SDC Conformance Principles

Notes Regarding this Document:

- This document represents the consensus view of the “OR.NET e.V.” association (OR.NET association) Regulatory Affairs-Team on SDC Conformance Principles and their utilization for placing SDC-enabled products on the market. The content of this document is planned to be standardized in the future.

Change- Log:

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Abbreviations and Definitions:

Abbr. / Def.	Description
Intended Use, Intended Purpose	Objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. [GHTFT]
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • 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, • disinfection of medical devices, • providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means. [GHTFT] Note: For the purpose of this document, a Medical Device furthermore provides support for electronic communication.
Medical Device Manufacturer (Manufacturer)	Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). see [GHTFT]
System Function	Clinical functionality provided by a system of Medical Devices, that are either physical device or software, and that are connected by a IT-Network.
System Function Contribution	Function of a device that add value to an overall System Function.

Abbr. / Def.	Description
SDC System	Instance of a Service-Oriented Medical Device System as defined in [11073-20701] that is operated on a Medical IT-Network
Service	Part of a software system that exposes functional capabilities on a IT-Network.
Service Consumer	Network node that utilizes at least one Service.
Service Provider	Network node that provides at least one Service
SOMDS	Instance of a distributed system that implements a service-oriented architecture composed of Service Providers and Service Consumers as defined in [11073-10207].
SDC	Service-oriented Device Connectivity
IEEE 11073 SDC Communication Protocol	IP-based service-oriented protocol supporting interoperability between devices acc. to IEEE SDC standards family: • [11073-10207] • [11073-20702] • [11073-20701]
SDC Participant	Medical or non-medical device, physical device or software on its own, that implements the SDC Communication Protocol either with the SDC Participant Key Purposes as SDC Service Provider or SDC Service Consumer or both.
SDC Participant Key Purpose	Set of requirements an SDC Participant is conforms to and that allows it to act in a SOMDS accordingly. See [11073-20701] Note: An SDC Participant Key Purpose can be a set of requirements that guarantees Safe and Effective communication with SDC Participants that participate in a System Function, e.g. external control of a Medical Devices. Moreover, an SDC Participant Key Purpose can be a set of requirements that guarantees Safe and Effective communication with SDC Participants that represent specific Medical Devices contributing to a System Function such as patient monitors, ventilators, infusion pumps, endoscopic camera system, insufflators, endoscopic light sources, dissectors.

Abbr. / Def.	Description
SDC Conformant Participant	SDC Participant that conforms with the principles outlined in this document, the requirements specified in related SDC Participant Key Purpose Definitions and the applicable sections of the SDC Roles & Responsibility
SDC Roles and Responsibilities	Document specifying requirements for SDC Conformant Participants and their manufacturers
Instructions for Use, IfU	Instructions for Use
TLS	Transport Layer Security
Governance Body	Entity responsible for assessing conformance of an SDC Participant and managing the conformance requirements.
Responsible Organization	Entity accountable for the use and maintenance of a Medical IT-Network and the Medical Devices.[VDE]
System Integrator	Organizations that place SDC Systems on the market.
Medical IT-Network	IT-Network that incorporates at least one Medical Device
Safety	Freedom from unacceptable risk
Effectiveness	Capability of producing a desired result or the ability to produce desired output
Efficiency	
X.509 certificate	Digital as defined in RFC 5280 that allows to verify that a public key belongs to the user, computer or service identity contained within the certificate.
Clinical Workplace	Set of Medical Devices that interacts with, monitors, or provides treatment to a single patient, or is setup to interact with, monitor, or provide treatment to a single patient by some other means. [11073-20701]
Labelling	Labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article at any time while a Medical device is held for sale after shipment or delivery for shipment in interstate commerce. Examples: IfU, technical Documentation

References

Abbr. / Def.	Description
[11073-10207]	P11073-10207™ Standard for Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication (2017)
[11073-20702]	P11073-20702™ Draft Standard for Medical Device Profile for Web Services (2016)
[11073-20701]	P11073-20701™ Draft Standard for Service-oriented Medical Device Exchange Architecture & Protocol Binding (2018)
[GHTFT]	Glossary and Definitions of Terms Used in GHTF Documents, 2012
[VDE]	VDE Study, Risk Management for IT-networks incorporating medical devices in operating theatre, ISBN 978-3-925512-17-9

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1 Intent and Scope

Medical Devices that support interoperability by offering a communication interface as defined by the IEEE 11073 SDC Communication Protocol are intended to be integrated into an IT-Network by a Responsible Organization such as a hospital organization (see section 3). By incorporating multiple of these Medical Devices into an IT-Network, the Responsible Organization creates a system of SDC Participants (SDC System).

