HELP! IS MY M-HEALTH SOFTWARE SUDDENLY A MEDICAL DEVICE?

A Challenge of convergence between eHealth, mHealth and Medical Devices

A short introduction

Hansjörg Riedwyl, CEO
Hansjoerg.riedwyl@iss-ag.ch
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Agenda

Regulatory Framework for Medical Devices
In what cases is a Software a medical device?
Impact of new European Regulation (MDR)
Some Examples
What is applicable if a SW is a Medical Device?
Validation of Stand-Alone-Software
ISS at a glance
Global iOS & Android
• >165'000 mHealth apps
• 500 m users
• CAGR > 40%
• Certified ~10%

Apple's updated App Store guidelines place added scrutiny on health, medical apps

By Heather Mack | September 06, 2016

Developers of health and medical apps will now have strict rules to abide by with Apple's new App Store Guidelines that establish a high bar for any app aimed at health and wellness.

Previous iterations of the guidelines already laid out the proper protocol for human research subjects and avoiding physical harm, but the new rules carry much more detailed

Fitness-Tracker
Kunden reichen Sammelklage gegen Fitbit ein

Various (so far separated) disciplines are converging (IT, mHealth, Medical Devices, HIS etc.)

Chaos! says the pessimists
- Confusion all over (safety, privacy, efficacy???)
- Non regulated
- Dangerous for patients
- Transparent patient

Chance! says the optimist
- Potential for prevention, monitoring…
- Simplified processes
- Cost saving possibilities
- Creates jobs
Regulatory Framework for Medical Devices

In general

- **EU**
  - IVDD, MDD

- **National (CH)**
  - HMG
  - HFG
  - MepV, KlinV

**Standards**

**Recommendations and Guidances**
- MEDDEV, ZLV, NB-Recommendations
- Medical specialist’s recommendations
Upcoming changes (red)

EU
- IVDR, MDR
- IA, DA

National (CH)
- HMG
- HFG
- MepV, KlinV

Standards
- ISO 13485:2016
- IEC 14971
- IEC 62304
- IEC 62366
- IEC 60601
- IEC 61010
- ISO 10993
- New: IEC 82304

Recommendations and Guidances
- MEDDEV
- ZLV
- NB-Recommendations
- Medical specialist’s recommendations
In what cases is a Software a medical device?


‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

− diagnosis, prevention, monitoring, treatment or alleviation of disease,
− diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
− investigation, replacement or modification of the anatomy or of a physiological process,
− control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

....
What does this mean exactly?

Help is given by the MEDDEV 2.1/6 (latest issue from July 2016)


“Qualification and Classification of stand alone software”

Below the relevant Flowchart from the above mentioned MEDDEV for answering the question „is my SW a Medical Device?“
START

1. Is the product a software according to the definition of this document?
   - Yes
   - No

   2. Is the software a stand-alone software according to the definition of this document?
      - Yes
      - No

      3. Is the software performing an action on data different from storage, archival, communication, or simple search?
         - Yes
         - No

      4. Is the action for the benefit of individual patients?
         - Yes
         - No

      5. Is it for the purposes defined in art 1.2a of Dir. 93/42 CEE?
         - Yes
         - No

   - Part of a medical device
   - Not covered by the medical device directives*
Impact of new European Regulation (MDR)

New classification of Standalone Software

**MDR classification Rule 11**

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

– death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

– a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software are classified as class I.
Some Examples

Hospital Information Systems are not qualified as medical devices. However they may be used with additional modules, as described hereafter. These modules might be qualified in their own right as medical devices.

Decision Support Software are qualified as medical devices, e.g.

- Radiotherapy treatment planning systems
- Drug (e.g.: Chemotherapy) planning systems
- Computer Aided Detection systems… for example, such systems would be able to automatically read x-ray images or interpret ECGs
Information systems

**Electronic Patient Record Systems**

*That simply replaces a patient’s paper file does not meet the definition of a medical device.*

**But** certain modules can be a medical device, e.g.:

- an image viewer with functionality for diagnosis based on digital images;
- a medication module.

