“BREATHMENT” Wellness app or Medical Device

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1. Abstract

Health and wellness apps and apps with a medical purpose, have a similar area of application. Both may measure parameters of physical performance. However, there is a fine line regarding the fulfillment of legal requirements and risk classification. The classification strictly follows the claims and proposed usage of the product.

In this publication, we describe the difference by using the example of “BREATHMENT”. This is an app developed with the background of the increasing worldwide viral respiratory diseases starting in the 2020s. The technical capabilities and possible claims for the usage are evaluated against the different classification criteria.

When evaluating the technical capabilities of “BREATHMENT”, reasons can be found for any classification. Hence it is extremely important to clearly specify the intended use and functionality of the product. By doing so, the product can either be claimed as a health and wellness product, a class I or class IIa medical device DiGA.

Considering the time to market and the current availability restrictions of Notified Bodies (NBs), it is highly recommended to restrict the product functionality for a market launch as a wellness app for a quick win scenario, as the market offers many opportunities to grow without regulatory restrictions.

In the following step, a QMS according to ISO EN 13458 should be implemented and the class I medical app functionality should be developed and validated in order to market as a DiGA to benefit from the reimbursability within the standard care of the national health insurance system.

Diagnostic features that result in a class IIa classification and therefore require more V&V activities should be developed and implemented at a later stage, based on the need and availability of NBs.

Keywords: #well-being, #wellbeing, #digitalhealth, #digital health, #medicalapps, #medical apps, # lifescience, #life science, #physiotherapy, #physiotherapist #fitnessapp #health fitness app #healthapp #wellness app

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2. General description of the problem

Am I a legal manufacturer of a medical device and how do I have to classify my product? These questions currently arise for many products regarding the MDR (medical device regulation 2017/745). The questions are being asked by manufacturers within the life science industry (e.g. pharma, food, cosmetics etc.) concerning their health and wellness product /software that assists the therapy without having a direct therapeutic or diagnostic benefit.

This paper investigates this question regarding the product “BREATHMENT”. The overall idea behind “BREATHMENT” provides the technical functionality to claim a wide variety of functions in the field of “Pulmonary Rehabilitation”. These functions may serve the patients, the health professionals or the medic. On one hand, the diary functions may structure the therapy program and feedback from the patient to the physiotherapist, on the other hand, Artificial Intelligence (AI) functions may serve as a diagnostic input.

Generating the business case and release pipeline of the product the following questions arise and must be answered:

- What are the general guidelines on classification of borderline products?
- Are there examples of similar products?
- What effects does the different classification of the product have on use and marketing?
- Which functions and claims can be made (and in case of a medical product) and have to be clinically validated?
- Which effort is associated with each classification?

3. Overview of the classification variety

Devices that measure the performance / condition of the human body can be categorized by the risk even with the same basic function but differing intended use.

The following table can serve as a rough orientation of the classification using the example of different pulse measuring functionalities. These tables provide only an exemplary overview. Exact classification may vary by the exact definition of the intended use as discussed later in this paper.

Classification	Intended use	Possible use	Associated risk
No classification	Wristwatch with seconds display	Used for pulse measurement by a medic.	none
Health & Wellness device	Pulse measurement for a **wellness purpose**.	Used by patient with heart attack risk to control intensity of training.	none
Borderline: probable health & wellness device	Pulse measurement device for wellness **purpose with data logging software**.	Generated and stored data used by a medic to evaluate fitness activity of heart attack risk patient.	none
Borderline: probable medical class I	Pulse measurement software for data logging and the **claimed possibility to serve a medic** for data analysis.	Generated and stored data used by a medic to evaluate fitness activity of heart attack risk patient.	moderate
Medical class I	Pulse measurement software **for simplest medical purpose**.	Pulse measurement logging for general medical purpose.	moderate
Medical class IIa	Pulse logging and analysis of pulse pause deviation to **assist diagnosis.**	Diagnose heart function deviation by a medic.	medium
Medical class IIb	Pulse monitoring (vital function)	Live monitoring of pulse	high
Medical class III	Pulse monitoring in **an intensive care scenario**, with threshold alarm.	Intensive care unit scenario where pulse falling below a threshold will result in a life-threatening scenario. Medic must be informed by an alarm.	very high

Table 1 Variety of classification possibilities for same technical application

4. Health and wellness devices

A wellness app does claim a medical benefit. Example of devices are:

- bicycle trainer and bicycle ergo meter for a wellness purpose
- pulse measurement devices for a wellness purpose
- fun contact lenses and optical contact lenses

Furthermore, products can be found that serve both purposes. Both products are often built in the same way. They only differ in the legal market access. For example, an Ergometer can be marketed for a wellness purpose or a medical device for a physiotherapy purpose.

