When do I need a medical product … and when is a sports product sufficient?

Laws, directives, regulations, rules, applications, indications, definitions and interpretations.

Emphasis: treadmill ergometers for sport, sports science, sports medicine, biomechanics, therapy, rehabilitation, ergometry, diagnostics, CPET / stress testing

Interpretation of the verdict of the European Court of Justice (third chamber) from 22.11.2012 C-219/11

Preliminary reference – medical products – directive 93/42/EWG – field of application – interpretation of the term "medical product" – for non-medical purpose distributed product – examination of a physiological process – free movement of goods

Topic:

Is a device, which is intended to be used by people for the purpose of examining a physiological process, only a medical product according to Article 1, paragraph 2, letter a, third dash of directive 93/42, if it is manufactured with the intention of medical use?

Result:

Article 1, paragraph 2, letter a, third dash of directive 93/42/EWG of the council from July 14th 1993 on medical devices, amended by the directive 2007/47/EG of the European Parliament and the council from 05.09.2007, a medical device is only laid out as one, if a device, which is designed to be used for the purpose of examining a physiological process by the manufacturer is used for medical applications.

Excerpt from the verdict:

… Therefore, in certain cases, in which a device is not designed for the use with medical applications, a medical certification can not be requested for the device.

This especially pertains to the numerous sports equipment, which allow the measuring of the function of certain organs of the human body, without it being a medical utilization. If such equipment would be classified as a medical product, it would underlie a process of certification, which would not be justifiable….

The following chart shall clarify the necessities for the utilization of medical devices for different applications and indications under consideration of:

a) The European Medical Device Directive 93/42/EWG (MDD) from 14.06.1993
b) The German Act of Medical Devices (MPG) from 02.08.1994
c) The Medical Devices Operator Ordinance (MPBetreibV) from 29.06.1998
d) The Medical Devices Safety Plan Ordinance (MPSV) from 24.06.2002

Applications	Indications	Systems	Requirements
Stress tests, Stress – EKG, ergometry, running- / gait analysis for patients	• Clinical suspicion of coronary heart disease • Precautionary examinations for patients with high risk factors • High risk professions (bus drivers, pilots) • Pre and post bypass surgery or balloon dilation • After a heart attack to evaluate residual ischemia • Pre rehabilitation	Treadmill ergometer and 12 channel ECG, mostly via interface connection to a stress test system. Frequently with blood pressure measurement	**medical device**
Cardiopulmonary Exercise Testing CPET, cardiopulmonary stress examination treadmill spiroergometry cardiopulmonary rehabilitation	• Chronic Obstructive Pulmonary Disease COPD • chronic obstructive bronchitis and pulmonary emphysema • Endangerment of capacity to work • Impending need of care • Necessity of rehabilitation specific non-medicamentous therapy methods	Treadmill ergometer and 12 channel ECG and spirometry measuring device for respiratory gas analysis, mostly via interface connection to a stress test system. Frequently with blood pressure measurement.	**medical device**
Neurological / geriatric rehabilitation, gait therapy, locomotion therapy, orthopedic rehabilitation	• Cerbrovascular diseases, especially conditions after cerbrovascular insults and brain hemorrhage • Conditions after head / brain damage with and without concomitant polytraumatization • Inflammatory, degenerative, metabolic and toxically vested disease of the brain • Condition after tumor operations, or tumor irradiation of the brain and spine • Inflammatory, traumatic and other vested damages of nerve roots and peripheral nerves • Non-inflammatory, for instance metabolic, toxic, among others polyneuropathy syndromes • Neuromuscular diseases • Extrapyramidal movement disorders • Brain seizure diseases • Psychological brain deficit • Psychosomatic disorders concomitant from neurological diseases and injuries • Orthopedics: consequences of injuries in the spinal area, lower extremities, pelvic, etc. • Hip reconstructions • Muscular diseases	Treadmill ergometer, frequently in combination with an unweighting system and/or arm support and / or system components for patient safety and / or patient fixation. Frequently also with manual support of therapists for leg guidance and mobilization or often with additional technical aid, such as robowalk expander, exoskeleton, gait robots, etc.	**medical device**

