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Software as a Medical Device (SaMD) International Classification Introduction IEC 62304 / IEC 82304-1

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Asian Harmonization Working Party

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AGENDA

> International Classification

> Introduction of IEC 62304 and IEC 82304-1

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INTERNATIONAL CLASSIFICATION

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STANDALONE SOFTWARE
What is SaMD?

"Software intended to be used for one or more medical purposes that perform these purposes without being part of a medical device"
(Source: IMDRF 2013)

"Software which is not incorporated in a medical device at the time of its placing on the market or its making available"
(source: European MEDDEV 2.1/6 2012)

"Software intended to run on general purpose computers"
(source: FDA Murray 2010))

"Software that is intended for use as a MEDICAL DEVICE"
NOTE This includes a MEDICAL DEVICE software product, which then is a MEDICAL DEVICE in its own right.
(source: IEC 62304 Ed.1.1 2015)

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STANDALONE SOFTWARE

Classification Risk Based; FDA

2005, FDA defines a Major, Moderate or Minor "Level of Concern"

An estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use.

- **Major**
  - if a failure or latent flaw could **directly result in death or serious injury** to the patient or operator
  - if a failure or latent flaw could **indirectly result in death or serious injury** of the patient or operator through incorrect or delayed information or through the action of a care provider.
- **Moderate**
  - if a failure or latent design flaw could **directly result in minor injury** to the patient or operator.
  - if a failure or latent flaw could **indirectly result in minor injury** to the patient or operator through incorrect or delayed information or through the action of a care provider.
- **Minor**
  - if failures or latent design flaws are **unlikely to cause any injury** to the patient or operator.

(Source: FDA Guidance 337 2005)

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STANDALONE SOFTWARE

Classification Risk Based, IEC 62304 Ed 1.0

2006, IEC 62304 Ed. 1.0 defines Software Safety Classes A, B and C

The MANUFACTURER shall assign to each SOFTWARE SYSTEM a software safety class (A, B, or C) **according to the possible effects** on the patient, operator, or other people resulting from a HAZARD to which the SOFTWARE SYSTEM can contribute.

The software safety classes shall initially be assigned based on severity as follows:

- Class A: No injury or damage to health is possible
- Class B: Non-SERIOUS INJURY is possible
- Class C: Death or SERIOUS INJURY is possible

*Classification can be reduced form C to B or B to A by a **hardware risk control measure***

(source: IEC 62304 Ed. 1.0 2006)

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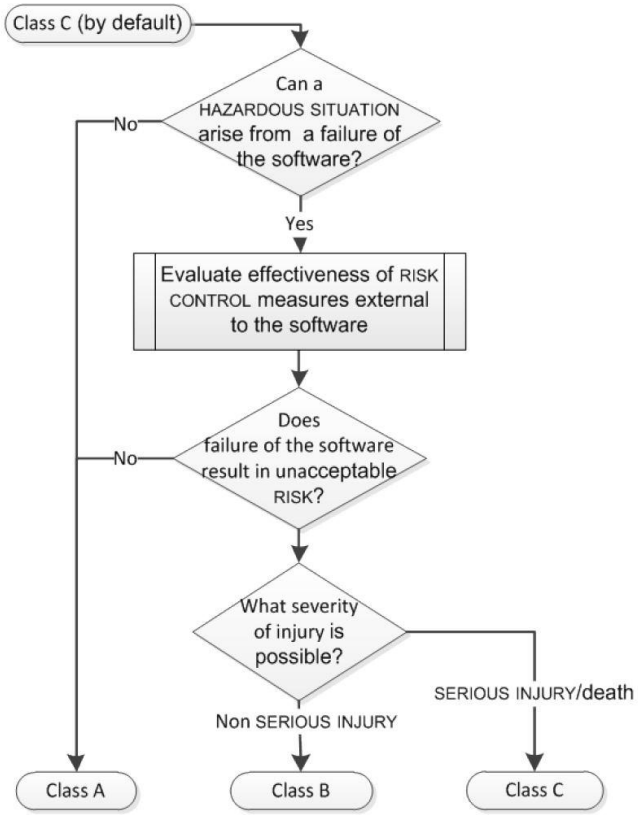
STANDALONE SOFTWARE

Classification Risk Based; IEC 62304 Ed 1.1

2015, IEC 62304 Ed. 1.1 introduces RISK of HARM and a flowchart approach

The MANUFACTURER shall assign to each SOFTWARE SYSTEM a software safety class (A, B, or C) **according to the RISK of HARM** to the patient, operator, or other people resulting from a HAZARDOUS SITUATION to which the SOFTWARE SYSTEM can contribute in a worst-case scenario
(source: IEC 62304 Ed.1.1 2015)

