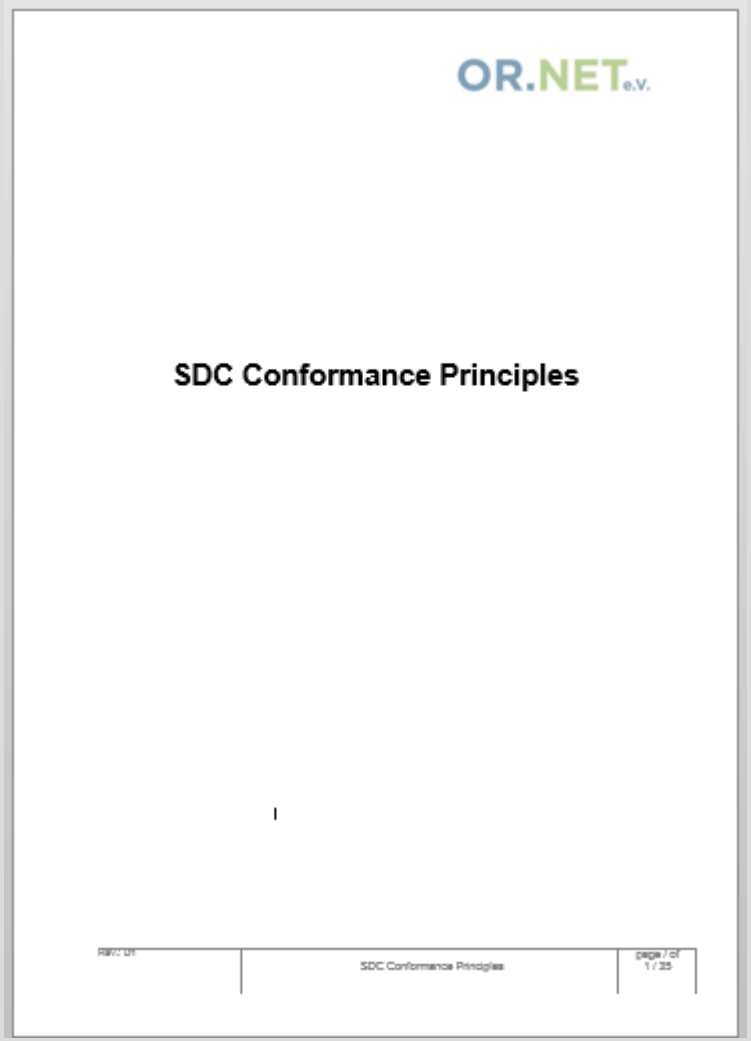
OR.NET e.V.