Applications	Indications	Systems	Requirements
Sports medicine lactate-performance diagnostic and performance psychological examination with blood sampling	• Persons with manifest diseases, in particular cardiovascular system, metabolic diseases and also orthopedic diseases. Diseases that need a training program tailored to the situation.	Treadmill ergometer with built-in heart rate measurement often in conjunction with a fall stop prevention system to protect the user from falling during the strenuous phase. Lactate test meter often in combination with a lactate analysis software with functions for determination of the anaerobic threshold and the calculated and recommended training areas.	Medical product Excerpt from DGSP guidelines: The institution must provide evidence that regularly calibrated ergometers of sufficient quality are used (manufactuerer's specificatios) ….. That examinations under the supervision of a physician with the additional title of sports medicine and the certificate "Sports Medical Lactate Performance Diagnostics" (proof must always be enclosed) …. That a comprehensive and independent from examination evaluation procedure, with available respective documents. (example must be enclosed)
Fitness training, fitness diagnostics (only for healthy athletes / users) bloodless and with sub-maximal load, e.g. UKK 2 km walking test, run / gait analysis for healthy users.	• Previously untrained people, who wish to change their lifestyle and want to do more exercise • Performance oriented athletes of all performance levels	Treadmill ergometer with instrumented heart rate measurement	**sports device**

Information and recommendations on the subjects of blood sampling, which are important in sports medical lactate performance diagnostics with blood sampling. Source : http://www.bundesaerztekammer.de/page.asp?his=0.7.47.3225

8. blood sampling, injection and infusion

Capillary and venous blood samples may be delegated to suitably qualified non-medical staff. Since venous blood samples are not part of all training curriculums, the physician must check with nursing staff or other specialist personnel to ensure that they already have the necessary know-how and skills or give them special training. During the blood sampling, the Technical Rules for Biological Agents must be considered in it's current version.

….

V. Delegation to non-medical staff

services which, because of their nature or the particular danger they pose to the patient or because of the circumstances in which they are provided, in particular the seriousness of the case of illness, the doctor himself does not provide, he may delegate to non-medical staff. The decision as to whether and to whom the physician delegates a service, whether he has to instruct the employee concerned and how he has to monitor him, depends on the qualification of the respective employee.

…

If non-medical employees provide delegated services, the physician is generally obliged to be in the immediate vicinity (call range). It is therefore inadmissible to have services performed in the doctor's practice on the basis of general instructions to the practice personnel if the doctor cannot come to the practice in person or is absent for a longer period of time.

Information and recommendations on load tests and stress tests:

In many place, endurance tests and / or stress tests also require that a specialized physician and a defibrillator must be in the immediate vicinity in the event of a necessary resuscitation of a test person / patient.

The specialist personnel must be familiar with the stress of the corresponding test person / patient and a physician must be available at all at times and be personally available on site within a reasonable time.

The following is an exemplary assignment of some applications / indications integrated in the MPG:

§3 MPG Medical Device Act:
Medical devices are all instruments, apparatus, devices, software, substances and preparations of substance or other objects used individually or in combination, including software specifically intended by the manufacturer for diagnostic or therapeutic purposes and used by the manufacturer for the proper functioning of the medical device and intended by the manufacturer for human use by means of its functions for the purpose of:

a) the detection, monitoring, treatment, relief of compensation of injuries; or disabilities,
[>> We list the following application examples:
Stress test, exercise ECG, ergometry, running / gait analysis for patients, sports medical lactate performance diagnostics and performance physiological examinations with blood sampling and lactate analysis as well as heart rate analysis for the purpose of detecting, preventing, monitoring, treating or alleviating diseases, cardiopulmonary exercise testing (CPET), cardiopulmonary exercise testing, treadmill spiroergometry in patients and/or sick sportsmen/test subjects in the rehabilitation phase, cardiopulmonary rehabilitation (CPR), partly partly neurological/geriatric rehabilitation (e.g. gait therapy, locomotion therapy for Parkinson's, MS multiple sclerosis, spasticity, partially orthopedic rehabilitation, etc.)

b) the detection, monitoring, treatment, relief or compensation of injuries; or disabilities,
[>> we list application examples:
Orthopaedic rehabilitation and partly neurological rehabilitation (e.g. gait therapy, locomotion therapy for spinal cord and brain injuries, stroke, partly orthopedic rehabilitation, etc.)]

