DiGA REPORT

2021

CHERRY

GründerAtelier

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GründerAtelier helps young companies to scale, to fulfill their investment needs and to build strong relations. Beyond companies, we make fruitful connections. We support our clients across a broad range of objectives: our focus lies on one hand on Startups, on the other on Investors.

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We are here to redefine and innovate the strategic operations of startups by focusing on their core segments and providing useful guidelines to allow for efficient product development. We generate a solid financial plan and proposition to make sure each startup understands its future composition of inflow and outflow of cash in order to apply the right development strategies. We bring in our reliable network and lead the way in raising the capital needed. We will provide Startups with highly strategic Investors, Connections and first Customers that will enhance traction and foster business growth.

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Cherry Ventures is an early-stage venture capital firm led by a team of entrepreneurs with experience building fast-scaling companies such as Zalando and Spotify. The firm backs Europe's boldest founders, usually as their first institutional investor, and supports them in everything from their go-to-market strategy and the scaling of their businesses. Cherry Ventures has previously invested in the seed stage of over 60 companies across Europe, including FlixBus, Auto1 Group, Infarm, Rows, Forto, and TourRadar. Cherry Ventures is based in Berlin and invests across Europe with operations in London, Paris, and Stockholm.

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Keywords:
DiGA, DVG, BSI, BfArM, Healthcare, Application, Software, Digital Care,Digital Experience, Medical Devices, eHealth, Reimbursement

ACRONYMS AND ABBREVIATIONS

Acronyms & Abbreviations	Definition
AAL	Ambient Assisted Living
BDSG	Bundesdatenschutzgesetz *Federal Data Protection Act*
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte *Federal Institute for Drugs and Medical Devices*
BSI	Bundesamt für Sicherheit in der Informationstechnik *Federal Office for Information Security*
B2C	Business to Client
CAGR	Compound Annual Growth Rate
CE	Conformité Européenne *Business to Client*
CBT	Cognitive Behavioural Therapy
DiGA	Digitale Gesundheitsanwendungen *Digital Health Applications*
DiGAV	Digitale-Gesundheitsanwendungen-Verordnung *Digital Health Applications Regulation*
DVG	Digitale Versorgung Gesetz *Digital Healthcare Act*
EEC	European Economic Community
EPA	Personal Health Record
EPR	Electronic Patient Record
GDPR	General Data Protection Regulation
IOP	Internal Operating Procedure

Acronyms & Abbreviations	Definition
ISMS	Information Security Management System
ISO	International Organization for Standardization
MDD	Medical Device Directive
MDR	Medical Device Regulation
mN	Medizinischer Nutzen *Medical Benefit*
Mn	Million
MPG	Medizinproduktegesetz *Medical Devices Act*
SGB	Sozialgesetzbuch *Social Code*
STD	Sexually Transmitted Diseases

1. DIGITAL HC ECOSYSTEM SIZE - EUROPE

If we dwell into the digital healthcare ecosystem in Europe, we can divide it into different segments:

1. **AAL:** Ambient Assisted Living (AAL) helps elderly people, but also people with special needs, to manage their household activities better on their own. It is ideal for people who require monitoring in general including e.g. children and chronically ill people. The trend is part of the eHealth sector since the respective devices track the user's health data at home. Furthermore, it can be seen as the smart home part of eHealth as AAL products usually aim at assisting in a domestic context.

2. **Fitness:** There are different ways in which customers can benefit from Fitness wearables/trackers and Fitness apps. Fitness wearables analyze physical activities or body functions. They are usually combined with an app to give valuable insights into an individual's fitness. These insights can help users to understand their body better and support them in reaching specific fitness goals, for example losing weight, by tracking calories or calculating burned calories with a tracker.

3. **ePharmacy:** The ePharmacy and Personal Care segment contains the online sale of medicine, cosmetics, and pharmaceutical and personal care products (inclusive of prescription drugs for the private end-user (B2C)). This segment also includes products for private use (e.g. blood pressure monitors, disinfectants, dressings).

4. **Heart Failure:** The 'Heart Failure' segment covers the user and revenue development for two eHealth product categories for people with chronic heart failure. Hardware and software solutions for healthcare professionals, e.g. medical equipment for hospitals and doctors' surgeries, are not included.

5. **Diabetes:** The 'Diabetes' segment includes the user and revenue development for two eHealth product categories for people with diabetes. Hardware and software solutions for healthcare professionals, e.g. medical equipment for hospitals and doctors' surgeries, as well as professional health services like telemedical monitoring are not included.

6. **Hypertension:** The 'Hypertension' segment covers the user and revenue development for eHealth product categories for people with hypertension.

All these segments have different impacts on different countries. As reported in the table below[1]:

United Kingdom	AAL	Fitness	ePharmacy	Heart Failure	Diabetes	Hyper-tension
Revenue in 2019 (€Mn)	70.00	660.00	6,783.00	21.00	11.00	28.00
CAGR next years	52%	4.7%	8.8%	7.8%	15.9%	8%
Market volume by 2022 (€Mn)	208.00	829.00	8,500.00	27.00	17.00	38.00

Table 1. Segments' economic impact - United Kingdom (Source: Statista, eHealth Outlook 2020).

Italy	AAL	Fitness	ePharmacy	Heart Failure	Diabetes	Hyper-tension
Revenue in 2019 (€Mn)	14.00	206.00	1,443.00	20.00	7.00	27.00
CAGR next years	41%	5%	14.8%	6.8%	9%	8%
Market volume by 2022 (€Mn)	33.00	263.00	2,183.00	24.00	9.00	35.00

Table 2. Segments' economic impact - Italy (Source: Statista, eHealth Outlook 2020).

France	AAL	Fitness	ePharmacy	Heart Failure	Diabetes	Hyper-tension
Revenue in 2019 (€Mn)	42.00	351.00	3,600.00	23.00	7.00	26.00
CAGR next years	37%	5%	8.7%	7.4%	8.4%	8.6%
Market volume by 2022 (€Mn)	90.00	844.00	4,623.00	28.00	9.00	36.00

Table 3. Segments' economic impact - France (Source: Statista, eHealth Outlook 2020).