SDC Conformance Principles

SERVICE-ORIENTED DEVICE CONNECTIVITY

2019-05-07, OR.NET Regulatory Affairs

SDC Conformance Principles

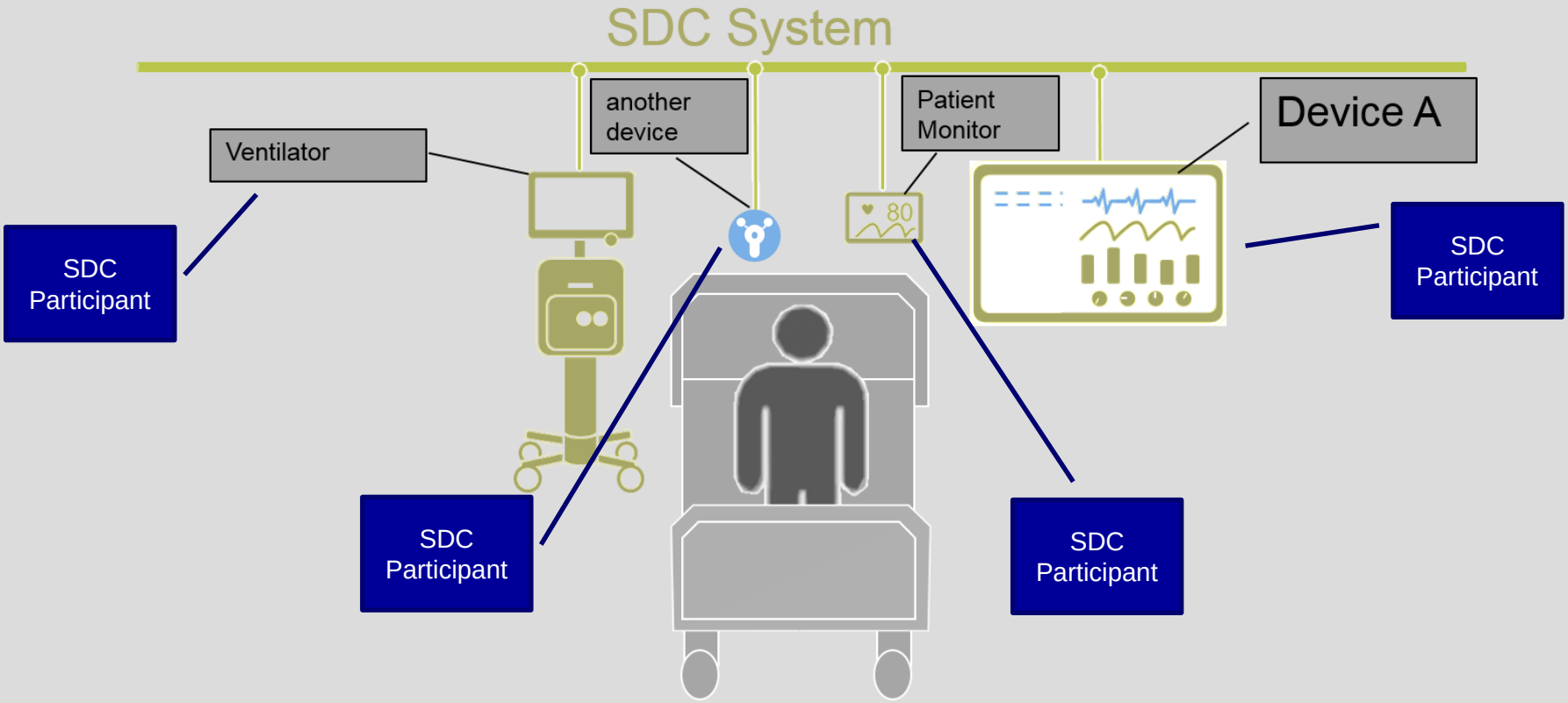


WORK IN PROGRESS

This document describes the **concepts**

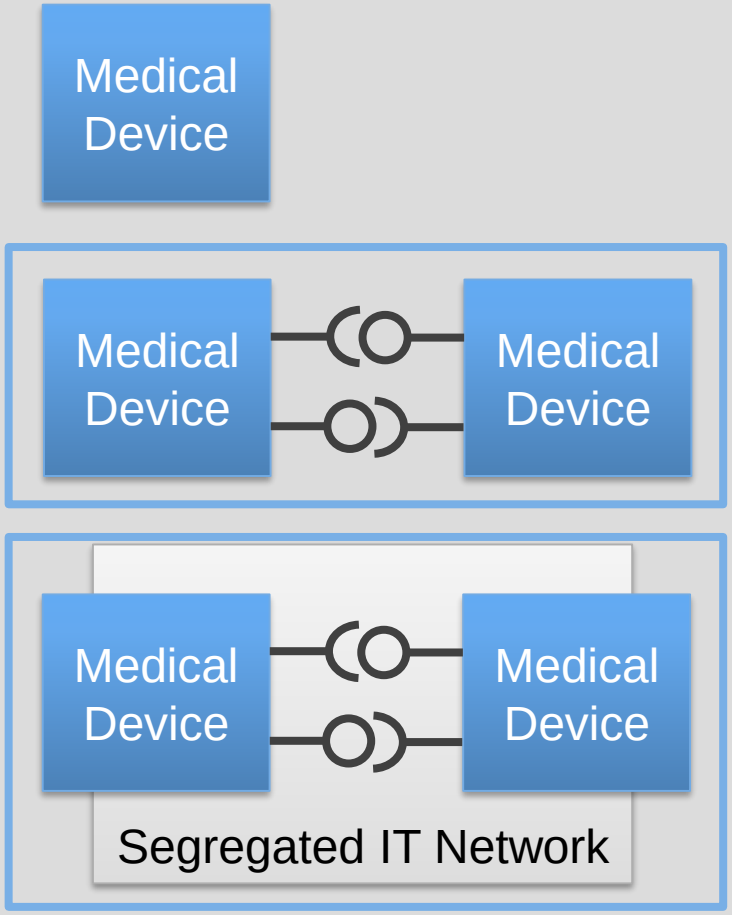
- how **SAFETY** and **EFFECTIVENESS** of these Medical Devices and their **SYSTEM FUNCTIONS CONTRIBUTIONS** is achieved
- and defines **rules** for the **development** of an SDC Participant and for **post-production activities** of the manufacturer.