c) the examination, replacement or modification of the anatomical structure or a physiological process,
[>> we list application examples:
Sports medicine lactate performance physiological examinations with blood sampling and lactate analysis as well as heart rate analysis for the purpose of detecting, preventing, monitoring, treating or alleviating diseases]

c) the conception regulation
and whose intended principal effect in or on the human body is achieved neither by pharmacologically or immunologically active agents nor by metabolism, but whose mode of action can be support by such agents.
--- End of excerpt from the MPG---

And who's intended principal effect in or on the human body is achieved neither by pharmacologically or immunologically active agents nor by metabolism, but who's mode of action can be supported by such agents
--- End of excerpt from the MPG ---

Award:

Decisive for the classification of a treadmill as a medical product is its intended purpose. According to § 3 No. 10 MPG, this results from the manufacturer's information in the labelling, the instruction for use and the advertising materials for the product. If the claim is clearly made as medical, the products are medical devices within the meaning of European Directive 93/42/EEC. The same applies to the evaluation of the product requirements of the purchaser. Results from the performance description of the client an intended medical use of the treadmill in the sense of § 3 No. 1 MPG, it must be assumed that the client wants to procure a medical device. If the service description contains the intention to perform a **sports medical examination**, then the description clearly contains the term "medical".

Definition of sports medicine according to : http://de.wikipedia.org/wiki/Sportmedizin
Sports medicine embodies theoretical and practical medicine which examines the influence of exercise, training and sports, as well the lack of exercise, on healthy and unhealthy people of all ages to produce results that are conclusive to prevention, therapy and rehabilitation as well as beneficial for the athlete himself. This description from Wildor Hollmann (1958) was adapted as the official definition by the International Federation of Sports Medicine (FIMS) in 1977
--- Ende des Auszugs aus Wikipedia ---

Should the treadmill also be used for ***sports medical examinations*** (even if it is "only" the examination of a physiological process) on sick people (see definition Wildor Hollmann and the International Federation of Sports Medicine (FIMS)) or also on athletes in the rehabilitation phase (who is then also considered a "sick or unhealthy" person after a sports injury or illness), then a medical application is unequivocally planned, in which case a medical device according to the European Directive 93/42/EEC should be used in order to avoid liability risks for the user/operator.

It is of fundamental importance while interpreting the verdict of 22.11.2012- C-219/11 of the EuGH, that the Dutch manufacturer "**BioSemi VOF"** does NOT offer the relevant products for the examination of physiological processes (EEG, ECG and EMG), but as instruments for research in the electrophysiology.

Excerpts from the manufacturer's website: www.biosemi.com
BioSemi's goal is to provide the scientific community with state-of-the-art instrumentation for electro physiology research. Using the latest available technology and offering maximum freedom of configuration and flexibility to integrate our hard- and software in your laboratory setup are the key principles in our designs. Our products are specifically designed to be used in research applications only. They are optimized for this specific application by offering features like: freely configurable hardware and completely open-source software, BioSemi does not develop or produce products for medical applications.
Please note: BioSemi products are intended to be used for research applications only. Our products are not sold as Medical Device as defined in EU directive 93/42/EEC. Our products are not designed or intended to be used for diagnosis or treatment of disease.
--- End of the excerpt from the website ---

The manufacturer BioSemi therefore deliberately chooses NOT to them for medical purposes, but clearly restricts the claims to purely scientific research of physiological processes. The manufacturer explicitly states that it is not a medical device according to the Directive 93/42/EWG and that BioSemi does not develop or manufacture medical devices.

Conclusion:

According to the verdict of the European Court of Justice of 22.11.2012 C-219/11, a product for the examination of a physiological process besides medical purposes (e.g. performance diagnostics of a non-medical nature) is not a medical device. Pure sports or fitness devices can be used in this area. A CE marking according to Directive 93/42/EWG is therefore not required for such a sports or fitness device

Treamdills as medical devices are subject to a number of regulatory requirements as well as harmonized standards within Germany.

