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Date (yIr-kwh)
19.02.2021

**Lifetime of a medical device**

Dear Mr. Harrer,

we are responding to your request in which you asked for an opinion on the lifetime of a medical device with regard to the regulatory requirements for medical devices and liability risks.

## I. Situation

As a manufacturer, you place various treadmills with a medical purpose on the market. Due to their specific medical purpose, these treadmills are medical devices in the sense of § 3 No. 1 German Medical Devices Act (MPG).

The lifetime of your treadmills as determined by you as the manufacturer, based on the information in the instruction for use, is between 10 to a maximum of 20 years within the normal use, provided that after 10 years all electrical parts and components are replaced (see for example the instruction manual of the h/p/cosmos®robowalk®expander, version 1.1, revision 08.04.2014, clause 10.2 and h/p/cosmos® laufband ergometer, MCU5-v1.07, revision 07.02.2013, clause 11.8, available on the homepage).

From the aforementioned facts, the question arises for you as to whether the specified lifetime means that the use and operation of a medical device beyond this lifetime can lead to risks for patients, operators or manufacturers or is legally impermissible and consequently generates a ban on use and the mandatory replacement of the treadmill becomes necessary.

## II. Legal situation

The term "*lifetime*" or "*life cycle*" of a medical device is used in the future European Medical Devices Regulation (EU) 2017/745 - MDR, but is not defined more precisely in Article 2 MDR. Rather, it follows from the overall context that the two terms refer to the period of use which, according to the technical evaluations of the manufacturer, can generally be passed by a medical device without the basic safety and performance characteristics being negatively affected.

Thus, the MDR requires in section 23.4 k) of Annex I MDR for all medical devices that any information must be provided by the manufacturer in the information to be supplied in the instruction for use, so that the user can verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer. This also includes information on any calibration that may be required to ensure the proper and safe operation of the device "*during its intended lifetime*". The clear intention of this mandatory information is to provide the user with an indication of how long the manufacturer expects the medical device to function and perform safely.

Contrariwise, this lifetime is described in relative terms as "*intended lifetime*" or "*anticipated lifetime*", since the change in the device and the associated possible loss of safety and performance is not a rigid momentum that can be defined according to individual days. Rather, this depends decisively on the type and manner of individual use in terms of qualitative and quantitative application. Thus, the "*lifetime*" can not only be determined by a calendar time, but also by certain circumstances (e.g. the number of uses or application intervals). In this sense, Section 6 of Annex I MDR establishes a basic performance requirement that the characteristics and performance of a medical device must not be degraded under normal conditions of use to such an extent that the health or safety of the patient or user could be compromised "*during the lifetime*". This performance requirement takes into account that improper or neglected maintenance is not considered to be such a hazard. In this respect, this aspect takes into account the "*normal condition of use*" *and the "proper compliance with the manufacturer's instructions for maintenance*" when considering the expected lifetime.

This assessment is also reflected in the harmonised standard DIN EN 60601-1 with regard to medical electrical equipment. Even if this standard is only indicative in accordance with

Article 8 (1) MDR and only a partial area of medical devices is affected by the standard, the definitions and regulations on lifetime mentioned there can be used for further understanding. As a definition of the expected lifetime, section 3.28 does not define a fixed date, but a period during which the medical device can be expected to remain safe for and during use. Thus, the manufacturer has to check and determine within the scope of his evaluation from what point onwards such fundamental safety can no longer be expected. However, even in DIN EN 60601-1, compliance with the specifically specified conditions of use is always assumed for the evaluation of the lifetime and only the reasonably foreseeable misuse is cited as an additional aspect in the context of the risk assessment. The standard specification therefore sees the lifetime as a period to be evaluated by the manufacturer rather than a definitive application limit for the operator.

The further requirements of the MDR, which are anchored in connection with the life cycle or the lifetime, also show that this is particularly about the manufacturer's obligation to observe this interval. According to Article 83 (2) MDR, the clinical data after placing on the market must be collected over "*the entire lifetime*" and the safety report according to Article 86 MDR must be kept or regularly updated "*throughout the entire lifetime*". The new post-marketing surveillance introduced in the MDR for clinical evaluation also lists the expected lifetime period for this surveillance in Annex XIV, Part B, Section 5.