The Challenge
SDC System



- SDC Participants are intended to support combinations with 3rd party SDC Participants via the Medical IT-Network

The Challenge
Conventional Medical Devices



Safety, security, and efficiency is primarily in responsibility of one medical device manufacturer

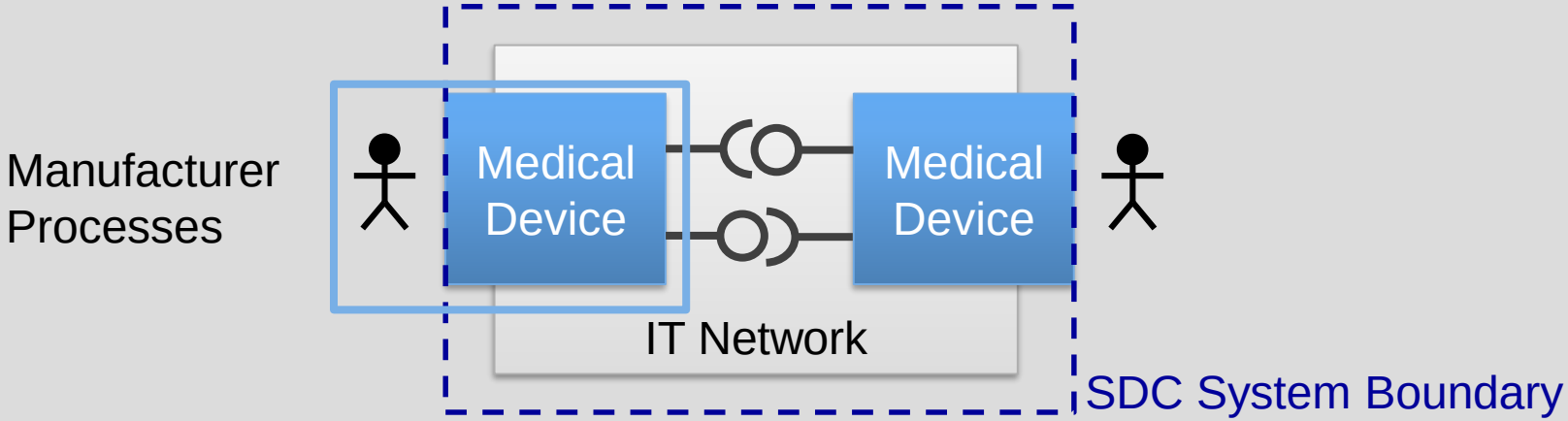
- Standalone Devices, e.g. Anesthesia System
- Device Combinations, e.g. Patient Monitor + Anesthesia System
- Device Combinations communicating via a network, e.g. Patient Monitor-Gateway

Safety & effectiveness of the combinations and systems is ensure by the Manufacturer

Intended combinations are considered in all development processes

The Challenge
Unspecified device combinations

System Functions are provided by the combination of two Participants communicating over the Medical IT-Network.
An SDC System is build by a Responsible Organization using SDC Participants from potentially different Manufacturers.