*For B and C classified systems, classification can be reduced by applying **risk control measures external to the software system***



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STANDALONE SOFTWARE

Classification Risk Based; IMDRF

IMDRF defines principles for "Categorization" in 4 levels (I, II, III, IV)

The four categories (I, II, III, IV) are based on the levels of impact on the patient or public health where accurate information provided by the SaMD to treat or diagnose, drive or inform clinical management is vital to avoid death, long-term disability or other serious deterioration of health, mitigating public health.

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

(Source: IMDRF 2013)

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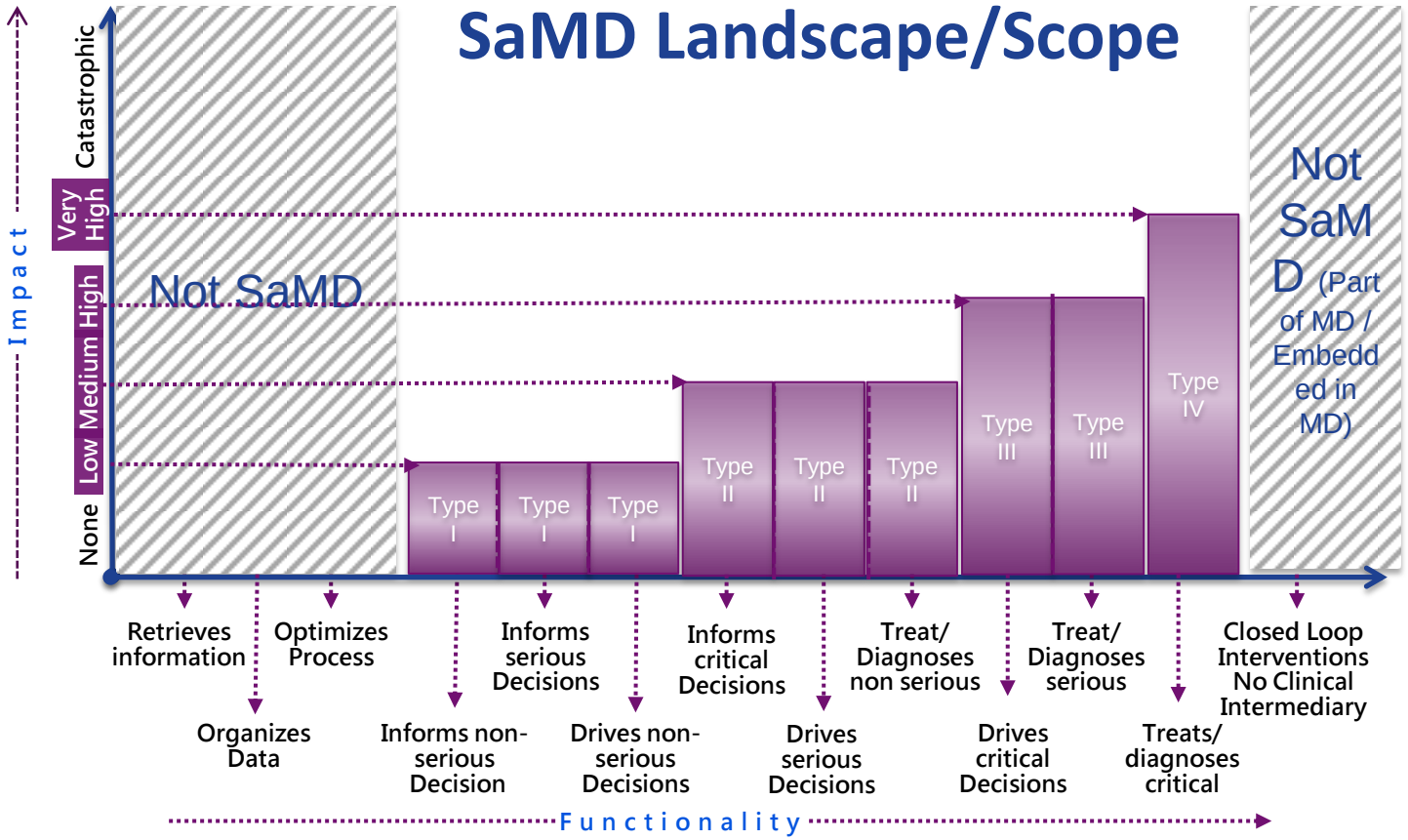
STANDALONE SOFTWARE

Classification Risk Based; IMDRF



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STANDALONE SOFTWARE

Classification Risk Based; EU MDD

Scope IEC 62304 for development

2007, EU's Medical Device Directive 93/42/EUintroduces Software. 2012, MEDDEV 2.1/6 provides guidance

Stand alone software that meets the definition of a medical device shall be considered as an **active medical device.** This means that rules 9, 10, 11 and 12 of Annex IX to Directive 93/42/EEC may apply.