**Aus dem Merkblatt der Swissmedic:**

Clinical Information Systems – CIS / Patient Data Management Systems – PDMS

...CIS/PDMS are not qualified as medical devices.

**But:** Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up (e.g. generate alarms) are qualified as medical devices.

Web systems for monitoring of data

- Modules that are intended to monitor non medical performance of medical devices do not fall under the scope of Medical Devices Directives (e.g. remote Maintenance Software)

**But:** Software modules on server(s) might be qualified in their own right as medical devices depending on their intended purpose

**Apps**

Apps are not separately mentioned in the MEDDEV, but they are to be treated like other SaMD.
What is applicable if a SW is a Medical Device?

Each Medical Device needs a **CE certification**.
This is as well applicable for **mHealth** Apps.

**Manufacturer have to maintain a Quality Management System, in most cases ISO 13485 is the best choice**

Following information is relevant if the concerned SW is a Medical Device in Europe (including Switzerland)

Next page: Normative Landscape for Medical Device SW (EU).
### Rough procedure for a CE-marking of a Medical Grade Software/App

<table>
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<tr>
<th>screening</th>
<th>review &amp; strategy</th>
<th>certification</th>
<th>operation</th>
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</thead>
<tbody>
<tr>
<td>• Clarify intended use and indication for use</td>
<td>• Gap analysis technical documentation</td>
<td>• proof safety</td>
<td>• Maintain certification</td>
</tr>
<tr>
<td>• Is it a medical device?</td>
<td>• Gap analysis technical documentation</td>
<td>• proof efficacy</td>
<td>• CAPA</td>
</tr>
<tr>
<td>• RA-Strategy</td>
<td>• Planning</td>
<td>• TechDoc, V&amp;V, Tests</td>
<td>• PMS (Post market surveillance)</td>
</tr>
<tr>
<td>• Classification</td>
<td>• Planning</td>
<td>• ev. Certification of legal manufacturer</td>
<td>• Handling of Adverse Events</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CE Marking</td>
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</tbody>
</table>
Alternative: outsourced CE certification by Decomplix

Medical Device Developer's Tasks for CE Marking

Decomplix Obtains and Maintains CE Marks

Start Here!
Validation of Stand-Alone-Software

- Validation against the intended use (inclusive clinical evaluation) is a requirement of EN ISO 13485 (chapter 7.3.6) and 21CFR820 chapter 820.3(z)(2) and 820.30(g).
- SW-validation is required in IEC 62304, but not really covered (SW-verification only)
- Actually, one has to create an own validation strategy (e.g. in the style of the strategies proposed in IEC 60601-1)
- Standard IEC 82304 closes this gap, but IEC 82304 is a draft only and not (yet) on the list of harmonized standards (EU, USA).
Validation can be quite extensive (and expensive): example of a glucose monitoring app from dexcom