Similarly, the risk management system (Annex I, Chapter I, Section 3) or the quality management system (Annex IX, Chapter I, Section 1) as well as the updating of the clinical evaluation according to Article 61 (11) MDR must be maintained "throughout the life cycle".

In principle, the lifetime or life cycle of a medical device and the manufacturer's obligation to use this as a basis for a certain degree of market surveillance are not new. In fact, Annex I, Section 4 of the Directive 93/42/EEC - MDD already ties the principle that the characteristics and performance of a medical device must not change so negatively during the life of the device that hazards could arise. What is new, however, is that the manufacturer is explicitly obliged in the various places mentioned above to extend his entire market surveillance (and not only the vigilance system with regard to incidents) to the expected lifetime of his device.

In this respect, it is indeed necessary for medical device manufacturers to evaluate an expected lifetime for their medical devices within the framework of the technical documentation in order to be able to determine for themselves over which period of time or over which intervals their market surveillance obligations for the respective individual device are to be observed and complied with.

Contrary, neither the MDD nor the MDR link the concept of lifetime or life cycle to a clear requirement for the user and operator that use beyond the lifetime determined by the manufacturer is fundamentally impermissible.

In this respect, it is up to each national legislator to regulate this matter itself, as the German legislator in particular has done in the MPG and in additional detail in the MPBetreibV. The provisions of the MPG will be transferred almost seamlessly into the MPDG, which will completely replace the MPG on 26th May 2021 (with regard to all medical devices, with the exception of in-vitro diagnostics).

In the MPG and the MPDG, there are three principles for the use and operation of medical devices that are relevant in the present case. Firstly, there is the general principle in § 14 MPG or § 11 MPDG, according to which medical devices may not be operated and used if they have defects that could endanger patients, employees or third parties. Furthermore, § 14 MPG/ § 11 MPDG stipulates that the use and operation of medical devices is only permitted in accordance with the requirements of the MPBetreibV. In addition, there is a further general ban in § 4 (1) MPG/ § 12 MPDG.

## 1. Ban of § 4 (1) MPG/ § 12 MPDG

According to § 4 (1) MPG, it is prohibited to put a medical device into operation, to operate it or to use it if

> *„1. there are grounds to suspect that the safety and health of patients, users or third persons could be compromised, directly or indirectly, to a degree which exceeds tolerable limits according to medical scientific knowledge when properly operated, maintained and used in accordance with their intended purpose, or*
>
> *2. the date until a safe use is verifiably possible has expired."*

The regulations in § 12 No. 1 MPDG are largely identical to those of § 4 (1) No. 1 MPG. Only the prohibition in No. 2 is slightly reworded as follows:

> *„2. the date until which the device can be used safely has expired".*

In the area relevant here, the lifetime specified by the manufacturer, Section 4 (1) No. 2 MPG/ Section 12 No. 2 MPDG could be the corresponding approach, which could lead to a legal ban of the application and use of a medical device if the lifetime specified by the manufacturer has expired.

Neither § 4 (1) No. 2 MPG nor § 12 No. 2 MPDG uses the term "*period of use*", "*lifetime*" or "*life cycle*", but abstractly defines a date until which a safe use is verifiably possible or the device can be used safely. In the original version of the MPG, until 14.06.2007, the legal definition of this ban was additionally enclosed with: "*expiry date*". The reason given for the deletion of the legal definition "*expiry date*" was that this term had been interpreted too narrowly by some of the players involved. The date described was not only to be understood as the manufacturer's indication of the date until which safe use of the medical device was possible, but also the date that could arise again thereafter for the medical device if, for example, it was a reprocessed (re-sterilised) medical device and the reprocessor indicated a corresponding date until which safe use of the device (e.g. guaranteed sterile), was possible. It had to be made clear that not only the manufacturer's information had to be observed, but also such information from any reprocessors.

It could thus be assumed that by deleting the term "*expiry date*", the date would have been extended to the effect that it should also be the basic lifetime of a device until which the safe use of the device would be possible. However, this is not only contradicted by the previously cited justification, which explicitly states that a new "*expiry date*" could arise during re-sterilisation and that this would then have to be observed. All other accompanying documents on this topic are also based on a different understanding.