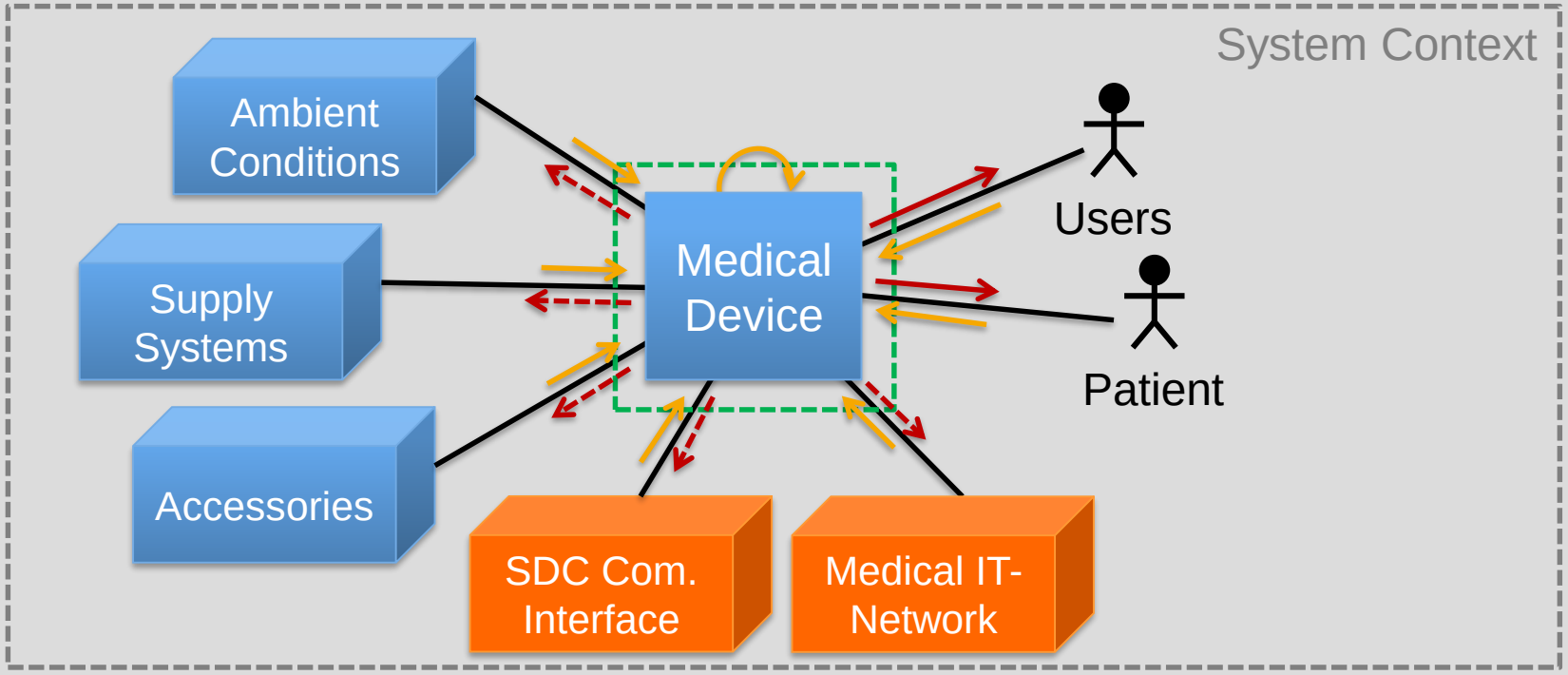
SDC Systems is not only about developing “the system”

Manufacturers need to develop SDC Participants (Medical Devices, UI Software, …) that can be used safe and effectively

- in unspecified systems
- in combination with “SDC conformance” products

The Challenge
The unknown system context

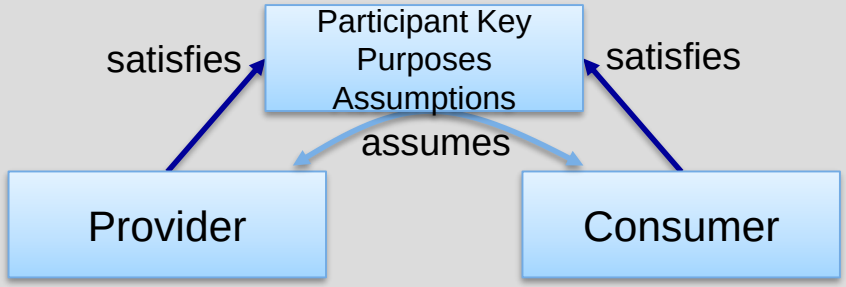
- System context is extended by SDC communication interface and related system function contributions
  - – intended to affect the clinical function of the SDC Participant → new causes
  - – intended to affect the clinical function of other SDC Participants → new hazards
- System context is extended by Medical IT-Network → new causes



Make reasonable assumptions about the Medical IT-Network, verify System Function under given assumptions, specify them in the IfU, monitor critical network characteristics

Consider generic System Functions, make assumptions how the responsibilities for the system function is split up into System Function Contributions for the SDC Participants and allocate them to Participant Key Purposes (Roles, Actors).

Ensure that only SDC Participants that satisfy all assumptions on their Participant Key Purposes can participate in a system function



Each SDC Participant can trust that all other SDC Participant will satisfy the Participant Key Purpose assumptions

Each SDC Participant evaluates safety and effectiveness based on the documented assumptions about other Participant Key Purposes

The assumptions on other SDC Participant include more than assumptions about the technical implementation

How are system functions considered in the risk management?