Germany	AAL	Fitness	ePharmacy	Heart Failure	Diabetes	Hyper-tension
Revenue in 2019 (€Mn)	62.00	433.00	5,942.00	32.00	20.00	37.00
CAGR next years	32.6%	5.5%	13%	6.8%	11.3%	7.7%
Market volume by 2022 (€Mn)	122.00	568.00	8,573.00	38.00	28.00	47.00

Table 4. Segments' economic impact - Germany (Source: Statista, eHealth Outlook 2020).

Spain	AAL	Fitness	ePharmacy	Heart Failure	Diabetes	Hyper-tension
Revenue in 2019 (€Mn)	13.00	195.00	1,510.00	13.00	8.00	17.00
CAGR next years	40%	5%	16%	7%	9.5%	10%
Market volume by 2022 (€Mn)	30.00	248.00	2,356.00	16.00	11.00	21.00

Table 5. Segments' economic impact - Spain (Source: Statista, eHealth Outlook 2020).

Overview	UK	Italy	France	Germany	Spain
Digital HC Revenue in 2019(€Mn)	7,573.00	1,717.00	4,049.00	6,526.00	1,756.00
Market volume by 2022 (€Mn)	9,609.00	2,547.00	5,230.00	9,376.00	2,682.00

Table 6. Segments' economic impact - Overall (Source: Statista, eHealth Outlook 2020).

The United Kingdom and Germany come out on top with an overall market revenue in 2019 of 7.5 bn and 6.5 billion Euro respectively. The healthcare industry is witnessing an evolution towards a new healthcare concept and these 2 countries are at the forefront of this innovation.

1.1 Focus - Germany

In Germany, an ever-surging demand for telemedicine and digital healthcare services paired up with a spreading interest in the topic is fostering innovation both in the public and private sphere. According to market statistics, 86% of German citizens are familiar with the term "eHealth" which proves the awareness and the extent of interest in the subject. Moreover, 49% of the respondents showed a high level of interest in the subject.[2]

42% of the respondents declared to be willing to pay for applications that can help them with emergencies while 40% of them provided useful insights about their interest into applications that can track fitness and nutrition. Other interesting data from these surveys reveal that 35% and 39% of the respondents were also interested in applications able to track their sleep quality and to aid them to quit smoking. In terms of what benefits these citizens expect, earlier detection of illnesses top the list with 56% of respondents, while 13% of them have low expectations stating that they don't foresee any benefit from these applications.[3]

In terms of digital services, on average 38% of Germans are willing to book their doctor appointments online. In particular 41% of respondents declare to be more than willing to use an online tool for doctors location and appointment scheduling. However, it is

also essential to mention that not all Germans are willing to use these services. It has been reported that 23% of the respondents are not keen on using any sort of digital service offered by their doctors.[4]

Moreover, one of the main constraints for German citizens when it comes to subscribing to or using medical online services is about costs and data protection. 40% of respondents reported that these new services are too expensive or that they are afraid these services might have some future hidden costs. Moreover, 35% of respondents don't feel secure providing personal data to these new companies.[5]

Germany is pushing new regulations to fend off these limitations and allow the new healthcare paradigm to achieve real traction in the market. One of the biggest steps in this direction is the signing by the government of the new law for digital health applications.

On November 7th the German Parliament decided to pass the DVG ("Digitale Versorgung Gesetz" also known as "Digital Healthcare Act"). From June 2020 onwards, any doctor in Germany is able to prescribe digital health applications to the 72 million insured citizens. This brought numerous changes to the standard system such as the possibility for statutory health insurances to invest into VC funds to foster digital health innovation as well as the creation of a statutory directory which will allow pre-screened applications (described in Germany as DiGA "Digital Health Applications") to be subject to reimbursement.

2. DIGA - INTRODUCTION AND OVERVIEW

2.1 A new Paradigm in German Healthcare - Introduction

The 7th November 2019 marked the introduction into the healthcare system of "app on prescription". German residents will be able to use DiGA and be reimbursed by the health insurance.

Digital health applications (DiGA – in German: "Digitale Gesundheitsanwendungen") can be classified as patients' digital assistants and can enhance the treatment and diagnosis process as well as support a healthier patient's lifestyle.[6]

2.2 Legal requirements of DiGA[7]

DiGA can be described as a CE-certified medical device and according to BfArM has the following holistic properties:

- Devices of Class I or IIa, according to the Medical Device Regulation (MDR) or the transitional regulation Medical Device Directive (MDD)
- The main function of the DiGA is based on digital technologies
- The digital function is one of the main features of the medical product
- Recognition, monitoring, treatment or alleviation of diseases, injuries or disabilities are recognized by the DiGA
- The DiGA is used by the patient alone or by the patient and healthcare provider together

All these requirements are defined in Section 33a of the German Social Act Book V (Fünftes Buch Sozialgesetzbuch, SGB V).

Moreover, the European Commission in consultation with the relevant authorities implemented the following screening criteria in order to qualify and classify a standalone software as such:

- It has to be a computer program
- The purpose of the software needs to be other than just merely storing or communicating information
- The software has to be created for individual patients' benefit
- The software has to have an intended purpose listed in Article 1(2)a) of Directive 93/42/EEC (described below in the Standalone Software paragraph)

Not every application can be defined as a DiGA. There can be apps such as standalone software while others are incorporated into medical devices as well as other devices. These types of features will lead to a different classification in terms of risk according to the MPG (Medizinproduktegesetz, Act on Medical Devices). Moreover, not only the use will be taken into consideration but also the instructions for use, labelling or marketing material marketed by the manufacturer or related parties.