These are among others:

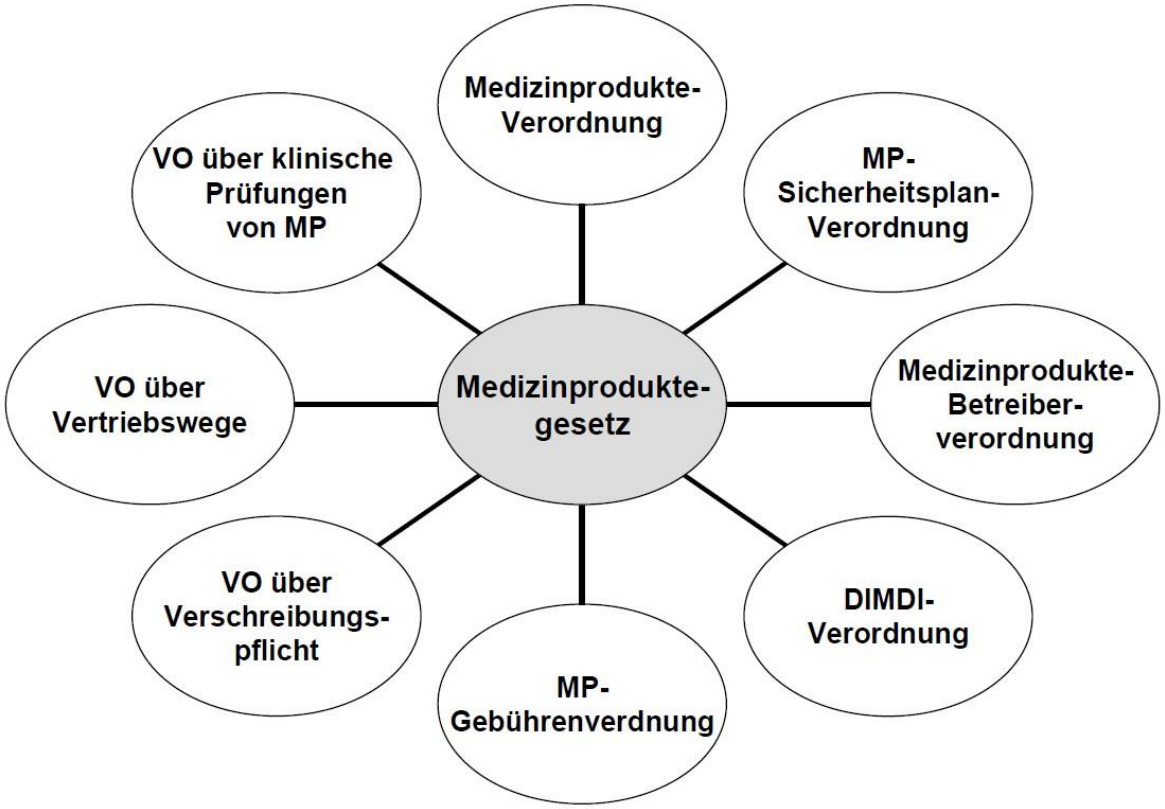
A) Regulatory requirements

1. Medical Device Act (MPG) of 02.08.1994
2. Medical Device Directive (93/42/EWG)
3. Clinical evaluation: A clinical evaluation must be based on objective and documented criteria, with direct involvement of medical expertise. The guidelines of the European Commission's guideline MEDDEV 2.7.1 Rev. 3 / December 2009 apply, which provides manufacturers and Notified Bodies with information on the procedure and methodology and defines applicable criteria for the implementation or assessment of the clinical evaluation. This is part of the requirements of the MPG regarding the marketability of medical devices, cf. §§ 19 ff. MPG
4. A vigilance system according to the guidelines of MEDDEV 2.12-1 Rev. 8 / January 2013 of the European Commission. The vigilance system is implemented in Germany by the MPSV. The non-binding specifications of the MEDDEV document 2.12 are only to be used for the interpretation of the MPSV.
5. 4 digit CE marking, e.g. CE 0123 or any other number (identification number of the "Notified Body", which has certified the quality management system of the manufacturer of medical devices in its entirety) as the manufacturer's declaration of conformity for the relevant directives. The CE – marking is part of the requirements for the marketability of medical devices, resulting from the MPG, cf. §§ 6 and 9 MPG.
6. EMC Directive 2004/108/EC on electromagnetic compatibility
7. Machine Directive 2006/42/EG (previous version 98/37/EG)
8. RoHS (Restriction of certain Hazardous Substances) Directive 2011/65/EU (valid for medical devices from 22.07.2014)
9. Medical Device Operator Regulation / Medizinprodukte-Betreiberverordnung (MPBetreibV) from 29.06.1998
10. Medical Device Safety Plan Regulation / Medizinprodukte-Sicherheitsplanverordnung (MPSV)

