



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# Software as a Medical Device (SaMD) Basic elements & Qualification

**Frans Jacobs**

*Philips, Global Regulatory and Standards*

**Asian Harmonization Working Party**

*Bangkok, 4 Nov. 2015*





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# AGENDA

- > Basic elements and qualification
- > Relation between Health or Medical software





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# BASIC ELEMENTS AND QUALIFICATION





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD? (SOURCE IMDRF)

- “Software as a Medical Device” or “SaMD” is a IMDRF term so Software is a SaMD if it meets the IMDRF definition of a “Software as a Medical Device”
- A “Medical Device” is defined in local regulations and knows many interpretations
- Fortunately most countries follow the basics of the GHTF definition of a medical device, but
- The different interpretations (like for example FDA’s MMA or MDDS) continue to require a country-by-country approach





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD?

(SOURCE IMDRF)

- **SaMD definition:**  
Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
- Medical purposes as defined in GHTF/SG/N71: 2012.
  - *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
  - *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
  - *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
  - *supporting or sustaining life,*
  - *control of conception,*
  - *etcetera.....*





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD? (SOURCE IMDRF)

- But also:
  - provide means and suggestions for mitigation of a disease;
  - provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities;
  - be an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.





DITTA GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD? (SOURCE IMDRF)



## Exercise: Is it a medical Device?

Prenatal 3D / 4D imaging offer on website

- Claims:
  - We bring incredible images of your unborn baby to life. Our desire is to provide our knowledge and ultrasound skills to maximize your prenatal experience
  - Does this take the place of an ultrasound at my doctor's office? NO
  - We make no claims that 3D/4D as used in this examination is performed to better assess the baby for abnormalities.
- Do they use Medical Software to create the 3D images?
- FAQ section:
  - **What if a problem is seen during your scan?**  
Your doctor will be notified at once. That is why it is so important to choose a facility that hires experienced sonographers that are licensed through the (ARDMS) American Registry of Diagnostic Medical Sonography
- Does this change things?



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD?

(SOURCE IMDRF)



## Exercise: Is it a medical Device?

### Lesson:

- Not only the intended use and labeling determine whether a device is a medical device.
- The way devices are used or misused is very relevant.

### Conclusion:

- Manufacturers need to be aware of the way the devices are used.





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# When is software a SaMD? (SOURCE IMDRF)

## Examples SaMD:

Software used for dose planning to control the setting of oncology treatment devices	Yes
Software used to analyze stored long duration cardiac signal from an ECG	Yes
Software used for diagnostic image processing	Yes
Software used for calculating, estimating, modeling or predicting surgical placements or dosimetry regimes	Yes
Software used with diagnostic test equipment for Alzheimer syndrome determination or	Yes
Software used during the design and manufacturing processes of medical devices	No
Software used for administrative handling of patients	No
Software used for the education of medical doctors	No





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# Relation between Health and Medical software





DITTA GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

(SOURCE IEC 82304-1)

## Definitions:

- **HEALTH**

state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[SOURCE: WHO definition (WHO 1946)]

- \* **HEALTH SOFTWARE**

software intended to be used specifically for managing, maintaining or improving HEALTH of individual persons, or the delivery of care

Note 1 to entry: **HEALTH SOFTWARE fully includes what is considered software as a medical device** (see Rationale Annex A.1).

Note 2 to entry: The scope of this standard refers to the subset of HEALTH SOFTWARE that is intended to run on general computing platforms.





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

## Medical and health software: software essential for providing healthcare

- Can drive medical hardware
- Can be a product in itself
- Can have a medical purpose
- Can have a health-related purpose
- Can drive health supporting hardware

And as IEC 82304-1 proposes; “health software” includes medical software





DITTA GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

(SOURCE IEC 82304-1)

## Health Software

*software intended to be used specifically for  
managing or improving health of individual  
persons, or the delivery of care*

Health Software  
fully incorporates  
Medical Software  
without a clear  
dividing line.