This is also reflected in the European Guideline document MEDDEV 2.2/3 rev. 3. This document also refers to the basic requirement of labelling by the manufacturer according to Annex I, Chapter II, Section 13.3 e) MDD on the date by which safe use of the device should be possible. This date, which is described as "use-by-date", refers to the time before the device is used for the first time. The date does not refer to the number or the period of repeated applications, which should rather be described as the "lifetime" of the device.

These considerations can also be seamlessly transferred to the MDR. Insofar as the wording "*up to which the device can be used safely*" was taken up in § 12 No. 2 MPDG, this was not intended to create a different or new regulation compared to the previous § 4 (1) No. 2 MPG, but rather to adapt the wording to the terminology of the MDR. In this respect, explicit reference is made to the labelling information required in Annex I, Section 23.2 i) MDR. Section 23.2 i) of Annex I requires a clear indication in the labelling of the period within which the device can be safely used or implanted, if this is applicable.

The MDR also differentiates this date from the expected lifetime. Such a date has to be mentioned by the manufacturer in the instructions for use according to number

23.4 k) Annex I MDR in connection with a required calibration to ensure the proper and safe operation of the device during the expected lifetime.

Thus, the date specified in § 4 (1) No. 2 MPG or § 12 No. 2 MPDG is the date until which a medical device can be stored and used for the first time without a corresponding deterioration of the safety and performance requirements and does not circumscribe the lifetime or period of use of a medical device. Consequently, exceeding the lifetime stated by the manufacturer of a medical device intended for multiple use or continuous use is not a violation of § 4 (1) No. 2 MPG/ § 12 No. 2 MPDG.

Furthermore, the ban of the respective No. 1 could lead to the fact that the lifetime stated by the manufacturer represents a binding specification for the period after which the device may no longer be operated or used. In other words, the device may no longer be operated or used if there is a well-founded suspicion that the device, even if it is properly used, maintained and used in accordance with its intended purpose, may directly or indirectly endanger the safety and health of others to an extent that no longer appears justifiable according to the findings of medical science.

The definition of the lifetime of a medical device is linked to the manufacturer's expectation that after this time, based on normal conditions of use and proper compliance with the manufacturer's instructions for maintenance and the expected average use, it can be assumed that the performance requirements and the safety of the device can no longer be guaranteed in principle and without restriction. In this respect, however, this specification is not a fixed specification, uninfluenced by any parameters. Rather, it represents an average expectation, determined on the basis of experience and technical tests, of a statistically average application under normal use of the device.

In this respect, the specification of the lifetime of a device cannot be defined as such a rigid limit after which an application is excluded per se or guaranteed to be dangerous. Conversely, however, exceeding the lifetime evaluated by the manufacturer signals at least a first indication that there is a possibility that the safety of the device and thus the safety of the patients or users could no longer be completely guaranteed.

The ban, however, requires "*reasonable suspicion*" and does not allow every conceivable danger to be sufficient. Rather, it must be a level that is no longer considered justifiable according to the current findings of medical science. The justification for the suspicion must therefore be based on specific evidence either from the behav-

iour of the device or from a change in the state of medical knowledge (e.g. due to newer or safer procedures). Merely exceeding the period stated by the manufacturer as the average life expectancy can therefore not generate such a concretely justifiable suspicion in general.

Contrariwise, however, exceeding this period indicates an increased device monitoring obligation on the part of the operator alone to check the performance and safety of the device even more regularly. This device monitoring obligation must take into account the risk-benefit assessment reflected in § 4 (1) No. 1 MPG/ § 12 No. 1 MPDG. In this context, the aspects that are likely to be of particular importance are the specific risks that may arise in the event of the failure of the device and the effects of classic consumption and ageing effects (wear and tear, material fatigue, etc., especially in the case of electronics and insulation) in the event of the sudden occurrence of a failure.

However, if the corresponding risk-benefit analysis leads to the conclusion that in the event of a spontaneous failure or defect of the medical device due to ageing or wear and tear, a risk for patients, users or third parties arises that goes beyond medical knowledge and is generally no longer justifiable, use of the device is prohibited in accordance with § 4 (1) No. 1 MPG or § 12 No. 1 MPDG, irrespective of any lifetime stated by the manufacturer. Conversely, if this risk analysis shows no such risk, at least the manufacturer's declaration does not prevent use in such a way that it would be inadmissible.

