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Anforderungen an Health Software

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Das Unternehmen

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Was ist eigentlich Software?

SOFTWARE

Programs, procedures, rules, and any associated documentation pertaining to the operation of a system. Contrast with hardware.

[FDA: Glossary of Computer Systems Software Development Terminology]

Als Terminus wird ‚Software' in zwei typischen Entgegensetzungen gebraucht:

1. Eine *uneingeschränkte Definition* beschreibt Software als 'Gegenstück zu Hardware', wobei Software hier jede Art von digitalen Daten umfasst, die auf einer Hardware gespeichert sein können, von der Firmware dem Betriebssystem, den Anwendungsprogrammen bis hin zu allen (möglichen) Dateien eines softwaregesteuerten Gerätes.

2. Im allgemeinen Sprachgebrauch und in der Literatur zu Softwaretechnik wird die Definition von ‚Software' eingeschränkt auf Computerprogramme und die mit ihnen eng verbundenen Ressourcen, wie z. B. Konfigurationsdaten neben Icons und Schriftarten, die zum Betrieb notwendig sind. Die zur Verarbeitung bestimmten Daten (z. B. digitalisierte Musikstücke) werden hier meist nicht als Software verstanden.

[Quelle: http://de.wikipedia.org]

Elektronische Aufzeichnungen, Daten und Parameter sind KEINE Software!

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Health Software vs. Medical Apps

Als (mobile) **App** (Kurzform für *Applikation)* wird Anwendungssoftware für Mobilgeräte bzw. mobile Betriebssysteme bezeichnet.

Obwohl sich der Begriff **App** als Abkürzung von englisch *Application software* auf jegliche Art von Anwendungssoftware bezieht, wird er im deutschen Sprachraum oftmals mit Anwendungssoftware für Smartphones und Tablet-Computer gleichgesetzt, die über einen in das Betriebssystem integrierten Onlineshop bezogen und so direkt auf dem Smartphone installiert werden können.

[Quelle: http://de.wikipedia.org]

Health Software vs. Medical Apps

HEALTH SOFTWARE
Software intended to be used specifically for managing, maintaining or improving **health** of individual persons, or the delivery of care.

SOFTWARE-ONLY PRODUCT (STANDALONE SOFTWARE)
Software which is not intended for incorporation in another product at the time of its being placed on the market

[Quelle: IEC/CD2 82304-1: Health Software – Part 1: General requirements for product safety]

MEDICAL SOFTWARE
software intended to be used specifically for incorporation into a physical medical device or intended to be a SOFTWARE MEDICAL DEVICE

SOFTWARE MEDICAL DEVICE
software intended to be a medical device in its own right

MEDICAL DEVICE SOFTWARE
software intended to be used specifically for incorporation into a physical medical device

Health Software

Included in scope

- **Software-only products for health use**
- **Mobile apps without "applied parts"** (*)
- Laboratory information Software
- Radiology information Software
- Software for individuals in fitness centres
- Software for finding best conception moment
- Computer-aided diagnosis Software
- Analysis Software for medical images
- Clinical Decision Support software used to aid diagnosis, treatment, and health management of individuals
- Individual stress relief Software
- Training plan Software for revalidation purposes
- Software for stimulating activity by Alzheimer patients
- Electronic Health Record systems, including Electronic Medical Record systems
- **Hospital information systems**
- HEALTH SOFTWARE provided as a service hosted by an external organisation

(*) "applied parts" are specific sensors or detectors that are applied to the human body to capture (bio)signals, e.g., for health purposes. A camera or microphone on a smartphone or tablet computer is not considered a specific sensor or detector.

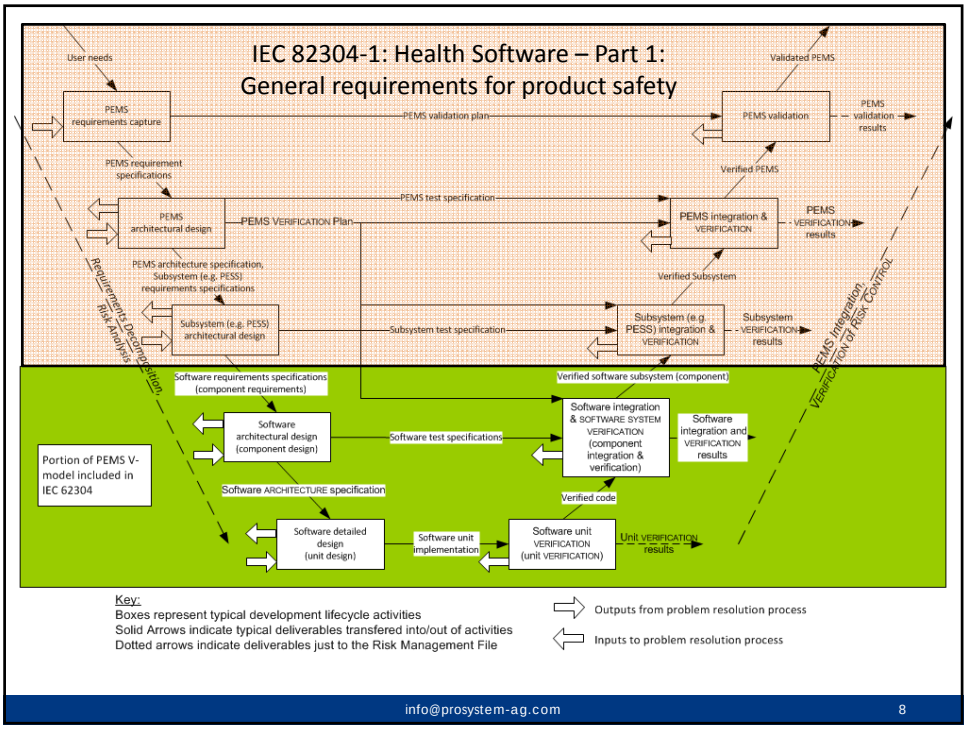
[Quelle: IEC/CD2 82304-1: Health Software – Part 1: General requirements for product safety]