2.3 Standalone Software classification[8]

Standalone software can be classified as medical devices, but they need to

be intended for human treatments and need to satisfy one of the following criteria (Article 1(2)a) of Directive 93/42/EEC):

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps
- The investigation, replacement or modification of the anatomy or a physiological process
- Control of conception

The Indicative functions that the device would need to possess are, but not limited to:

- Decision support or decision-making software (e.g. concerning therapeutic measures)
- Calculation (e.g. of dosing of medicines, as opposed to mere reproduction of a table from which users can deduce the dosage themselves)
- Monitoring patients and collecting data (e.g. by measurements if the results thereof have an influence on diagnosis or therapy)

Storage, communication or search-only products *do not* result in a medical device classification.
Software applications must fulfil the basic requirements of Council Directive 93/42/EEC. This includes accessories manufactured and used in a health facility without being placed on the market or custom-made device according to Section 3 numbers 21 and 22 MPG.

93/42/EEC also provides a list of different risk classes. They range from Class I (low risk), IIa, IIb to Class III (high risk). Class I products are furtherly divided according to whether they require sterilisation or include a measuring function.

The classification is based on the rules reported in Annex IX of Council Directive 93/42/EEC. Here follows the classification reported (the exceptions are for in-vitro diagnostic medical devices and active implantable medical devices).

As a premise:

- *Standalone software* falls within the category of active medical device
- *Active therapeutic devices* restore, replace, modify or support structures or biological functions with the purpose of treatment or alleviation of an injury, illness or handicap
- *Active devices* supply information for treating, monitoring, diagnosing or detecting illnesses, physiological conditions, congenital deformities or other states of health

Class II b:

- All active therapeutic devices that might be hazardous for the human body in the process of administering energy to the body for monitoring or diagnosis
- All active devices intended to control other active therapeutic devices in Class IIb or intended directly to influence their performance are in Class IIb
- All devices that are used as contraception or prevention of STDs are also Class II b

Class II a:

- These are all devices that might not be considered as a source of potential harm for the patient in case of diagnostic process alteration. In this category are allocated all the devices that supply energy to the patient and that all their possible measurement variations do not harm the patients

Class I:

- All other devices are in this class

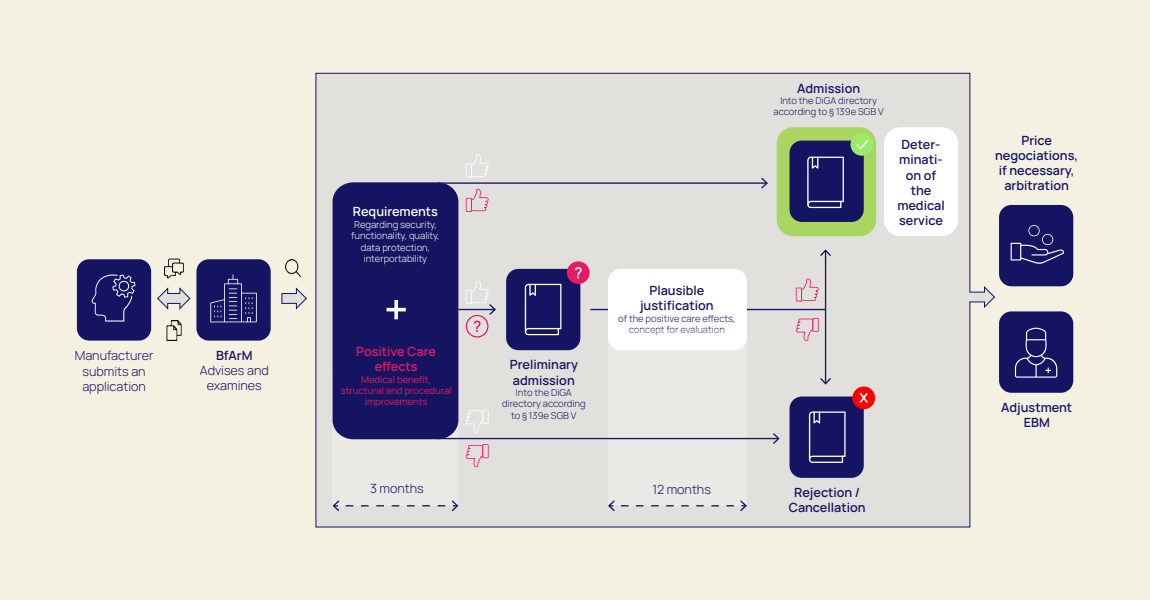
This classification shows that most of the medical apps on phones, tablets or similar devices are classified as Class I while devices for the diagnosis and/or monitoring of vital parameters might fall within the above classes.

According to the class of the device, the manufacturer needs to fulfil some prerequisite to receive a CE certification. Generally speaking, certification of class I devices does not need the involvement of a notified body while it is mandatory for the above classes.

2.4 How the application process works[9]

The process is straightforward: after submitting the application, the BfArM will review the claims done by the manufacturer on but not limited to quality, usage, data protection, interoperability, user-friendliness, and evidence of a positive healthcare effect.

Below is a flow chart showing the overall process.



Figures 1. Sequence of the DiGA Application (Source: BfArM).