But even if the failure would theoretically represent an unacceptable risk, the operation of the device could be permissible if it is ensured by correspondingly close-meshed precautions and regular material tests that a corresponding failure can be detected in good time before its complete realisation. However, the operator alone is responsible for this and also bears the corresponding assessment and damage risk.

Whether possible consumption and ageing effects, especially in electrical parts and their insulation, can be detected in time through regular inspection depends on the specific device. The fact that, for example, an age-related hidden insulation damage or an insulation damage that occurs spontaneously at the next movement / touch can hardly be detected during the normal inspection of the electrical system with the means available to the operator on site must be taken into account by the operator or user in the risk-benefit assessment.

## 2. Ban of operation and use of medical devices with defects, § 14 MPG/ § 11 MPDG

According to § 14 MPG/ § 11 MPDG, medical devices may not be operated or used if they have defects that could endanger persons. This prohibition presupposes that a device has a defect which can then lead to a hazard.

In this respect, this prohibition differs from the offence mentioned in § 4 (1) No. 1 MPG/ § 12 No. 1 MPDG in that it must already be recognisable that the device has a defect and the user and operator continues to operate and use the device despite this knowledge. In view of the increased obligation to monitor the device after the average lifetime indicated by the manufacturer has been exceeded, it goes without saying that medical devices with defects that could endanger persons during further use must be discarded.

Contrariwise, however, no direct and immediate ban can be derived from this to the effect that the lifetime stated by the manufacturer represents a fixed limit of use of a medical device and that the continued use thereafter would be an application or the operation of a medical device which has defects. Rather, exceeding the average stated lifetime does not constitute a defect of the device per se.

The German MPBetreibV also does not contain any explicit regulation to the effect that the use or operation of a medical device must be terminated or discontinued immediately upon expiry of the lifetime specified by the manufacturer.

Consequently, only the general requirements for the use and operation of a medical device in the sense of § 4 (1) or (6) MPBetreibV could be applied here.

According to § 4 (1) MPBetreibV, medical devices may only be operated and used in accordance with their intended purpose. § 3 No. 10 MPG/Article 2 No. 12 MDR defines the intended purpose as the use of the device specified by the manufacturer in accordance with the information provided in the labelling, the instructions for use or the advertising or sales materials. In this respect, the indication of the lifetime could be interpreted as a partial aspect of the intended purpose if this date were set by the manufacturer as the limit after which any use should be inadmissible.

The determination of the lifetime is a statistical estimate based on experience and test results and can naturally not be precisely determined for each individual device. Rather, the actual lifetime in a specific individual case depends on the type and in-

tensity of use, the respective type of application and, last but not least, on external factors.

In this respect, a manufacturer's indication of the expected lifetime is not a substantive indication of the intended purpose of his device within the meaning of § 3 No. 10 MPG or Article 2 No. 12 MDR. Consequently, exceeding the expected lifetime stated by the manufacturer does not constitute a violation of § 4 (1) MPBetreibV by the operator or user.

## 3. Manufacturer's repair and maintenance services

According to § 7 MPBetreibV, the operator is obliged to carry out maintenance and repair measures in accordance with the state of the art and any specifications of the manufacturer. If components of a medical device are replaced, this does not mean that the use of the device as a whole would be inadmissible, provided that the component complies with the basic specifications of the manufacturer in the context of the conformity assessment, and is compatible with the rest. Especially with such a repair or replacement of a wear part, the basic lifetime of a medical device can be validly extended over time until it can no longer provide its functionality. This can go well beyond the time that the manufacturer has determined in the context of his conformity assessment on the basis of average values, test investigations and other statistical findings.

Whether a manufacturer is entitled to refuse a repair, maintenance measure or other work on an old medical device does not result directly from the legal matter (this may of course be regulated differently in any purchase or service contracts). Neither the MPG and the MPBetreibV, nor the future MDR directly authorise the manufacturer to refuse a repair or maintenance measure. Conversely, there is also no obligation in the law for the manufacturer to always and forever offer or carry out repairs or maintenance measures.