E.g., are risk related to unintended SDC Participant bindings are mitigated?

Which part of a system function is tested during usability evaluation?

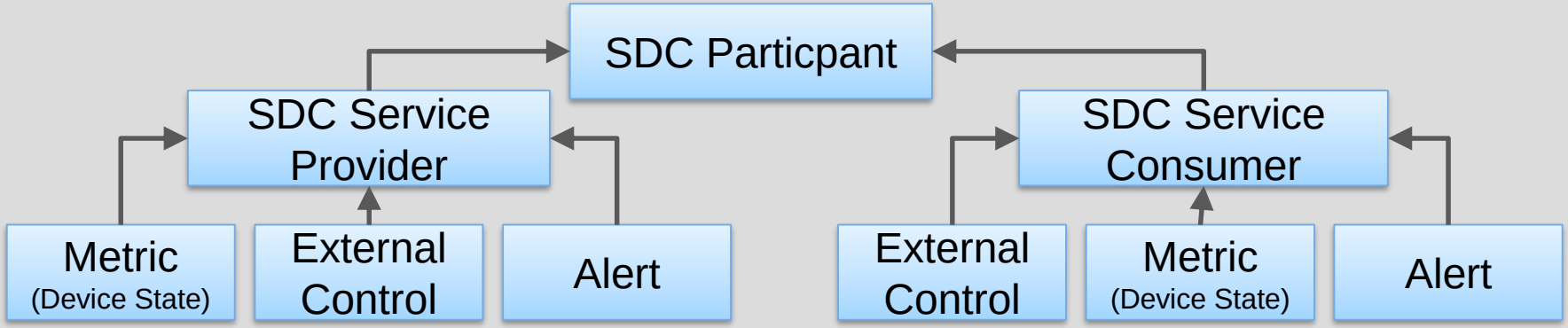
How are system functions verified?

- Scope and content of an interface test
- Scope and content of tests in a representative system
- Content of tests when integrating the SDC Participant in an actual SDC System

Where are complaints related to systems functions reported?

We claim Medical Devices are safe and effective when used in an SDC system
→ This will not be ensured by technical requirements alone

The Concept
Allocate responsibilities to Key Purposes



SDC supports different types of data exchange between two SDC Participants

These are more or less suitable to support different system functions, e.g., remote display, external control

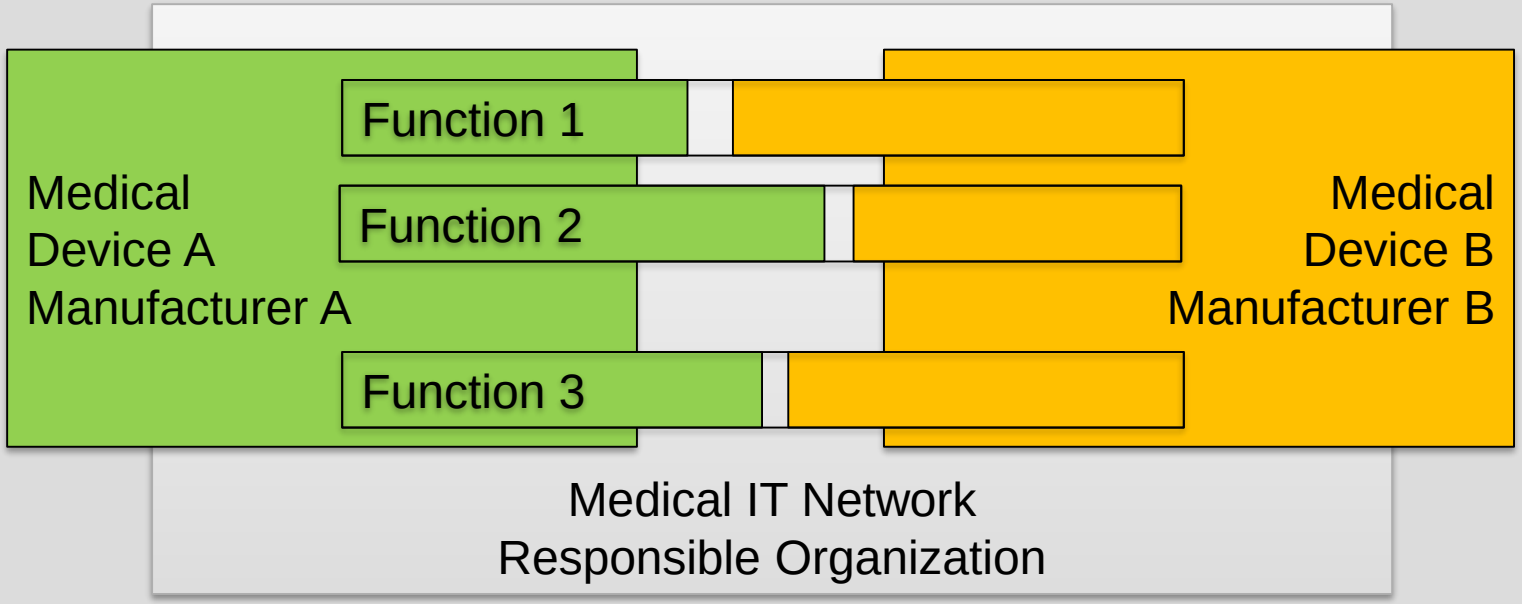
For each type of data exchange we specify a Participant Key Purpose (Role) for each of the two involved SDC Participant