## Medical Software

*No single definition for all jurisdiction  
No clear boundary*





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

(SOURCE IEC 82304-1)

## Examples Health software:

SW-only products for health use	Yes
Mobile apps without “applied parts” (*)	Yes
Laboratory information SW	Yes
Radiology information SW	Yes
SW for individuals in fitness <u>centres</u> ,	Yes
SW for finding best conception moment	Yes
Computer-aided diagnosis SW	Yes
Analysis SW for medical images	Yes
SW not addressing health issues for individuals	No
Hospital billing SW	No
Hospital equipment maintenance scheduling SW	No
Epidemiological study SW	No



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

(SOURCE IEC 82304-1)

## Examples Health software :

Clinical Decision Support software used to aid diagnosis, treatment, and health management of individuals	Yes
Individual stress relief SW with feedback	Yes
Training plan SW for revalidation purposes	Yes
SW for stimulating activity by Alzheimer patients	Yes
Electronic Health Record systems, including Electronic Medical Record systems	Yes
Hospital information systems	Yes
Nurse training SW	No
Self-study for medical professionals	No
Electronic logbook for nursing home	No
Medical electrical equipment or systems covered by the IEC 60601 series	No

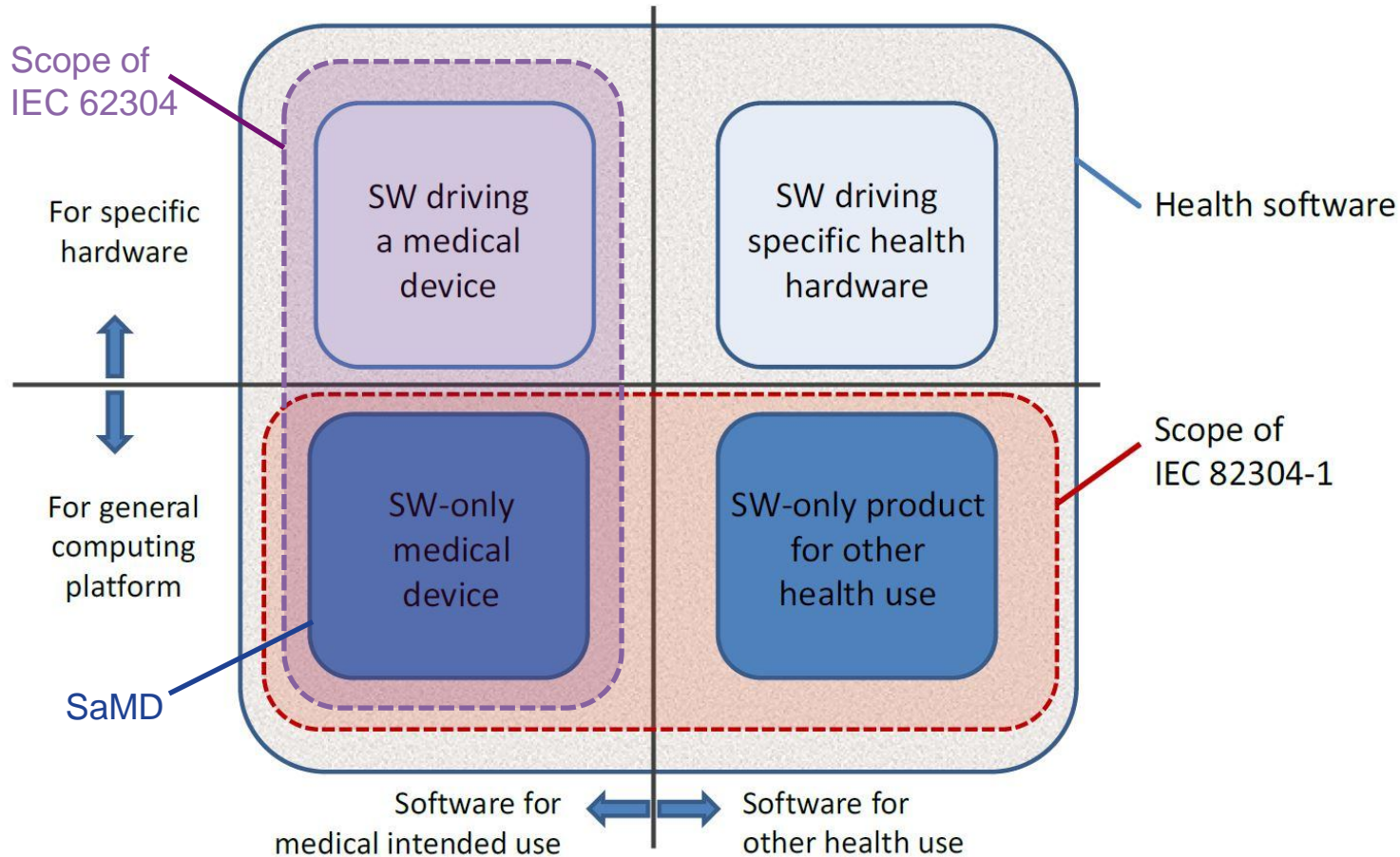




DITTA GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# RELATION HEALTH AND MEDICAL SOFTWARE

(SOURCE IEC 82304-1)







# DITTA

GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# THANK YOU!