We can divide this process into 4 parts:

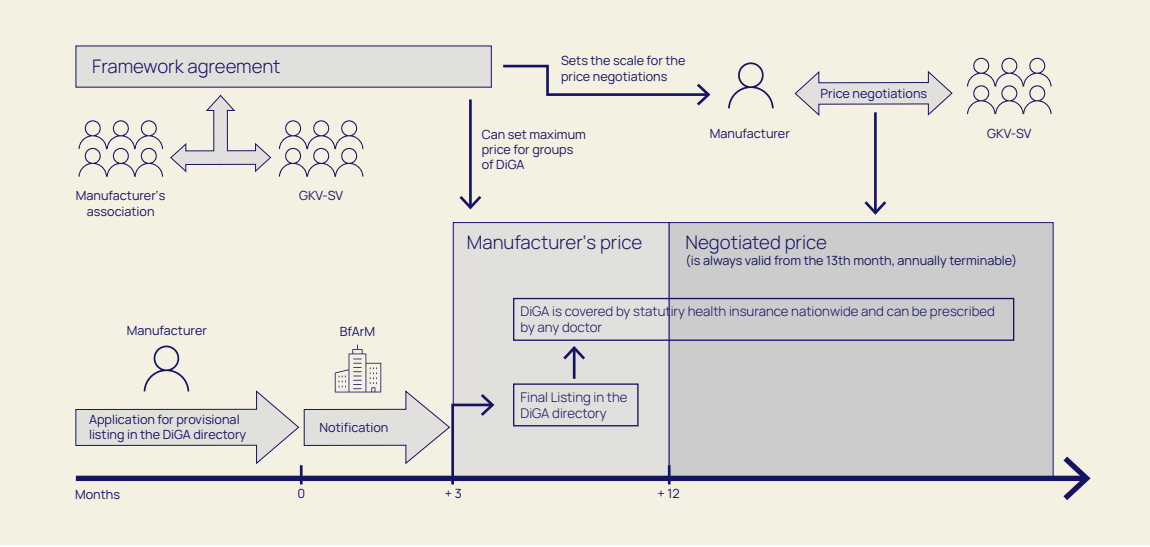
1. Manufacturers need to confirm that their product fulfils all the DiGA requirements that are formulated in Sections 3 to 7 of the DiGAV (or 3 to 6 in case of Provisional Listing)
2. Manufacturers need to provide evidence that their products can generate positive healthcare effects
3. According to the documents provided we have different paths:
   - 3.1 The manufacturer provides all the documents and awaits a reply from BfArM
   - 3.2 The manufacturer provides all the documents besides the study of positive healthcare effects and it has up to 12 months to provide the finished study for the examination
4. Listing in the DiGA directory: a DiGA becomes visible in the DiGA directory as soon as a positive decision on the inclusion in the DiGA directory according to Section 139e SGB V has been issued

2.5 Initial Document Submission

Before an application is made, the manufacturer of the DiGA has first to decide whether to apply provisionally or directly for the final listing in the directory. This decision essentially depends on whether the manufacturer of the DiGA can already present a comparative study to prove a positive healthcare effect that meets the requirements of Sections 10 to 12 DiGAV (see also Chapter 4 Evidence of Positive Healthcare Effect of this guide).

Before applying, the manufacturer needs to decide whether to apply for the direct listing or provisional listing.

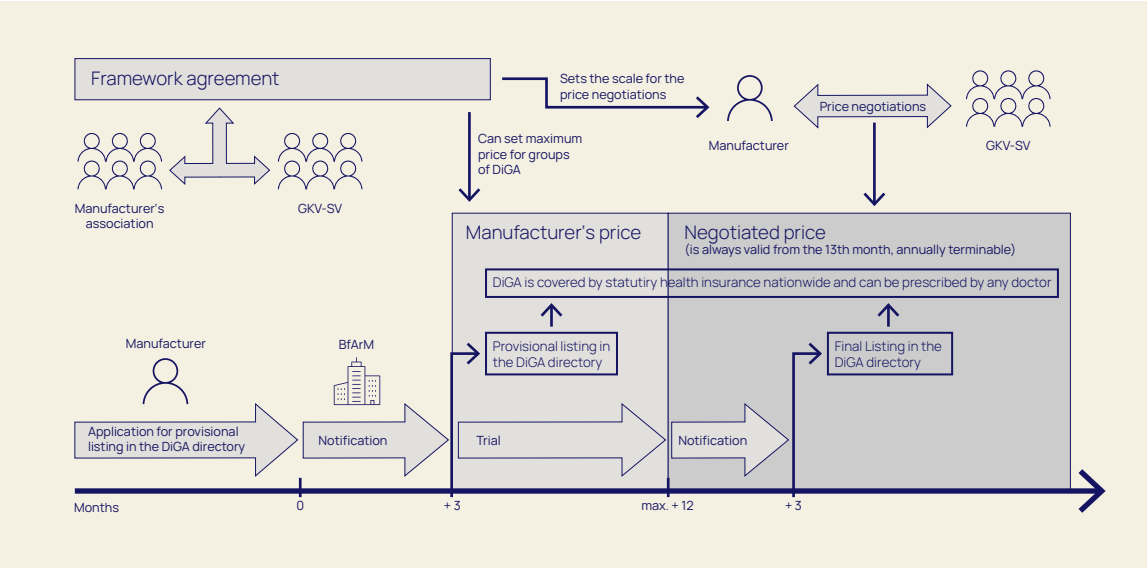
Final listing: Manufacturers that already have a study that proves their products have a positive healthcare effect, will be included in the DiGA Directory within 3 months from the submission of the application and BfArM positive decisions. Negotiation of reimbursement will follow.