We allocate responsibilities to each of these Participant Key Purpose

For more specific functions we can derive specific Participant Key Purposes, e.g., “Metric Provider” vs. “Metric Provider for FiO2 Closed Loop” vs “Metric Provider for HF Device”

A derived specific Participant Key Purpose can take responsibilities for specific clinical functions

The Concept
Consistently split responsibilities

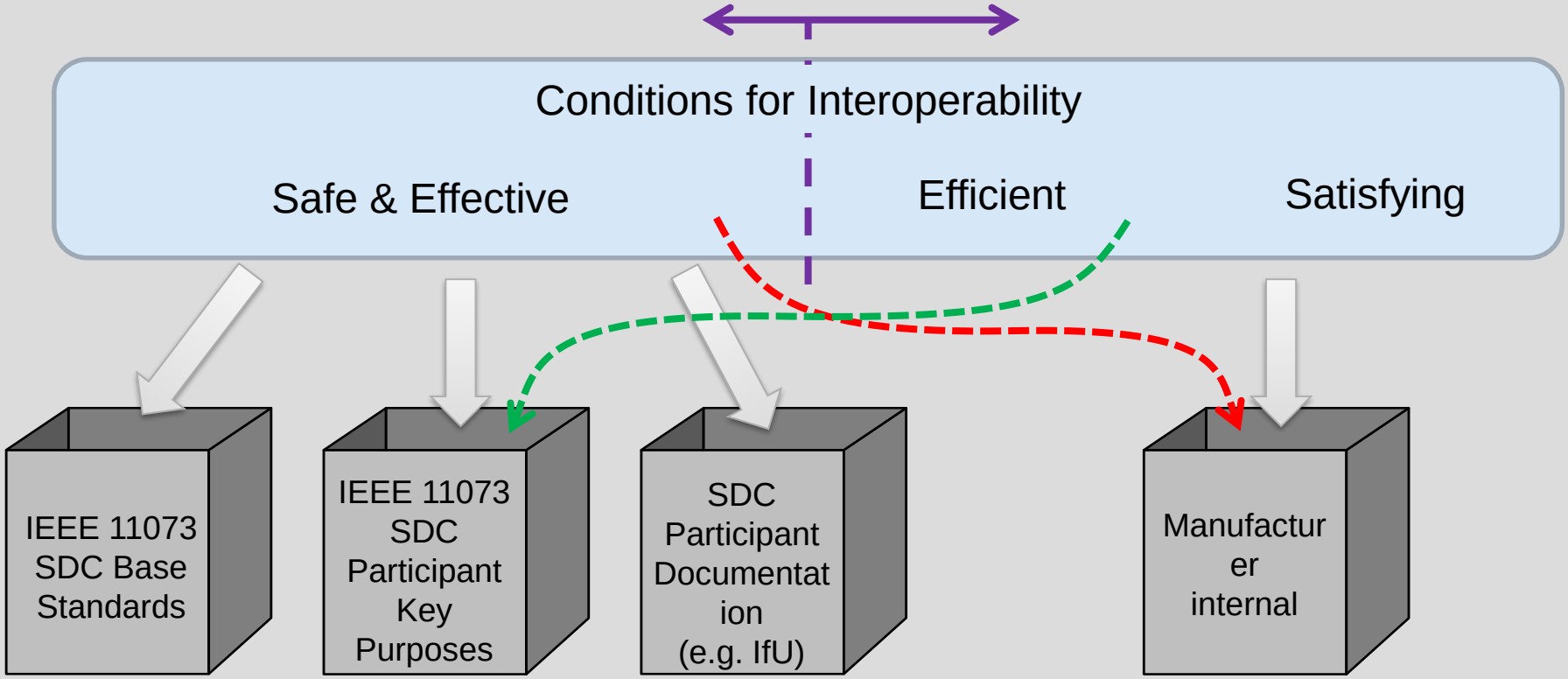


Clear guidance is required for all related processes to prevent any gaps and to ensure consistency:

- Quality, Risk Management, Verification, Usability, Approval
- Definition, Design

An SDC Participant cannot take the responsibility for a function that it does not have or for properties it cannot verify