Health Software

NOT included in scope

- Software that is not an executable, such as libraries, sets of reference values, ...
- **Embedded software**
- **Updates/upgrades to embedded Software**
- Software not addressing health issues for individuals
- **Hospital billing Software**
- Hospital equipment maintenance scheduling Software
- Epidemiological study Software
- Nurse training Software
- Self-study for medical professionals
- Electronic logbook for nursing home
- .....

[Quelle: IEC/CD2 82304-1: Health Software – Part 1: General requirements for product safety]



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Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

The draft of this guidance was issued on July 21, 2011.

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Health Software vs. Medical Apps

MOBILE PLATFORM

For purposes of this guidance, "mobile platforms" are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature.

~~Examples of these mobile platforms include mobile computers such as the iPhone®, BlackBerry® phones, Android® phones, tablet computers, or other computers that are typically used as smart phones or personal digital assistants (PDAs).~~

Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.

MOBILE APPLICATION (MOBILE APP)

For purposes of this guidance, a mobile application or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

[Quelle: Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications]

Health Software vs. Medical Apps

MOBILE MEDICAL APPLICATION (MOBILE MEDICAL APP)
For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of "device" and either:

- is used as an accessory to a regulated medical device;
- or transforms a mobile platform into a regulated medical device.

When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

[Quelle: **DRAFT** Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications]

Examples of mobil apps that are NOT medical devices

- **Medical dictionaries**
- Library of clinical descriptions for diseases and conditions
- Encyclopedia of first-aid or emergency care information
- Medical abbreviations and definitions
- Translations of medical terms across multiple languages
- Medical flash cards with medical images, pictures, graphs, etc.
- **Question/Answer quiz apps**
- Interactive anatomy diagrams or videos
- **Surgical training videos**
- Medical board certification or recertification preparation apps
- Provide information about gluten-free food products or restaurants
- Provide tutorials or training videos on how to administer first-aid or CPR
- Help match patients with potentially appropriate clinical trials and facilitate communication between the patient and clinical trial investigators

…

[Quelle: Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications]

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Examples of mobil apps that are the focus of FDA´s regulatory oversight (MOBILE MEDICAL APPS)

- **Mobile apps that transform a mobile platform into a regulated medical device**
- **Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source**
- **Mobile apps that display, transfer, store, or convert patient-specific medical device data from a connected device**

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
862.1345	Glucose test system	System, Test, Blood Glucose, Over The Counter (NBW)	2	510(k)
862.2100	Calculator/data processing module for clinical use	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System (NVV)	1	510(k) exempt
868.1850	Monitoring spirometer	Spirometer, Monitoring (W/Wo Alarm) (BZK)	2	510(k)
868.1920	Esophageal stethoscope with electrical conductors	Stethoscope, Esophageal, With Electrical Conductors (BZT)	2	510(k)
868.2375	Breathing Frequency Monitor	Ventilatory Effort Recorder (MNR)	2	510(k)
868.2377	Apnea Monitor	Monitor, Apnea, Home Use (NPF)	2	510(k)
870.1025	Arrhythmia detector and alarm (including ST-segment measurement and	Detector and Alarm, Arrhythmia (DSI)	2	510(k)

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Examples of mobil apps that that MAY meet the definition of a medical devices

- **Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home**
- Mobile apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported
- Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks
- Mobile apps that prompt the user to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for later review

…

The FDA understands that there may be other unique and innovative mobile apps that may not be covered in this list that may also constitute healthcare related mobile apps.