Rule	Active device type
Rule 9	Active therapeutic devices are in IIa or IIb
Rule 10	Active diagnostic devices are in IIa or IIb and, Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology are in IIb
Rule 11	Active devices intended to administer and/or remove medicines are in IIa or IIb
Rule 12	All other active devices are in Class I

(source: MEDDEV 2.1/6 2012)

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STANDALONE SOFTWARE Classification Risk Based

General overview of IMDRF, FDA, EU and IEC 62304

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision			Classification		
	Treat or diagnose	Drive clinical management	Inform clinical management	FDA	EU	IEC 62304
Critical	IV	III	II	Major	IIb	Class C
Serious	III	II	I	Major	IIa	Class C
Non-serious	II	I	I	Moderate	I-IIa	Class B
No risk				Minor	I	Class A

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Introduction of IEC 62304 and IEC 82304-1

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IEC 62304 - IEC 82304-1

(SOURCE IEC 62304)

Purposes of IEC 62304 and IEC 82304-1

- IEC 62304:
  This standard defines the life cycle requirements for MEDICAL DEVICE SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this standard establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.
- IEC 82304-1:
  This International Standard applies to the SAFETY of HEALTH SOFTWARE PRODUCTS designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for MANUFACTURERS.

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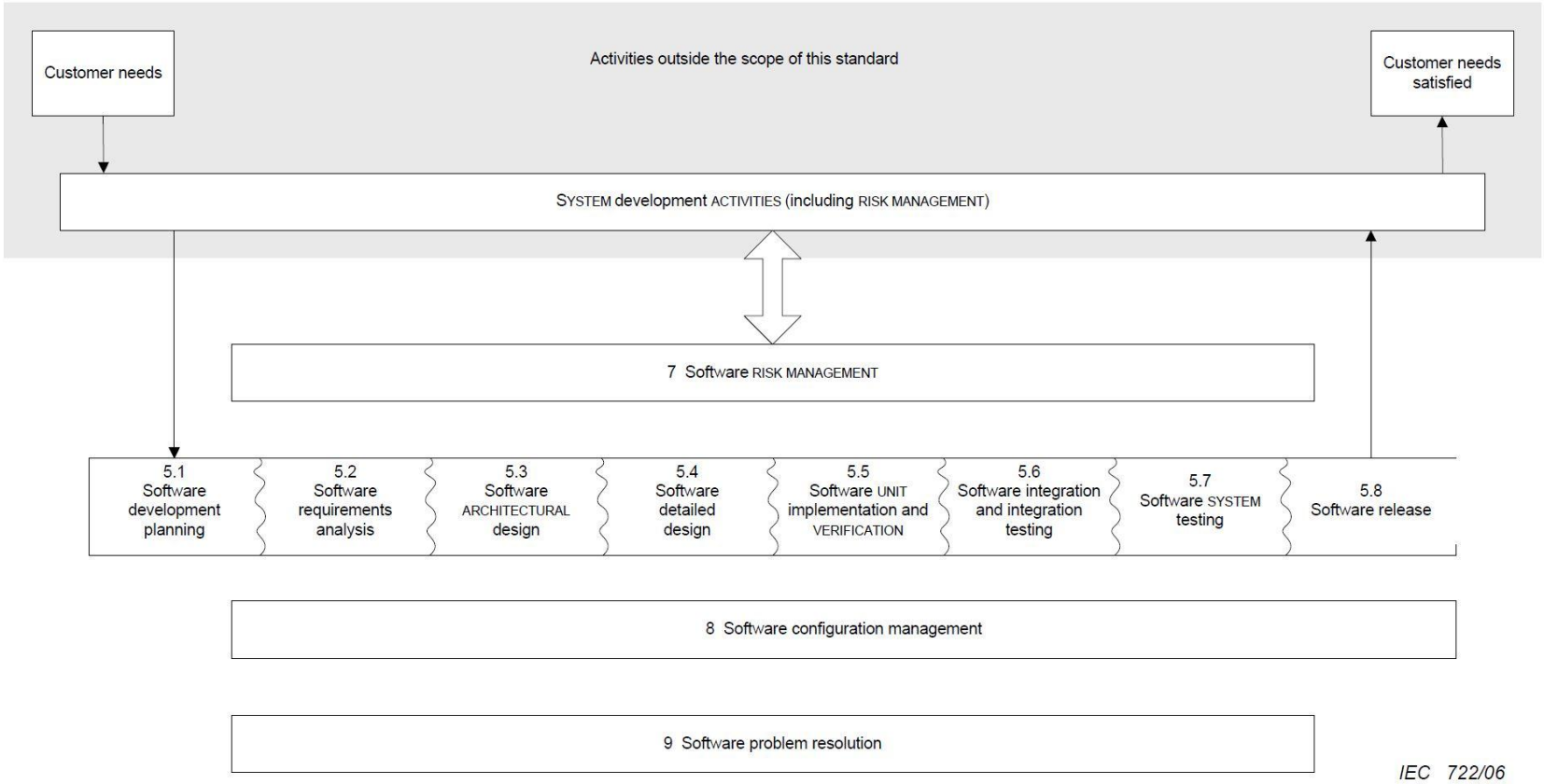
IEC 62304 - IEC 82304-1