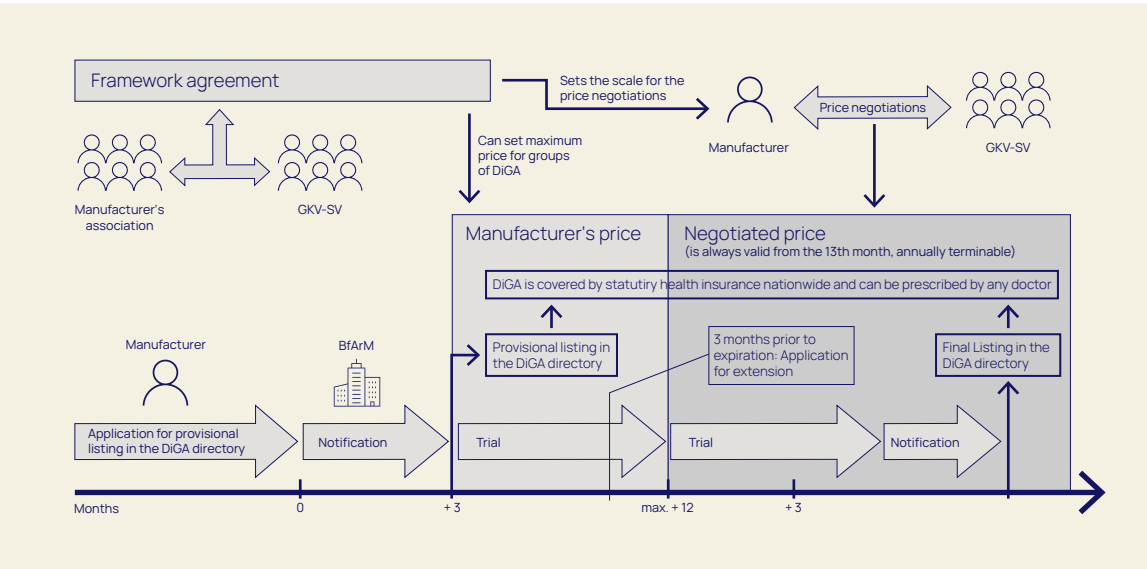
Figures 2. Application for final listing in the DiGA directory (Source: BfArM).

Provisional listing: In case the studies are not present, the manufacturer has to apply to the provisional listing. The candidate will be given a 12 months trial period to provide the study to the BfArM for review. The candidate can't re-apply for 12 months in case of no submission.

It is possible to obtain an extension of the trial phase, up to 12 months. The condition allowing this extension is that the study submitted "makes it likely that evidence will be provided later". The manufacturer that needs the extension will need to apply for it.



Figures 3. Application for provisional listing in the DiGA directory (Source: BfArM).



Figures 4. Application for an extension of the trial phase (Source: BfArM).

This depends mainly on the presence of studies that already prove that the product has a positive healthcare effect.

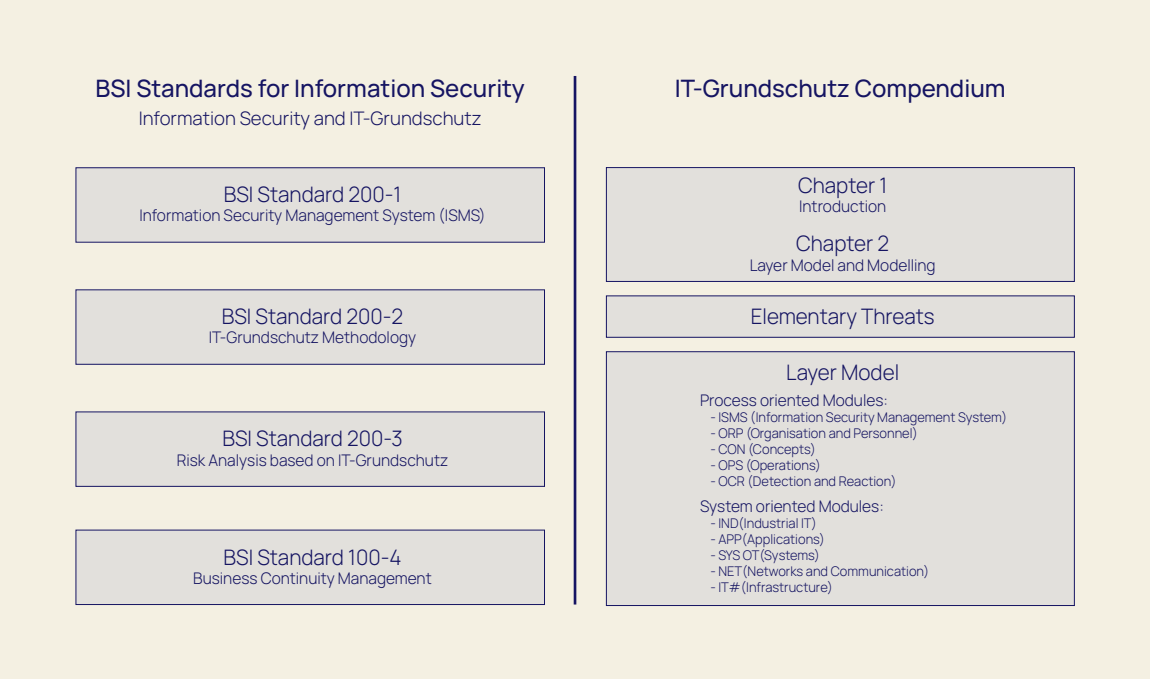
2.6 Criteria needed to be eligible to be filed into the DiGA Directory

The product needs to satisfy the following criteria:

Safety and Suitability of use: Need a certificate of conformity

Data Protection: Compliance with the GDPR, BDSG and other data protection regulations according to the nature of the company. The checklist to be completed by the manufacturer of the DiGA for the application contains 40 statements that take into account both the technical implementation of the DiGA (e.g. technical and organizational measures in accordance with Article 32 GDPR) and the organization of the manufacturer and its processes. Moreover, DiGA manufacturer needs to consent to data processing for the listing.