<table>
<thead>
<tr>
<th>Dexcom G5 Mobile App</th>
<th>iPhone 4S, iPhone 5, iPhone 5C, iPhone 5S, iPhone 6, iPhone 6 Plus, iPhone 6S, iPhone 6S Plus, iPhone 7, iPhone 7 Plus, iPhone SE</th>
<th>iPhone 4S, iPhone 5, iPhone 5C, iPhone 5S, iPhone 6, iPhone 6 Plus, iPhone 6S, iPhone 6S Plus, iPhone 7, iPhone 7 Plus, iPhone SE</th>
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<tbody>
<tr>
<td>iPod touch 5th Gen, iPod touch 6th Gen</td>
<td>iPod touch 5th Gen, iPod touch 6th Gen</td>
<td>iPod touch 5th Gen, iPod touch 6th Gen</td>
</tr>
<tr>
<td>iPad 3, iPad 4, iPad Air, iPad Air 2, iPad Mini, iPad Mini 2, iPad Mini 3, iPad Mini 4, iPad Pro</td>
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<td>iPad 3, iPad 4, iPad Air, iPad Air 2, iPad Mini, iPad Mini 2, iPad Mini 3, iPad Mini 4, iPad Pro</td>
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<td>iOS 8.1.2, 8.1.3, 8.2, 8.3, 8.4, 8.4.1, 9.0, 9.0.1, 9.0.2, 9.1, 9.2, 9.3, 9.3.1, 9.3.2, 9.3.3, 9.3.4, 9.3.5, 10.0.1, 10.0.2, 10.0.3, 10.1, 10.1.1, 10.2, 10.2.1</td>
<td>iOS 8.1.2, 8.1.3, 8.2, 8.3, 8.4, 8.4.1, 9.0, 9.0.1, 9.0.2, 9.1, 9.2, 9.3, 9.3.1, 9.3.2, 9.3.3, 9.3.4, 9.3.5, 10.0.1, 10.0.2, 10.0.3, 10.1, 10.1.1, 10.2, 10.2.1</td>
<td></td>
</tr>
<tr>
<td>Samsung Galaxy S5, Samsung Galaxy S6, Samsung Galaxy S7, Samsung Galaxy Note 5, LG G4, LG G5, Nexus 6</td>
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<tr>
<td>Android Wear Watches</td>
<td>Android 5.0, 5.1.0, 5.1.1, 6.0 (LG 4 and Nexus 6 only), 6.0.1 (LG 5, Nexus 6, Samsung Note 5, Samsung S5, S6, and S7 only), 7.0 (Nexus 6 only)</td>
<td>Android Wear 1.3, 1.4, 1.5</td>
</tr>
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Helpful Links


Merkblatt der Swissmedic zum Thema „Eigenständige Medizinprodukte-Software“ (Jan 2016) [https://www.swissmedic.ch/medizinprodukte/02635/02645/index.html?lang=de&download=NHzLpZeg7t_Inp6lONTU042t2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCdd358e2ym162epYbg2c_JkJbNoKSn6A--](https://www.swissmedic.ch/medizinprodukte/02635/02645/index.html?lang=de&download=NHzLpZeg7t_Inp6lONTU042t2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCdd358e2ym162epYbg2c_JkJbNoKSn6A--)


FDA Guidance Document, Software as a medical Device, (SaMD), clinical evaluation [https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904)
ISS at a glance

- Fully dedicated to MedTech
- 30 high profile employees (Engineers, Scientists, Medical Doctors)
- Projects, services and products for MedTech companies in the fields of QM and Engineering Support, Regulatories, Software development
- Certified per ISO 13485, IEC 62304 etc., audited CRO services (BVMA)
- International customers in various subfields of the MedTech industry
- Dedicated to “Doing” rather than “Consulting only”
- Founded in 2003 as spin-off from Ziemer Group, an established manufacturer of ophthalmic High Tech devices
- Located in Biel, a core area of Switzerland’s watchmaking and high-tech industry
### ISS Services from a Project Perspective

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<td>RA-Intelligence</td>
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<td>RA Services</td>
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<td>Global Registrations</td>
<td>SW Validation</td>
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<tr>
<td>Clinical Srv.</td>
<td>Re-Registrations</td>
<td>Clinical Eval., Medical Writing, PMCF</td>
<td>Product Support</td>
</tr>
</tbody>
</table>

**BD**
Down-to-earth

**Q & Eng.**
Avoid problems

**RA Services**
Global Markets

**Clinical Srv.**
CRO for MedTech

**Software**
Applied IEC 62304

- Business Model Dev.
- Project Management
- Project Coaching
- ISO 13485/FDA 21CFR 820
- CAPA, Complaint handling
- RA Strategy
- Global Registrations
- RA-Intelligence
- PMS
- Cl. Strategy
- SW-Development
- Medical Writing, PMCF
- SW Validation
- Product Support

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Robert-Walser-Platz 7 | CH-2503 Biel | +41 32 513 67 67 | info@iss-ag.ch | www.iss-ag.ch

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