(SOURCE IEC 62304)

Scope IEC 62304 for development



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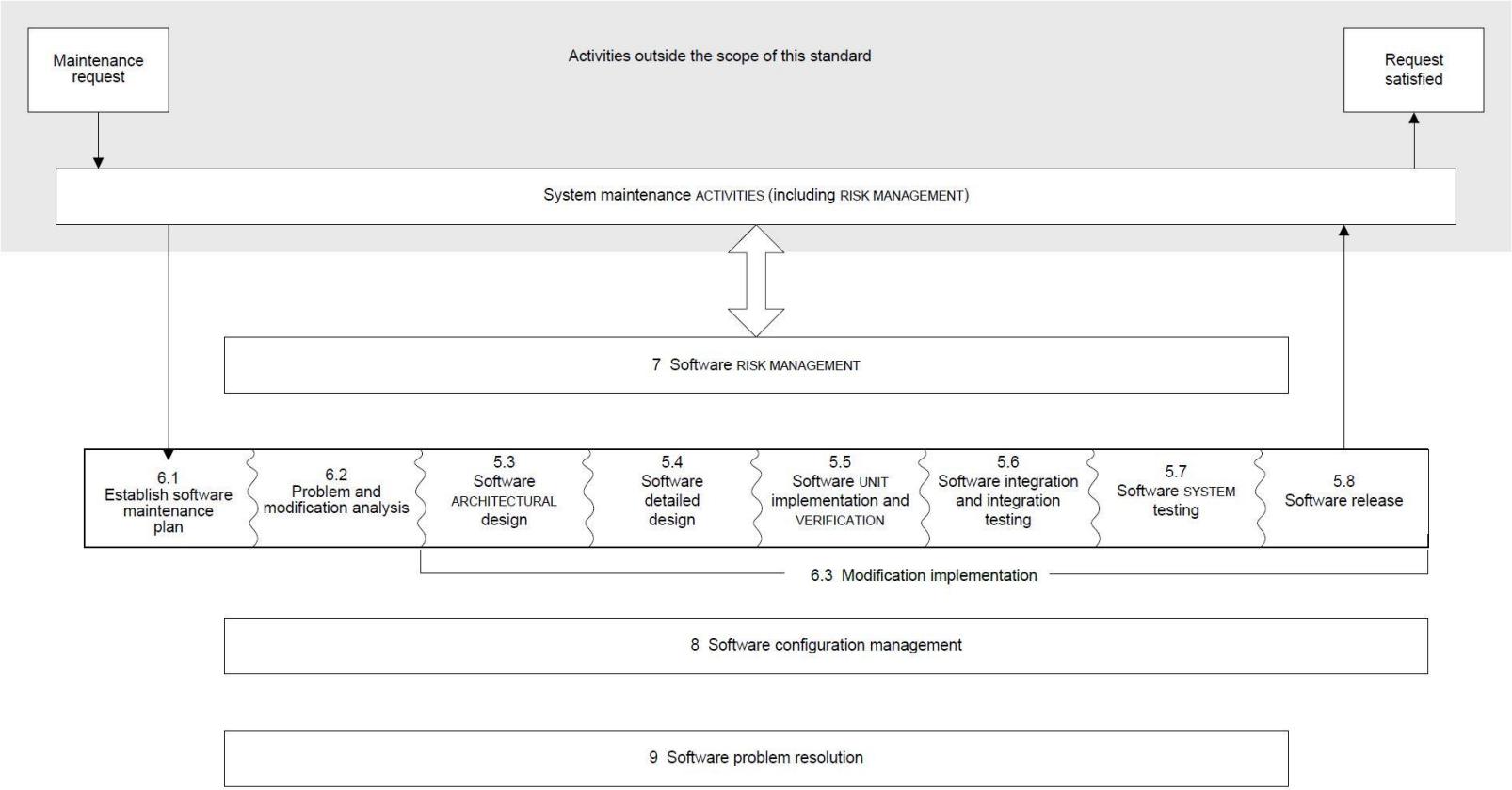
IEC 62304 - IEC 82304-1