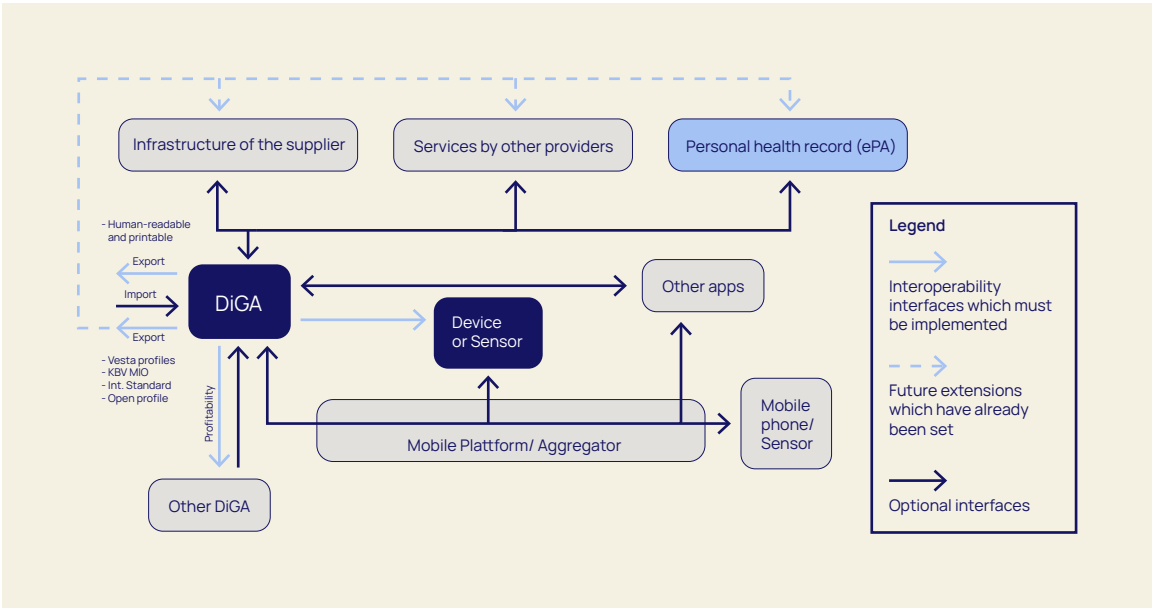
Information Security: The specifications are based on the recommendation of the BSI and can be summarized in the following. However, even though DiGA manufacturers are not yet required to implement an ISMS according to the ISO 27000 series or BSI Standard 200-2 by 2022, Annex 1 to the DiGAV requires the establishment of a series of processes for all DiGA in order to anchor the basic idea outlined above of security as a process at the manufacturer and to ensure the continuation of a security level once achieved.



Figures 5. Requirements and recommendations of the BSI regarding information security (Source: BSI-Standard).

Interoperability: The manufacturer of a DiGA must prove that it is interoperable regarding three selected issues:

- The DiGA has to allow the insured person to export therapy-relevant extracts of the data collected via the DiGA in human-readable and printable form so that he can use them for his own purposes or pass them on to a physician.
- The DiGA has to allow the insured person to export the data collected from the DiGA in a machine-readable, interoperable format so that the insured person or a third party authorized by the insured person can further process this data via other digital products. In future, it should also be possible to connect this interface to the EPA.
- If the DiGA obtains data from medical devices used by the insured person or sensors worn by the insured person for the measurement and transmission of vital signs (wearables), it may also address these devices via an interoperable interface.



Figures 6. IOP for DiGA (Source: BfArM)

Evidence of positive healthcare effect: The medical benefit (medizinischer Nutzen, mN) is defined in the DiGAV (based on the corresponding standards for the evaluation of drugs) as patient-relevant effect(s), particularly regarding:

- The improvement of the state of health
- The reduction of the duration of disease, Definition: Medical benefit Evidence of Positive Healthcare Effect
- The prolongation of survival
- An improvement in the quality of life

Those who claim a medical benefit for a DiGA must show that patient-relevant endpoints, in particular morbidity, mortality or quality of life, are positively influenced.

Further quality requirements: DiGA needs to also meet the following requirements

- Robustness: The device needs to be used by insured persons as far as possible without interference, loss of data, transmission errors or difficulties in connection with devices, power failure, interruptions in internet connections, malfunctioning that cause data falsification among others.
- Consumer Protection: The manufacturer of a DiGA must supply healthcare providers and insured persons with transparency regarding the purpose and functionality of the DiGA. Moreover, insured persons must be able to determine to what extent the application fits their own requirements, ideas and (technical) circumstances. It is possible to install paid functions on the application but in this case, the user will have to pay for them by him/herself. However, according to section 5 Paragraph 4, Digital health applications in the DiGA directory must be free of advertising.
- Ease of Use: The operating instructions implemented or supported in the DiGA must consider the areas of vision, hearing and motor skills. Exceptions are only permitted if this can be justified based on the target group or the purpose of the DiGA. From January 1st .2020 all DiGA listed in the register must either include operating aids for people with disabilities or support the operating aids offered by the platform.
- Support for healthcare providers: The DVG also allows the listing of a DiGA in the DiGA directory that involves physicians and other healthcare providers in the usage of the DiGA by the insured person.
- Quality of Medical Content: The procedure implemented by DiGA and the content presented must be based on sound medical knowledge and take into account recognized professional standards. Health information provided to the insured must be up-to-date and appropriately prepared for the focus group.
- Patient Safety: The manufacturer of a DiGA must ensure by appropriate organizational and technical measures that the risks of use of the application are as low as possible. While the CE marking ensures the basic technical safety of the DiGA, the measures required here are aimed at conscious handling of existing residual risks for the insured person.

2.7 Deadlines and fees

The application procedure begins when the manufacturer has filled out all the mandatory information in the application portal and attached the necessary attachments, clicked on the button that triggers the transmission of the application to the BfArM who receives the application online.

The candidate will receive a reply from BfArM within 14 days from submission. On the day of receipt of the complete documents by the BfArM, the legally prescribed maximum three-month evaluation period of the application by the BfArM begins.

If a manufacturer wishes to have a DiGA deleted from the directory, he can submit an application for delisting to the BfArM via the electronic application portal. This deletion is not bound to any preconditions however it bears a fee (reported below).

The BfArM charges fees for the processing of applications and notifications:

Application for final listing in the DiGA directory:	€ 3,000 to € 9,900
Application for provisional listing in the DiGA directory:	€ 3,000 to € 9,900
Assessment of the proof of positive effect (provisional):	€ 1,500 to € 6,600
Application for extension of the trial phase:	€ 1,500 to € 4,900
Notification of significant changes to the DiGA:	€ 1,500 to € 4,900
Notification of the need for changes in the DiGA directory:	€ 300 to € 1,000
Removing of a DiGA from the DiGA directory:	€ 200

3. ADJUSTMENTS NEEDED TO THE DIGA SYSTEM

Regardless of the innovative push that Germany created concerning digital healthcare, the system it has established needs to be fine-tuned in order to avoid opportunistic behaviours and to protect users.