4.1. Wellness claims

What differentiates wellness apps and medical devices?

Health and wellness devices do not claim a medical benefit. Claims of wellness devices might still sound medical but any medical claims should be avoided. In practice, the differentiation may become difficult. This is discussed in Chapter 5 Relevant Guidelines on medical devices and borderline.

Below are some examples for possible wellness claims:

- feel healthier / look healthier
- improve your health status
- measure fitness performance (pulse, steps, distance, pace, step length, frequency)
- improves hygiene
- establish a healthy routine

to avoid misperception as a medical product:

- do not claim any clinical performance
- do not refer to any kind of illness

4.2. User Groups

A wellness device is intended to be used by a healthy person, not a patient. A patient is suffering from his health condition.

However, a patient can use wellness devices. For example, a weight or elastic band which is used for individual resistance training to recover from a bone fracture is not considered a medical device.

4.3. Evaluation

“BREATHMENT” is clearly a wellness device if no patient is addressed, no medical purpose is claimed and delivered. A product that addresses patients may nevertheless be a non-medical product under certain conditions.

5. Relevant Guidelines on medical devices and borderline

Borderline products were addressed in the MEDDEV (medical device) guide (MEDDEV 2.1/3 „Manual on Borderline and Classification“ 2019) . This manual claims itself to serve as a “tool” for the case by case application of community legislation by the member states and gives a number of relevant examples.

MDR (MDR 2017/745 "Medical Device Regulation" 2017) defines the 'medical device' and provides in ANNEX VIII the relevant „CLASSIFICATION RULES". ANNEX XVI furthermore lists several products without an intended medical purpose.

MDCG (MDCG 2021-24 "Guidance on classification of medical devices" 2021) has been endorsed by the Medical Device Coordination Group (MDCG). It provides guidance to classification of medical devices in use by the EU medical device legislation as a risk-based system taking into account the vulnerability of the human body and the potential risks associated with the devices.

5.1. Relevant example classifications according to MEDDEV 2.1/3

In the following paragraphs some examples according to (MEDDEV 2.1/3 „Manual on Borderline and Classification" 2019) are listed with their outcome.

5.1.1. "Products evaluating the condition of respiratory muscles"

As described in (MEDDEV 2.1/3 „Manual on Borderline and Classification" 2019, Chapter 8.7)

- Outcome: The product measures how fast a person can exhale air. It is one of many tests that measure the function of the airways, which are commonly affected by diseases such as asthma. This product is intended to measure the condition of the respiratory muscles and as such is to be classified as a Class IIa medical device in accordance with classification rule 10 third indent"

- Evaluation: Measures condition of muscle – Class IIa

5.1.2. "Qualification and classification of software for delivery and management of cognitive remediation and rehabilitation programs"

As described in (MEDDEV 2.1/3 „Manual on Borderline and Classification" 2019, Chapter 9.5)

- Outcome: Based on the intended purposes, namely the treatment of a disease, injury or handicap, this software should be qualified as a medical device. When such software qualifies as a medical device it shall be classified as class I medical device according to rule 12 of Directive 93/42/EEC.

- Evaluation: Treatment of diseases – Class I Software

5.1.3. "Classification of software for information management and patient monitoring"

As described in (MEDDEV 2.1/3 „Manual on Borderline and Classification" 2019, Chapter 9.6)

- **Outcome:** This system is intended to be used in intensive care units with ventilators, pulse oximeters and other devices used for monitoring patients, although similar systems could be used with devices for monitoring non-vital physiological processes. According to MEDDEV 2.12/6 clinical information systems are not qualified as medical devices. The patient monitoring platform contains a number of different functions, each of which must be assessed when determining whether the software meets the definition of a medical device using the criteria described in MEDDEV 2.1/6.

According to MEDDEV 2.1/6 “if the software does not perform an action on data or performs an action limited to storage, archival, communication, "simple search" or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device”. This is applicable for the listed functions performed by the patient monitoring platform with the exception of the alarm filtering function.”

- Evaluation I: Software does not perform any action on the data or performs an action limited to storage, archival, communication **– No Medical Device**

- Evaluation II: Filtering Alarm **– Medical Device**

5.1.4. “Mobile application for managing pictures of nevi”

As described in (MEDDEV 2.1/3 „Manual on Borderline and Classification“ 2019, Chapter 9.7)

- Outcome: This app, which is not incorporated in a medical device, does not perform an action on data other than just storage. In accordance with the guidance document MEDDEV 2.1/6 rev. 1, this mobile app should not be qualified as standalone medical device software.”