(SOURCE IEC 62304)

Scope IEC 62304 for maintenance



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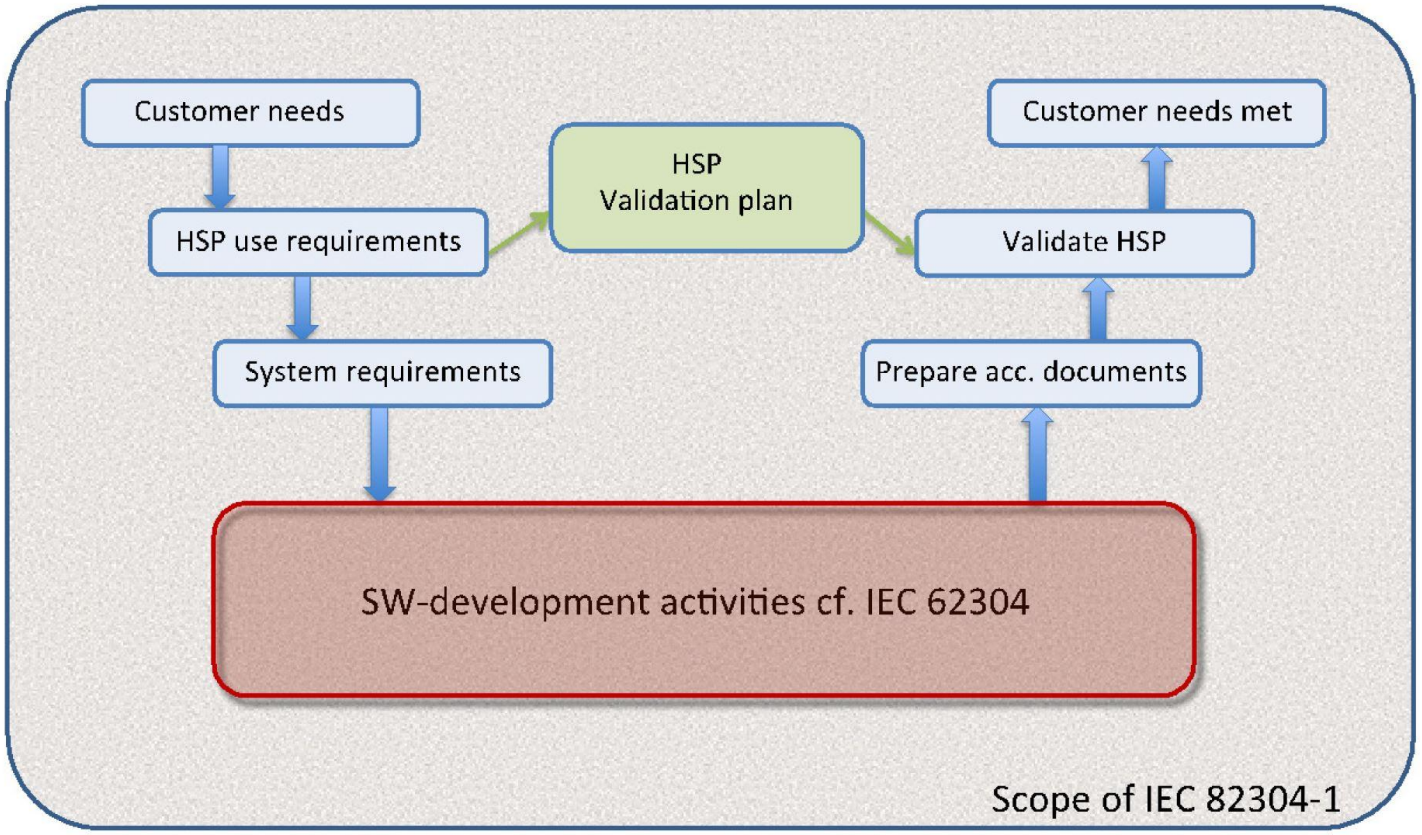
IEC 62304 - IEC 82304-1