3.1 Higher threshold for proofs concerning medical benefit

As of January 2021, access to the DiGA directory is allowed for companies that deliver studies proving positive medical benefits for the final user of the product. The positive medical benefits are not clearly defined and they are compared to a non-use scenario. Medical benefits would need to be assessed taking into consideration the services provided nowadays by the government to understand how the results of the applicant pair up with existing services. Allowing companies to be lifted into the directory, regardless of the quality of the medical benefit, might create the multiplication of the same type of service without bringing any value to the end-user.

3.2 Price regulation concerning products or services of DiGA applicants

DiGA admitted companies have the possibility to set prices over the first years since their inclusion into the directory. This possibility has led to excessive pricing with companies overcharging 400% to 500% more than in the self-payer market, compromising the principle of economic efficiency (Section 12(1) sentence 1 SGB V provides as follows: "Treatments must be adequate, fit for purpose and economically efficient; they must not exceed the dimension of the necessary."). Therefore, it would be advisable to negotiate a price between all the prices and develop a clear pricing strategy over the years according to the evolution of the market.

3.3 Specialized team for the creation of a seamless digital experience

DiGA applicants are required to provide a service to the end-user which delivers a positive healthcare effect. However, not enough emphasis is conveyed to the creation process of the application itself. An application that is not customer-friendly would suffer from phenomena of incorrect usage and also provide a low retention rate and therefore would impact in a limited way on the country's healthcare system.

3.4 Respect of GDPR and other data protection regulations

The program shall provide users full protection against data loss and full privacy according to the latest GDPR regulation. Data protection should be guaranteed from the manufacturer to the user of the application. Data protection evidence should be deemed mandatory since self-declaration is not enough.

3.5 Proven quality and uniformity of software and hardware

Besides data protection, the manufac-

turer should also provide proof of the quality of the hardware and software of the product. Moreover, interoperability would need to be provided together with a common interface for EPR. A simple and common interface shall be used in order to simplify data collection to improve the system.

4. COMPANIES WITH DIGA LISTING[10] *(AS OF 16.04.2021)*

The following companies are divided into companies that already obtained the approval and those that are temporarily added to the directory.

4.1 Permanently Approved

4.1.1 deprexis

deprexis is an interactive online self-help programme to support the therapy of patients with depression and depressive moods who are at least 18 years old. The programme is intended to be used in addition to an otherwise usual treatment (for example with a general practitioner, specialist or psychotherapist).

- *Target Patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Mild depressive episode, moderate depressive episode, severe depressive episode without psychotic symptoms, recurrent depressive disorder, present mild episode, recurrent depressive disorder, current moderate episode, recurrent depressive disorder, current major episode without psychotic symptoms

4.1.2 elevida

elevida is a digital health app for people with multiple sclerosis who also have fatigue and are at least 18 years old. Fatigue is when there is persistent tiredness or exhaustion. elevida aims to reduce fatigue and its programme is supposed to be used in addition to an otherwise usual treatment (for example by a general practitioner or specialist). elevida is based on established psychotherapeutic approaches and procedures, especially cognitive behavioural therapy (CBT).

- *Target patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Multiple sclerosis (Encephalomyelitis disseminata)

4.1.3 somnio

somnio is a digital application for the treatment of sleep onset and sleep maintenance disorders (insomnia). The application teaches evidence-based and guideline-compliant content from the field of cognitive behavioural therapy for insomnia (CBT-I). Users learn, for example, to optimise their sleep times, to follow an individually coordinated sleep-wake rhythm, to deal with thoughts that prevent sleep or to bring themselves into a sleep-promoting state by means of relaxation techniques.

- *Target Patients:* Between 18 and 65 years old
- *Disease/Condition:* Non-organic insomnia

4.1.4 velibra

velibra is a web-based program for patients with generalized anxiety disorder, panic disorder with or without agoraphobia or social anxiety disorder. velibra teaches established methods and exercises of Cognitive Behavioral Therapy - a very well scientifically studied form of psychotherapy. The program is intended as a supplement to an otherwise usual treatment (for example by the family doctor) for patients who are at least 18 years old.

- *Target patients:* Between 18 and 65 years old
- *Disease/Condition:* Agoraphobia, Panic disorder, social phobias, panic disorder (episodic paroxysmal anxiety), generalised anxiety disorder

4.2 Temporarily Admitted

4.2.1 Invirto

Invirto enables people with agoraphobia, panic disorder or social phobia to treat their anxiety disorder from home. Patients learn from therapists or doctors accompanied by an app and virtual reality glasses in order to better understand their anxiety, to cope with high levels of tension, manage anxious thoughts and to revisit anxious situations.

- *Target patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Agoraphobia: without indication of panic disorder, agoraphobia: With panic disorder, Social phobias, Panic disorder (episodic paroxysmal anxiety)

4.2.2 Kalmeda

Kalmeda offers patients (who have reached the age of 18) with chronic tinnitus a guideline-based, behavioural therapy. The structured programme is supplemented by relaxation instructions, soothing nature and background sounds as well as a knowledge section. The behavioural therapy programme, which lasts several months, consists of 5 levels with 9 stages each and shows patients step by step the way to a self-determined handling of the tinnitus and to a reduction of the tinnitus burden.

- *Target patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Tinnitus aurium

4.2.3 Mika

The Mika App is a digital health application to support the alleviation of psychological and psychosomatic consequences of diagnoses and therapies of malignancies. The application achieves relief through documentation of distress, symptoms and side effects in the course as well as resource-activating patient education in the areas of health literacy, stress management, exercise and nutrition.