B) Harmonized standards:

11. EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
12. IEC 62304:20016 Medical device software – Software life cycle processes
13. IEC 60601-1:2005 (3rd Edition) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
14. IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    Alternatively IEC 62366:2007 Application of usability engineering to medical devices
15. IEC 61000-6-1:2005 Electromagnetic Compatibility (EMC) – part 6-3:
    Generic standards – Immunity for residential, commercial and light-industrial environments
16. IEC 61000-6-3:2006 + A1:2010 Electromagnetic compatibility (EMC) – part 6-3:
    Generic standards - Immunity for residential, commercial and light-industrial environments
17. ISO 20957-1:2005 (available as draft ISO 20957-1:2012) stationary training equipment – part 1: General safety requirements and test methods
18. ISO 20957-6:2005 (EN 957-6:2010) Stationary training equipment – part 6:
    Treadmills, additional specific safety requirements and test methods

Medizinprodukte-Rechtsrahmen Stand: Juni 2010



Important links to the relevant regulatory requirements, laws, regulations / notices, publications, recommendations, directives, EUR-Lex, guidelines and norms:

https://www.dimdi.de/dynamic/en/homepage/index.html

For **treadmills purely used in the field of sports** (without medicine and rehabilitation) at least the following requirements must be met in Germany:
These are among others:

A) Regulatory requirements:

1. EMC Directive 2004/108/EG on Electromagnetic Compatibility
2. Low voltage Directive 2006/95/EC
3. Machinery Directive 2006/42/EC (previous version 98/37/EC)
4. RoHS (Restriction of certain Hazardous Substances) Directive 2011/65/EU
   a. (for electrical and electronic equipment valid from 1 July 2006)
5. CE-marking (WITHOUT 4 digit number) as manufacturer's declaration of conformity with the relevant directives. The CE-marking is part of the requirements for the marketability of machines and electrical equipment resulting from directives 2006/95/EC and 2006/42/EC
6. Product Safety Act / Produktsicherheitsgesetz (ProdSG) of 08.11.2011

B) Harmonized Standards:

7. IEC 61000-6-1:2005 Electromagnetic Compatibility (EMC) - part 6-1:
   Generic stadards – Immunity for residential, commercial and light-industrial environments
8. IEC 61000-6-3:2006 + A1:2010 Electromagnetic Compatibility (EMC) – part 6-3:
   Generic standards – Emission standard for residential, commercial and light-industrial environments
9. IEC 60335-1:2010 Housesehold and similar electrical appliences – Safety – part 1: General requirements
10. ISO 20957-1:2005 (available as draft ISO 20957-1:2012) Stationary training equipment – part 1:
    General safety requirements and test methods

11. ISO 20957-6:2005 (EN 957-6:2010) Stationary training equipment – part 6:
    Treadmills, additional specific safety requirements and test methods

Several years ago it was still possible for good machine builders with experience in conveyer belt construction also built treadmills as a fairly inexpensive special production or that fitness cheap fitness equipment was imported from abroad (where partly different requirements apply).

Today, not only the technology has developed immensely, but also the legal and regulatory requirements in Germany and also within the European Union have evolved and even become more stringent. This means that a large number of regulatory requirements and harmonized standards have to be met in order to be able to place such treadmills on the market.

Conclusion and recommendation:
Manufacturers and end users are well advised to clearly define the purpose and designation of the treadmills, the intended application and also the required regulatory requirements and the relevant harmonized standards already in the planning phase, in the tendering phase and of course also in the offers as well as delivery documents and invoices and other contracts.

This avoids misunderstanding as well as resulting and sometime serious problems.

Risk classification according to applications of rule 9 and rule 10 of the MDD:

Treadmills, which are used among other things also for cardiological stress tests, are devices, whose purpose it is to load the patient with an ill heart by energy supply ("mechanincal kinetic energy" from the patient by walking / running on the treadmill), until the patient's heart shows "irregularities" and / or "abnormalties" or even temporarily fails.

Such intended provocation is a potential danger. And the treadmill is the medical device that supplies energy and often also measures the heart rate.