(SOURCE IEC 82304-1)

Scope IEC 82304-1 using IEC 62304 as a “plug-in standard”



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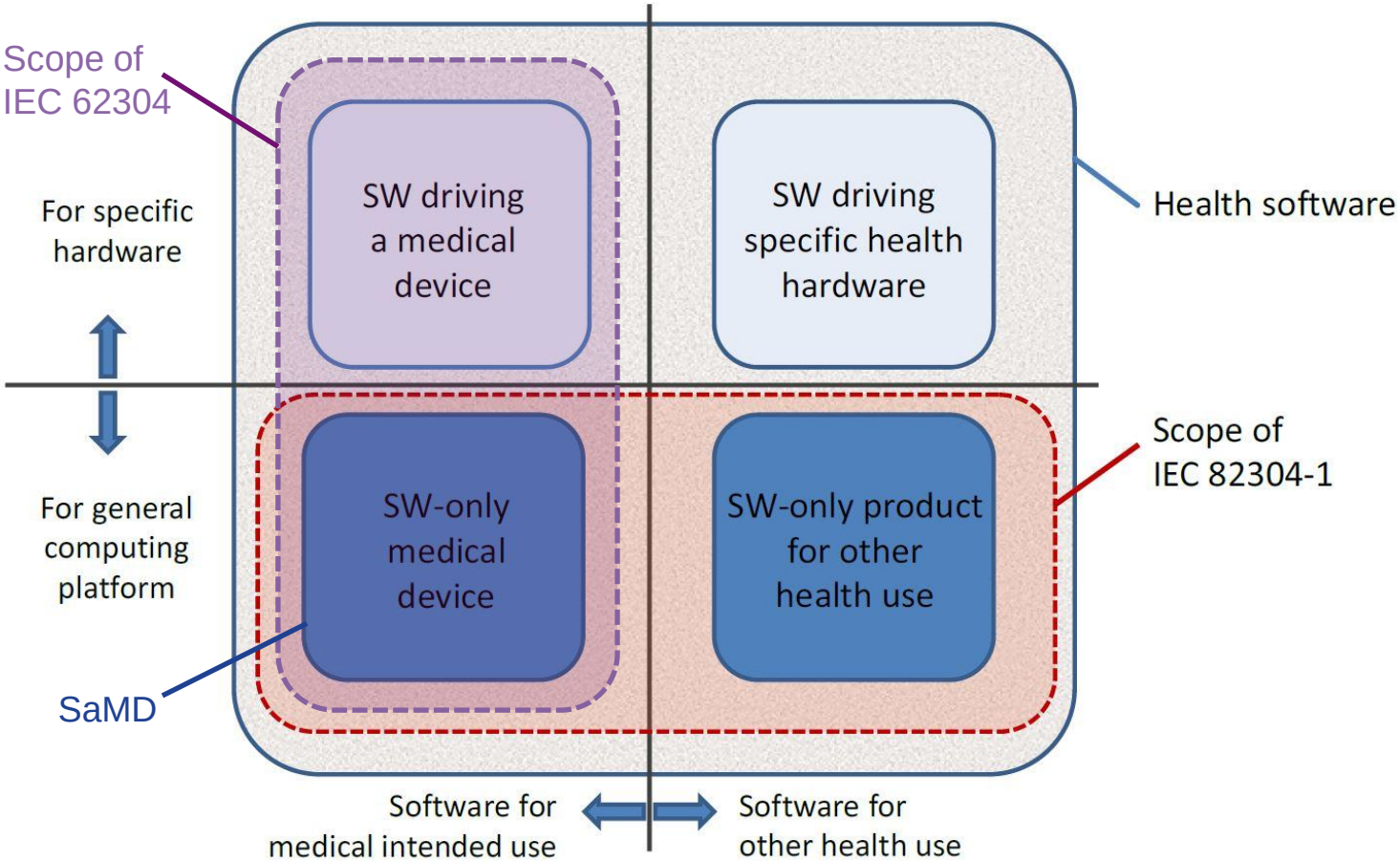
IEC 62304 - IEC 82304-1

(SOURCE IEC 82304-1)



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THANK YOU!

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