[Quelle: Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications]

Anforderungen der Food and Drug Administration

A mobile medical app, like other devices, may be **classified as class I (general controls), class II (special controls in addition to general controls), or class III (premarket approval).**

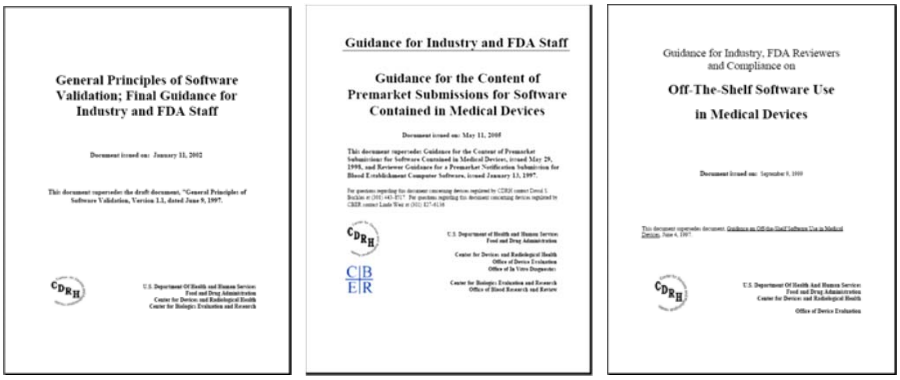
- Mobile apps that are an extension of one or more medical device(s) by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.
- Mobile apps that transform the mobile platform into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.
- Mobile apps that allow the user to input patient-specific information and - using formulae or processing algorithms - output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in making clinical decisions.

[Quelle: Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications]

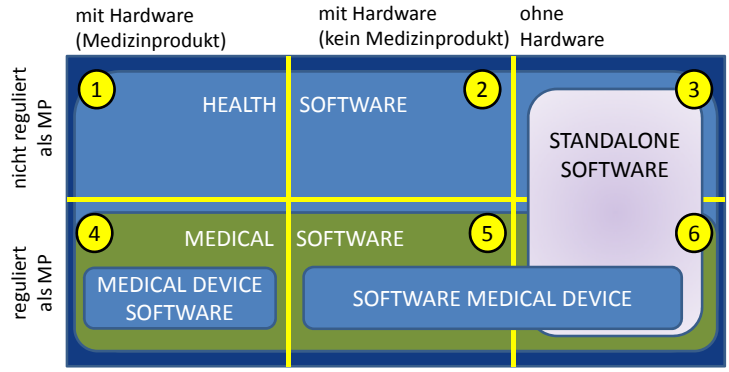
Anforderungen der Food and Drug Administration

Kapitel einer 510(k)	
01 Medical Device User Fee	11 Device Description
02 Premarket Review Submission Cover Sheet	12 Substantial Equivalence Discussion
03 Cover Letter	13 Proposed Labeling
04 Indications for Use	14 Sterilization and Shelf Life
05 510(k) Summary or 510(k) Statement	15 Biocompatibility
06 Truth and Accurate Certification	16 Software
07 Class III Summary	17 Electromagnetic Compatibility and Electrical Safety
08 Financial Certification or Disclosure Statement	18 Performance Testing – Bench
09 Declaration of Conformity and Summary reports	19 Performance Testing – Animal
10 Executive Summary	20 Performance Testing - Clinical

Anforderungen der Food and Drug Administration



Zusammenfassung: Übersicht über Health Software



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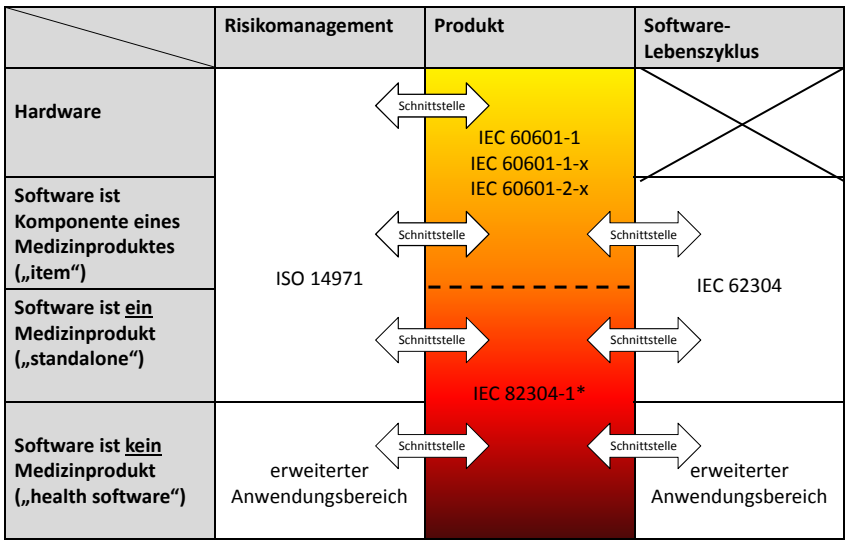
Zusammenfassung: Übersicht über Health Software



*IEC/CD2 82304-1 Health Software – Part 1: General Requirements for Product Safety

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VIELEN DANK FÜR IHRE AUFMERKSAMKEIT!