- *Target patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Malignant neoplasm of the cervix uteri, Malignant neoplasm of the uterus, part unspecified, Malignant neoplasm of the ovary

4.2.4 Vivira

Vivira is a digital health application for treating back, knee and hip pain in non-specific low back pain, osteoarthritis of the spine (osteochondrosis), osteoarthritis of the knees (gonarthrosis), non-specific knee pain, osteoarthritis of the hip (coxarthrosis) and non-specific hip pain.
The Vivira App for movement therapy offers 4 exercises daily, which are continuously adjusted in intensity and complexity based on the patient's feedback. The daily exercises are supplemented by weekly health queries, visualization of progress, monthly movement tests and educational content. Vivira supports the implementation of the training elements provided

for in guidelines for non-specific low back pain, knee arthrosis and hip arthrosis, as well as the implementation of the Remedies Directive.

- *Target patients:* Between 18 and 65 years old and over 65 years old
- *Disease/Condition:* Primary coxarthrosis bilateral, other primary coxarthrosis, coxarthrosis as a result of dysplasia bilateral, other dysplastic coxarthrosis, post-traumatic coxarthrosis, bilateral, other post-traumatic coxarthrosis, other secondary coxarthrosis bilateral, other secondary coxarthrosis, unidentified coxarthrosis, Primary gonarthrosis bilateral, other primary gonarthrosis, post-traumatic gonarthrosis bilateral, other post-traumatic gonarthrosis, other secondary gonarthrosis bilateral, other secondary gonarthrosis, gonarthrosis unspecified, joint pain: pelvic region and thigh (pelvis, femur, buttocks, hip, hip joint, sacroiliac joint), joint pain: lower leg (fibula, tibia, knee), other specified joint diseases: pelvic region and thigh (pelvis, femur, buttocks, hip, hip joint, sacroiliac joint), other specified joint diseases: lower leg (fibula, tibia, knee joint), joint disease, unspecified: pelvic region and thigh (pelvis, femur, buttocks, hip, hip joint, sacroiliac joint), joint disease, unspecified: lower leg (fibula, tibia, knee joint), juvenile osteochondrosis of the spine, osteochondrosis of the spine in adults, osteochondrosis of the spine, unspecified, Instability of spine, other specified diseases of the spine and back, disease of spine and back, unspecified, low back pain, thoracic spine pain, other back pain, back pain, unspecified, segmental and somatic dysfunction: thoracic (thoracolumbar) region, segmental and somatic dysfunction: lumbar region (lumbosacral), segmental and somatic dysfunction: sacral region (sacrococcygeal, sacroiliac), other biomechanical dysfunctions: thoracic region (thoracolumbar), other biomechanical dysfunctions: lumbar region [lumbosacral], other biomechanical dysfunctions: Sacral region (sacrococcygeal, sacroiliac), other biomechanical dysfunctions: Pelvic region (hip or pubic region), other biomechanical dysfunctions: lower extremity, biomechanical dysfunction, unspecified: thoracic region (thoracolumbar), biomechanical dysfunction, unspecified: lumbar region (lumbosacral), biomechanical dysfunction, unspecified: sacral region (sacrococcygeal, sacroiliac), biomechanical dysfunction, unspecified: pelvic region (hip or pubic region), biomechanical dysfunction, unspecified: lower limb.

4.2.5 zanadio

zanadio is an application that helps users to reduce their weight in the long term by changing their habits in the areas of exercise, nutrition and other behaviour. The DiGA is based on the scientific concept of multimodal, conservative obesity therapy, which addresses the various relevant areas and thereby brings about long-term, permanent weight reduction. The program implements this established treatment approach digitally.

- *Target patients:* Between 18 and 65 years old
- *Disease/Condition:* Obesity

4.2.6 M-sense Migräne

M-sense Migräne offers a comprehensive digital treatment programme for migraine patients. The application includes a digital headache diary and guideline-compliant procedures for migraine prophylaxis and acute treatment of attacks. Migraine patients can access customised knowledge transfer, animated physiotherapeutic exercises, instructions for endurance sports as well as audio files for relaxation and imagination exercises.

- *Target patients:* Between 18 and 65 years old and above 65 years old
- *Disease/Condition:* Migraine

4.2.7 Rehappy

Rehappy supports the aftercare of stroke patients. The support takes the form of an individually compiled supply of motivation and knowledge with a mobile app, an activity tracker and a web portal. The patients are activated, informed and accompanied in order to be able to tackle their path to recovery in a sustained, self-determined, competent and confident manner. The support is based on educational information and positive reinforcement for the perception of personal responsibility and an increase in therapy adherence as well as intrinsic motivation.

- *Target patients:* Between 12 and 17 years old, 18 and 65 years old and above 65 years old
- *Disease/Condition:* Cerebral transient ischaemia and related syndromes, subarachnoid haemorrhage, Intracerebral haemorrhage, other non-traumatic intracranial haemorrhages, cerebral infarction, stroke not classified as haemorrhage or infarction, other cerebrovascular disease, consequences of cerebrovascular disease

4.2.8 Selfapy

Selfapy offers sufferers of depression an individual online course based on evidence-based theories and techniques of Cognitive Behavioural Therapy. The therapeutic content can be worked on independently by the person affected via the internet-based course. The course is divided into individual lessons, each of which deals with one topic, such as dealing with negative thoughts, creating a positive daily structure, relaxation techniques, sleep problems, and relapse prevention strategies. The contents are taught with the help of audio and video clips, texts and exercises. The contents are individually adapted to the personal situation of the person concerned.

- *Target patients:* Between 18 and 65 years old
- *Disease/Condition:* Mild depressive episode, moderate depressive episode, other depressive episodes, depressive episode, unspecified, recurrent depressive disorder, current mild episode, recurrent depressive disorder, current moderate episode, recurrent depressive disorder, currently remitted, other recurrent depressive disorder, recurrent depressive disorder

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