assessment. For subsequent economic operators, this can be identified by the four-digit identification number of the notified body, which must be affixed next to the CE marking. The declaration of conformity must also contain the name and identification number of the notified body, a description of the conformity assessment procedures performed and an identification of the certificate(s) issued, cf. Annex IV to the MDR. Since both the importer and the distributor are responsible for checking whether a declaration of conformity has been issued before the treadmill can be placed on the EU market or made available, it is easy to verify the correct risk classification for such treadmills.

III. Legal consequences of incorrect categorisation or classification of a treadmill

The incorrect categorization of a treadmill intended for medical use as a non-medical product or the incorrect classification of a treadmill supplied as a medical device in accordance with the rules in Annex VIII to the MDR has far-reaching legal consequences.

1. Liability of the manufacturer or authorised representative

The fundamental consequence of incorrect categorization or classification of the product is, first of all, that the treadmill is not marketable for formal reasons and, accordingly, may not be placed on the market by the manufacturer. This legal consequence applies regardless of whether the use of the treadmill also poses health risks.

The same applies to the criminal offences regulated in the German Medical Devices Implementation Act (Medizinprodukterecht-Durchführungsgesetz - MPDG), which are already committed if the treadmill is placed on the market without the correct conformity assessment procedure being carried out.

In addition to this criminal liability, a manufacturer of such a non-marketable treadmill is also subject to strict product liability and tortious liability, according to which he can be held legally liable in the event of property damage or personal injury caused by the product. Such a claim for damages can be considerable in individual cases due to the potential risk involved, for example in the event of a patient falling.

Finally, there is a risk of extensive competition law claims, which can result in injunctions and claims for damages, even the obligation to recall the product, and can therefore also entail a considerable cost risk.

Where the manufacturer of the device is not established in an EU Member State, an authorised representative is required to place the treadmill on the Union market, acting under a mandate from the non-European manufacturer and responsible for compliance with all regulatory requirements within the EU. The authorised representative must provide evidence to the authorities that the treadmill complies with the applicable legal requirements. In this respect, the MDR also consistently stipulates that the authorised representative is legally liable for defective devices on the same basis as the manufacturer. The authorized representative can be held liable not only for possible claims for damages, but also for possible violations of competition law, e.g. with regard to incorrect classification of the treadmill.

2. Liability of importers and distributors

However, it is not only the manufacturer or its authorised representative who are exposed to liability risks. Rather, warranty and damages claims and injunctions may also be asserted against the importer or distributor of the treadmill by its customers or competitors.

The background to this includes the provisions of Articles 13 and 14 of the MDR, according to which importers and distributors must fulfil specific legal obligations to verify before they are allowed to place a device on the market or make it available. This involves verifying the existence and completeness of the documentation, but not checking the content for conformity itself.

According to Article 13 MDR, importers have a specific obligation to verify that

- the device is CE marked,
- the EU declaration of conformity of the device has been drawn up,
- the manufacturer and, where applicable, its authorised representative are identified,
- the instructions for use/labelling are available in the required language,
- the required UDI has been assigned by the manufacturer,
- the product has been registered in the UDI-database.

Before the product is placed on the market by the importer, the importer must indicate their contact details on the packaging or on a document accompanying the device and supplement the registration with their own data.

Where an importer has reason to believe that the device is not in conformity with the requirements of the MDR, it shall not place the device on the market. Where the importer has reason to believe that the device presents a serious risk, it shall also inform the competent authority.

Importers who are responsible for placing the product on the European market are also subject to strict product liability and tortious liability, parallel to those of the manufacturer. The same applies to the fulfilment of criminal offences under the provisions of the German Medical Devices Implementation Act (Medizinprodukterecht-Durchführungsgesetz - MPDG).

The obligations of a distributor are set out in Art. 14 MDR. Distributors are also not allowed make a device available on the market if they have reason to believe that the device is not in conformity with the requirements of the MDR. They shall also inform the competent authority if they believe that the device presents a serious risk.

Before making available a device, the distributor must specifically check whether

- the device has been CE marked,
- the EU declaration of conformity of the device has been drawn up,
- the instructions for use/labelling are available in the required language,
- the required UDI has been assigned by the manufacturer,
- the importer has provided its contact details.

Since it is hardly possible in practice to check each individual product, the distributor may, in accordance with legal requirements, apply a sampling method that is representative.

In this context, the question of the extent to which a distributor must also understand and verify the content of the manufacturer's categorization and classification of the device has not yet been conclusively clarified. Since the provisions of the MDR specifically impose specific testing and control obligations on distributors of devices, it is not possible for them to shift the responsibility for making available the device solely to the manufacturer. A case is currently pending before the European Court of Justice (ECJ) to clarify further details, in particular the question of the extent to which the risk classification must also be critically examined before the specific device is distributed.

3. Liability of healthcare facilities

In addition to the economic operators involved, there are also considerable liability risks for the relevant healthcare facilities (e.g. doctors' surgeries, hospitals or rehabilitation facilities) in which an incorrectly categorized or classified treadmill is used.

These healthcare facilities regularly act in the role of operators in accordance with the provisions of the German Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung - MPBetreibV). If a non-marketable treadmill is put into operation there which, due to incorrect categorization or classification, does not comply with the legal requirements of the MDR, the operators of these treadmills may also be held liable under liability law. If they culpably violate their duty to ensure public safety, they are liable for any personal injury or property damage that occurs as a result.

In addition, the following must be taken into account:

If a treadmill that has been marketed by the manufacturer as a sports equipment is used in a health institution by employees, doctors or therapists working there as part of medical treatment or diagnostics, this use changes or extends the intended purpose of the specific treadmill. From a legal perspective, the medical purpose that then exists creates a new product. In this case, the health institution is responsible for this treadmill, which is manufactured and put into service within the healthcare facility, in accordance with the provisions of the MDR, cf. Article 5 MDR.

We hope that this overview of the key legal issues relating to the marketing of treadmills has been helpful. Please do not hesitate to contact us if you have any questions or would like a more detailed explanation of individual aspects.

Yours sincerely

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