- Evaluation: Software does not perform an action on data **– No Medical Device**

5.1.5. “Mobile application for the assessment of nevi”

As described in (MEDDEV 2.1/3 „Manual on Borderline and Classification“ 2019, Chapter 9.8)

- Outcome: This app, which is not incorporated in a medical device, uses computer image processing technology to make assessments of the moles, whereby performing an action on data other than just storage, for the medical benefit of individual patients. In accordance with the guidance document MEDDEV 2.1/6 rev. 1, a mobile app for the assessment of moles should be qualified as a standalone class I medical device, according to Rule 12 of Annex IX to Directive 93/42/EEC.

- Evaluation: Software uses computer image processing technology to make assessments **– Medical Device Class I Software**

5.2. General classification as a medical product according to MDR

According to MDR (MDR 2017/745 "Medical Device Regulation" 2017) and regarding the Scope of “BREATMENT” as software in the following a condensed definition:

“Medical device means any software intended by the manufacturer to be used for human beings for one or more of the following specific medical purposes:

(a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation **of disease**

(b) diagnosis, monitoring, treatment, alleviation of, or compensation for **an injury or disability**

(c) investigation, replacement, or modification of the anatomy or **of a physiological or pathological process or state**

5.3. Risk Classification according to MDR Annex VIII Classification rules

MDR (MDR 2017/745 "Medical Device Regulation" 2017, Annex VIII) provides detailed rules for Risk classification of medical devices. The application of these rules is detailed in MDCG (MDCG 2021-24 "Guidance on classification of medical devices" 2021).

It is important to keep in mind that each function or claim of the product is evaluated individually. The classification will follow the function with the highest risk classification.

5.4. Digital Health Applications

SaMD (software as medical device) has been a growing sector for several years. Germany established a digital health program DiGA (Digitale Gesundheits Anwendungen) (DIGA - Leitfaden 2022) describes in 167 pages the “fast-track procedure” for DiGA Applications.

In a nutshell: A DiGA application is a medical product class I or class IIa. Registration of provisional inclusion in the DiGA directory can be requested if GSPR (General Safety and Performance Requirements) are fulfilled. After provisional registration there is a 12-month time slot to execute a study to prove the positive treatment coverage effect.

For the manufacturers, the application for (possibly provisional) inclusion of a DiGA is the decisive step towards the reimbursability within the standard care of the national health insurance system.

Other countries provide similar programs:

- US (https://www.fda.gov/medical-devices/digital-health-center-excellence),
- Australia (https://www.digitalhealth.gov.au/),
- Japan (https://globalforum.diaglobal.org/issue/february-2021/digital-health-regulation-in-asia-pacific-overview-and-best-practices/)

5.5. Evaluation:

Considering the idea behind “BREATHMENT”, the overall maximum possibilities may serve to:

- diagnose the status of pulmonary rehabilitation
- monitor the status pulmonary rehabilitation
- assist treatment of pulmonary rehabilitation
- presenting AI diagnosis recommendations

If any of these functions is implemented in the software the software is clearly a medical device. A detailed classification depends on individual functions and claims.

6. Classification of “Breathment”

The final claims and functions of “Breathment” are not defined yet. Hence a reverse engineering approach is followed, to define the product classification first and then evaluate the functions which can be claimed with a reasonable certainty. The following classifications will be addressed:

- No medical Product
- Medical Product class I

- Medical Product class IIa

For each classification claims and functions, marketing scenarios, effort and implementation risk (not to be mistaken with product risk) will be analyzed.

6.1. "Breathment" as a health and wellness product

Story: Correct breathing is a goal in many disciplines. This includes yoga, swimming, singing, or playing an instrument. In addition, proper breathing is also important in everyday situations and especially for health.

A new app that will support breathing instruction designed for these types of usage will certainly be considered a well-being product. This also is true if the skill and execution of breathing and body exercises are analyzed by an AI.

6.1.1. Possible intended use, functions and claims

- Scheduling exercises
- Proposing exercises
- Measuring the exactness of execution of exercises
- Communication and data transfer to a supervising person
- Tracking exercises and compare the quantity and quality of execution with schedule
- Give AI bases recommendations to improve skill of execution of exercises
- Improvement of skill and breathing technique
- Establish a healthy routine

6.1.2. Functions and claims to be avoided

- Improvement of health / treatment quality
- Collection of medical data
- Claimed medical suitability
- Diagnosis of illness
- Measurement of diagnostic parameters like lung volume

6.1.3. Marketing scenario

"Breathment" as an AI based breathing training app for any situation where the professional training of a correct breathing technique is required. AI based breathing and body training reduces onsite and personal training sessions, gives AI autocorrection and tracks the success of training activities.

6.1.4. Implementation effort

No regulatory restrictions. Market will decide if price / performance of the training app is adequate.