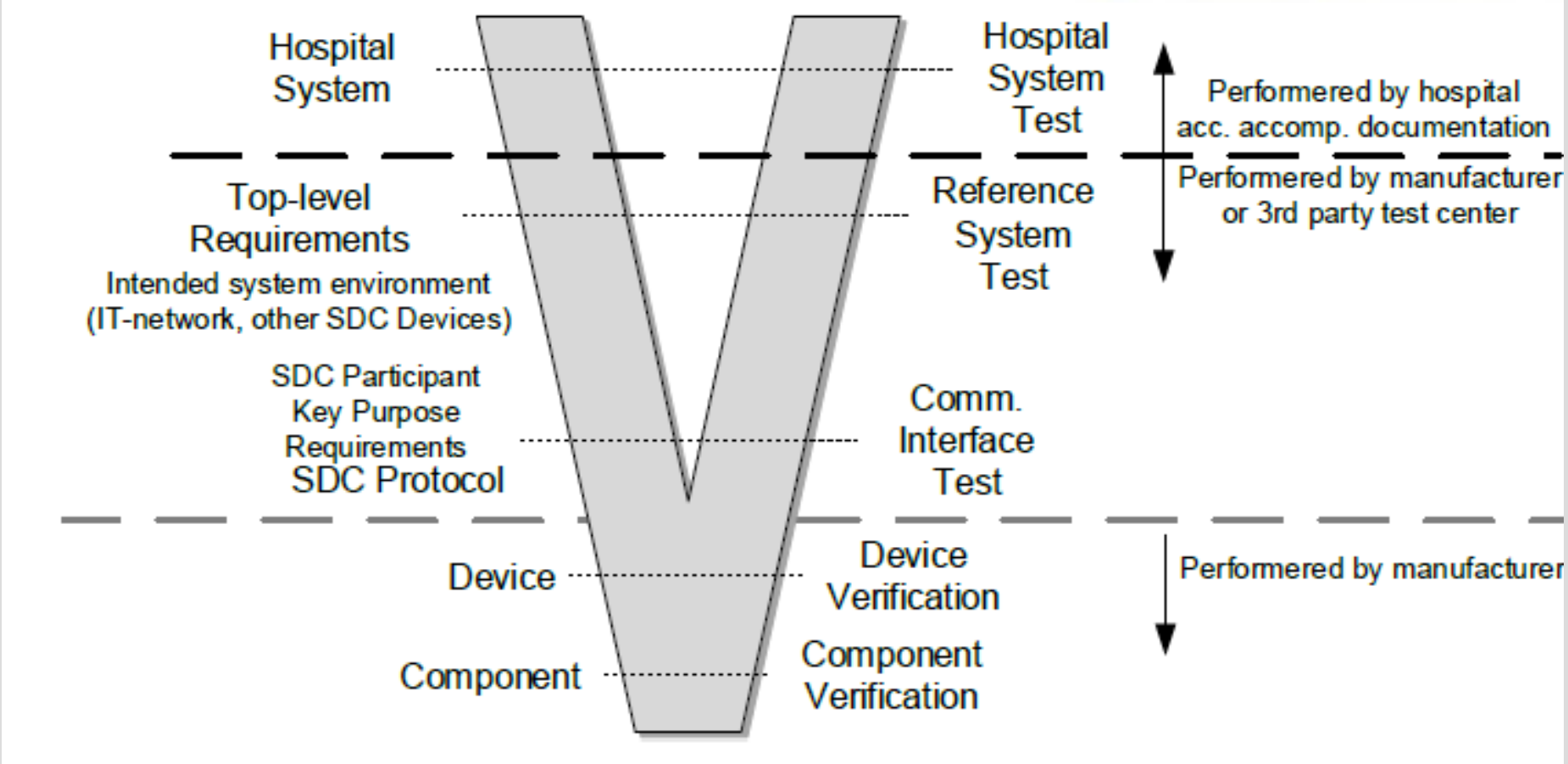
The Buckets
Where to put assumptions



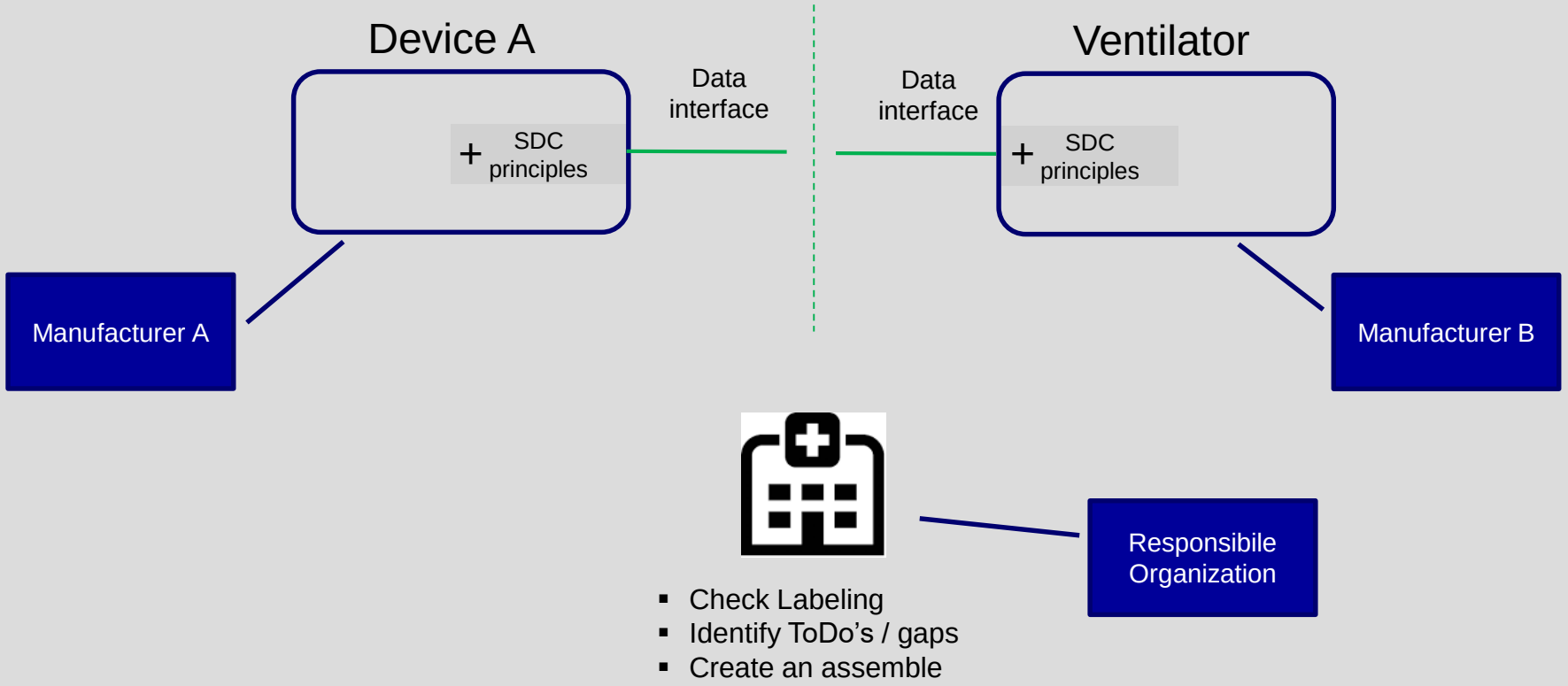
System Functions shall be available if all requirements of SDC, SDC Participant Key Purpose, and Documentation (e.g. IfU) are met

Manufacturer will have additional requirements, e.g. to harmonize UI and provide further customer expectations

Verification of Technical Requirements
Methods of Verification



Responsible Parties



SDC Systems are brought to life by Responsible organizations

Thank you for your attention.