The ECG connected to the treadmill and/or ergospirometry or other medical systems will then be used to diagnose the patient's problems in detail. Also while the stress load, the patient will be stressed accordingly either by the load protocols integrated in the treadmill (e.g. Bruce, Balke, Naughton, Ellestand-A, Ellestad-B, etc.) or optionally through the protocols from the ECG sent via interface to the treadmill, which will stress the patient until the heart problem (and/or lung problem) occurs.

This means that it is not always an electrically connected system of treadmill and ECG via an interface. Load profiles can also be controlled autonomously from the treadmill UserTerminal itself. Virtually every modern treadmill today has these control and programming options.

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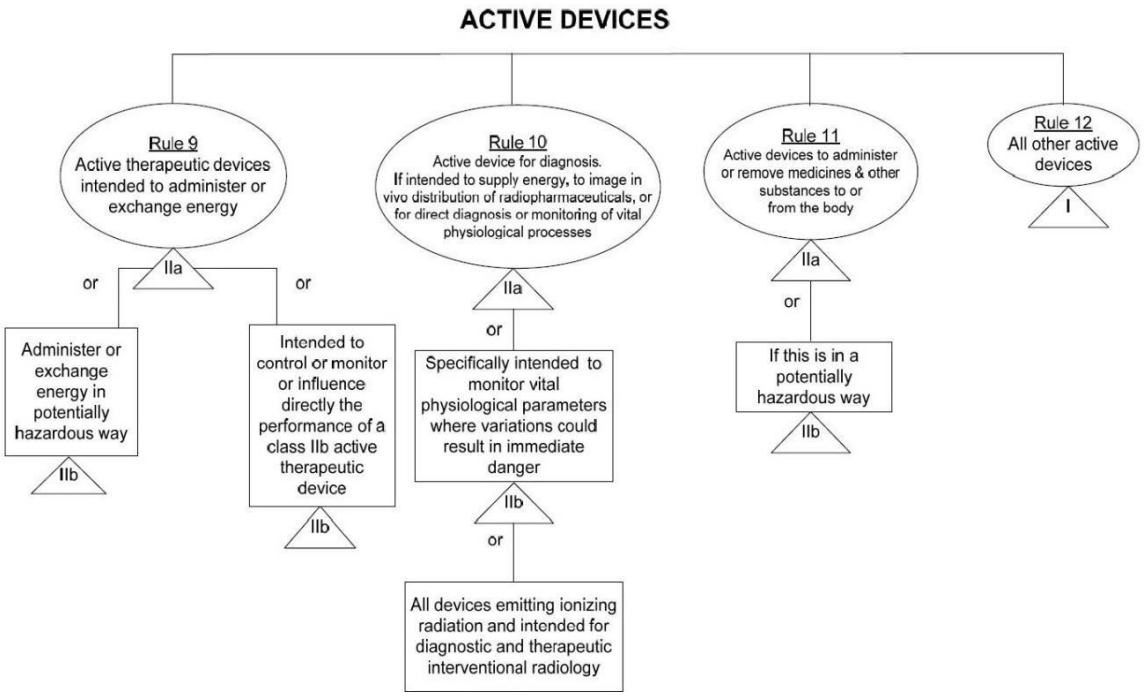
On the basis of this energy supply and monitoring, the physician often decides on abort criteria; these are not specified by the treadmill but result from the guidelines of the professional associations for ergometry.

Examples: Guidelines of the Germany Society for Cardiology – Cardiovascular Research
http://leitlinien.dgk.org/
Examples of treadmill ergometry, cycle ergometry and abort criteria of load examination.
http://leitlinien.dgk.org/files/2000_Leitline_Ergometrie.pdf

ACC/AHA Guidelines for Exercise Testing: Executive Summary
A Report of the American College of Cardiology / American Heart Association Task Force on Practice Guidelines
(Committee on Exercise Testing) http://circ.ahajournals.org/content/96/1/345.full

The subsequent treatment and emergency care is then no longer carried out on the treadmill, but the patient is then taken off the treadmill and, if necessary, reanimated with other devices and further diagnosed and treated with other monitoring systems (no longer connected to the treadmill diagnostic system),



Source of this graphic:: http://ec.europa.eu/health/medical- ices/files/meddev/2_4_1_rev_9_classification_en.pdf

Treadmill ergometers für medicine and therapy are to be classified as **active therapeutic medical devices and/or as active diagnostic medical devices of risk class IIb** according to Annex IX to the MDD.

We hope we were able to help you with this information.

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