6.1.5. Implementation Risk and drawbacks

No implementation risk. GDPR needs to be considered if user data is stored and made accessible to the trainer or community.

App must not be marketed as DiGA as it is not a medical product.

6.2. "Breathment" as a medical product class I

Story: Pulmonary rehabilitation experiences increasing demand according to the spread of respiratory diseases. Onsite personal physiotherapy is highly demanded and patients suffer from a lack of personal attention.

Required training activities must be performed at home without proper supervision, correction of breathing technique and a continuing lack of motivation. It is impossible for the supervising physiotherapist to track the quality and quantity of the training remotely.

An App, which claims to "improve treatment" will certainly be considered a class I medical product.

6.2.1. Possible intended use functions and Claims

- Track exercises to improve treatment quality
- Proposing exercises to increase treatment motivation
- Measuring the exactness of execution of exercises to improve the treatment quality
- Communication and data transfer to a supervising person to improve the treatment quality
- Tracking exercises and compare the quantity and quality of the execution with a schedule
- Give Ai-based recommendations to improve the skills of execution of exercises to improve the treatment
- Improvement of the skill and breathing technique to improve the treatment quality

6.2.2. Functions and claims to be avoided

Claims which will enforce a class IIa classification must be avoided

- Diagnosis of the state of illness
- Measurement of diagnostic parameters like lung volume
- (AI-based) diagnosis of the recovery of illness
- Software to provide information with diagnostic purpose
- Software to provide information with therapeutic purpose

6.2.3. Marketing scenario

"Breathment" as an AI based breathing and body training app especially for physiotherapy where a professional training of a correct breathing technique is required. AI-based breathing and body training reduces onsite and personal training sessions, gives AI autocorrection and tracks the success of training activities to improve the treatment.

"Breathment" as a class I medical product can be registered as DiGA which results in highly desirable reimbursability within the national health insurance system.

6.2.4. Implementation effort

The class I medical product development requires a QMS according to ISO 13485. Essential Performance and Safety requirements and standards must be defined and followed. Design control must be documented in the technical file according to MDR (MDR 2017/745 "Medical Device Regulation" 2017).

Medical claim of the "improvement of treatment" must be validated in a Clinical Evaluation Report and tracked in Post Market activities.

The registration as a DiGA results in follow up costs for the mandatory study to prove the positive treatment coverage effect.

6.2.5. Implementation risk

Development and documentation of medical products requires significant resources. However, as a class I medical product, conformity can be declared in the own responsibility of the manufacturer.

Therefore, no delays in involving the notified body must be taken into account.

It is important to keep the classification rules in mind. The MDR (MDR 2017/745 "Medical Device Regulation" 2017, Annex VIII Rule 11) states that "Software intended to monitor physiological processes is classified as class IIa. Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa"

Furthermore, it must be made clear that the software is not used for decisions with therapeutic purposes. The intended use must be very clear about the fact that the software is evaluating the quality of the exercise not the quality of the therapy.

Decisions about the diagnosis and decisions about the right therapy are not supported by the software. The software only tracks that the therapy is performed in the right way as decided by the medic or physiotherapist beforehand. The basic effectiveness of the therapy method is not affected.

Registration for DiGA is a relatively new process with potentially unexpected results.

6.3. "Breathment" as a medical product class IIa

Any diagnostic functionality or decision support as stated above will result in a risk classification class IIa. From April 2022, Notified Bodies are very limited available for new manufacturer to enter the market. According to this the development and registration of a class IIa product is associated with great and unmanageable uncertainties and is therefore not recommended.

7. Recommendation

Considering the time to market and the current availability restrictions of Notified Bodies (NBs) it is strongly recommended to limit the product functionality to a health and wellness app for the market launch, then implement a QMS according to ISO EN 13458 and develop and validate the medical app functionality accordingly. Diagnostic features that will result in class IIa categorization and therefore require more V&V activities should be developed and launched based upon the need and NB availability.

8. Literature

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9. Authors

Dr. Volker Klügl is the owner and managing director of IPP with 30 years of professional experience, mostly in project management and regulatory compliance of medical products. It Dr. Klügls fundamental belief, that good products, efficient project management and regulatory requirements do not contradict each other.

Marcelo Lackner acquired comprehensive and in-depth knowledge of medical devices at the Notified Bodies. Here he tested various devices in the laboratory according to IEC 60601-1. In addition, Marcelo Lackner is a trained auditor. This provides an additional benefit for his work as an expert for MDR and IEC 60601-1.

IPP is a Medical Device Management Consultancy with 20 employees: With us as a strong partner, you as a manufacturer gain security and efficiency in complying with all directives and standards relating to your medical device. This allows you to focus on your medical device, as well as its development, marketing and sales.

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