In the area of stocking necessary spare parts, legal practice has assumed, applying the general principle of good faith pursuant to § 242 of the German Civil Code (BGB), that parts to be replaced which, according to all experience, do not reach the life of the device as a whole and thus appear to be necessary at least for use until the expected end of the device's life as a replacement, should in principle also be supplied by the manufacturer within this period. It should be noted, however, that the manufacturer is not obliged to stock and offer such parts for the specified period if identical or comparable parts are generally available elsewhere on the market. In this context, it is necessary to evaluate which investment is associated with the respective device on the one hand and, for this reason, a good faith expectation on

the part of the user and operator for the supply of spare parts appears to be justified.

The question of whether an offer of repair or service after the expiry of a certain lifetime can also be rejected has, as far as can be overseen, not yet been decided in legal practice and literature. Under the aspects mentioned above and the principle according to § 242 BGB - good faith - one will have to evaluate the legitimate expectations of the buyer on the one hand and the interests of the seller as manufacturer on the other hand. The more expensive the respective device is and the more singular the possibility of repair, the more likely it is to be assumed that the manufacturer is obliged to actually carry out the corresponding repairs.

Thus, in principle, you should be entitled to refuse a service or repair request at least after the expiry of the lifetime of your devices assumed by you, since it is assumed on the basis of the lifetime determined by you that the medical device can no longer fulfil its intended purpose completely safely, in the same quality and with the same performance.

In any case, the obligation and probably also the possibility of a repair does not apply if, according to § 4 (6) MPBetreibV, the functionality and safety of the devices itself could no longer be guaranteed via such a repair measure.

## III. Liability rules

In the absence of special liability law provisions, the question of liability in connection with medical devices is governed by the general liability rules, the German Product Liability Act (ProdHaftG) and the general law of torts pursuant to §§ 823 et seq. BGB.

The lifetime of the devices is between 10 and 20 years, so that in any case after the expiry of this period, a product liability claim against the manufacturer is excluded on the basis of the absolute exclusion period of 10 years after placing on the market stipulated in § 13 (1) ProdHaftG.

Likewise, the statutory manufacturer's liability pursuant to § 1 (2) No. 2 ProdHaftG is generally excluded if the damage is clearly causally associated with a failure of the product and this is based on excessive use, i.e. on wear and tear, material fatigue or similar ageing aspects. Such defects of the product are not already inherent in the product at the time it was placed on the market by the manufacturer. This would be different if the manner of use specified by the manufacturer himself and the generally expected period of use meant that the stability of the device could be expected for a defined period of time, even beyond the specified lifetime.

By providing a plausible statement of the expected lifetime of a product based on objective parameters, the manufacturer creates a release from liability, as he defines how he assesses the material stability and product safety with regard to the expected lifetime. In this way, he expresses what safety the consumer can expect from the product over what period of time. Only if the expected requirement for the safety of a product is violated can a product liability claim be assumed.

Therefore, as the expected safety and performance in terms of time is insofar recognisable to the user and operator by the manufacturer through a clear indication of the expected lifetime of the device, the user and operator generally assumes any liability for damage occurring after expiry and caused on the basis of age alone, without this giving rise to a product liability claim against the manufacturer.

## IV. Summary

In summary, it can be stated that the manufacturer's statement of the expected lifetime of a medical device does not represent a legally binding time limit on the possibility of using and operating a medical device. However, the general duty of care of the user and operator triggers an increased obligation for the user and operator to observe the device with regard to its functionality and proper condition if the expected lifetime specified by the manufacturer is exceeded. In addition, it must be determined by the user or operator, taking into account their risk-benefit assessment, whether the device still currently meets the safety requirements and cannot create a hazard for the user, patient or third party that would go beyond a level that can no longer be justified. Corresponding maintenance, tests and safety checks may have to be carried out more closely by operators on the basis of a risk analysis after the statistical lifetime has been exceeded. In this context, the device-specific characteristics must also be taken into account, such as age-related insulation damage, which cannot be easily detected in advance and can thus lead to a hazard for the user, patient or third parties. If the operator or user has a well-founded suspicion that the safety of a person using the device appears to be endangered beyond the generally acceptable level, the medical device may no longer be operated and used.

We hope that we have answered your enquiry sufficiently and are always available to answer any questions you may have.

Yours sincerely,

(Dr. Lücker)
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