By integrating SDC Participants into an SDC System, the Responsible Organization does not take over the responsibility of the individual Medical Device Manufacturers. This is because the Intended Use of each individual SDC Participant in the SDC System remains unchanged.

It is the responsibility of the Manufacturer, whose SDC Participant contributes to the function of the SDC System, to ensure that the functional contributions of the SDC Participant to the SDC System (System Function Contribution) are Safe and Effective in the intended context of use. The Manufacturer does not need to predefine which other specific SDC Participants are part of an SDC System and therefore cannot predefine the overall set of provided System Functions of an SDC System.

This document describes the concept of:

- Safety and Effectiveness of Medical Devices (SDC Participants) that form an SDC System, and qualifying how their System Function Contribution is achieved and
- the rules for development of an SDC Participant and the post-production activities required of the Manufacturer.

However it is important to note that implementing the IEEE 11073 SDC Communication Protocol alone will not be sufficient to ensure Safety and Effectiveness of all clinical System Functions (see section 5). For this reason, all responsible parties, e.g. Medical Device Manufacturers or Responsible Organizations, are required to follow the design principles laid out in this document. Especially Manufacturers need to satisfy all requirements related to the SDC Participant Key Purposes their SDC Participants claim to support in order to be an SDC Conformant Participant.

1.1 Intended Readers of this document

This document is intended for a variety of readers, and include the following:

a) Manufacturers of Medical Devices that support interoperability by offering an interface as defined by the IEEE 11073 SDC Communication Protocol, who intend to release their Medical Device as an SDC Conformant Participant shall understand the responsibility they take and the associated requirements. Additionally, this document may help to support the argument why such Medical Devices are safe and effective with regards to their System Functions Contributions.

b) Notified Bodies and Regulatory Authorities shall be able to understand how it is ensured
   - that these responsible parties satisfy their responsibility and associated requirements as a contributing SDC Conformant Participant,
   - how the responsibility for each System Function is covered completely and is consistently allocated to contributing SDC Conformant Participants (see Chapter 3),
   - and why a contributing SDC Conformant Participants contribution to a System Function can therefore be claimed as safe and effective on its own.

c) Responsible Organizations shall be able to understand which responsibilities they assume by creating and operating a Service-Oriented Medical Device System (SOMDS).

2 System Architecture

This chapter describes the basic architecture of an instance of a Service-Oriented Medical Device System (SOMDS) as defined in [11073-20701]. The instance of an SOMDS is called Service-Oriented Device Connectivity System (SDC System) and follows the principles described in this document.

In this context, an SDC Participant is a medical or non-medical device that is a physical devices or a software on its own or with an accessory that implements the IEEE 11073 SDC Communication Protocol [11073-20701] with either the SDC Participant Key Purposes of the SDC Service Provider or SDC Service Consumer or both.

The IEEE 11073 SDC Communication Protocol is an Internet Protocol based service-oriented protocol supporting interoperability between SDC Participants.

An SDC System does not normally contain a central instance that controls the interoperation between SDC Participants. SDC Participants are able to discover each other within the same Medical IT-Network. As described in the following section, SDC Participants themselves determine which other SDC Participants they will communicate with in the same network.

Due to the self-describing capabilities of the IEEE 11073 SDC Communication Protocol, the interoperability between SDC Participants is not limited to combinations predefined by a Manufacturer, but rather depends on the actual Services provided and required by the SDC Participants. Consequently, a new SDC Participant may provide new System Functions by leveraging the Services already provided by existing SDC Participants.

After the discovery, the SDC communication between two SDC Participant is cryptographically secured and monitored by the SDC Participant, such that failures of the Medical IT-Network or malicious attacks are detected and will only lead to a detected interruption of the communication.

2.1 System Configuration

SDC Service Consumer should use the context information provided by SDC Service Providers to determine with which SDC Service Providers they interoperate.

Besides the patient context, which if applicable identifies the patient a Medical Device is connected to, or the ensemble context, which identifies one or more logical groupings in which the Medical Device is currently operated, the location context is used for this purpose.

Each associated context has at least one identifier that uniquely identifies the context, e.g. the physical location of a device or more specifically the location where the device is or is setup to be applied to a patient. That means if two SDC Participants are associated to either the same validated patient, ensemble or location context based on a identifier, it can be assumed that they belong to the same Clinical Workplace and are connected to the same patient or are setup to be connected to the same patient

Depending on the SDC Participant, the context identifier may be configured during installation by a service user or during a clinical workflow by a clinical user. The Manufacturer has to provide guidance in the accompanying documentation on how to configure the context identifier and the Responsible Organization has to provide guidance for their users how to choose this identifier.

The SDC Participant Key Purposes define how the exact matching works and how potential conflicts are resolved.

2.2 Security

After two SDC Participant have discovered each other in an Medical IT-network, their subsequent SDC communication is cryptographically secured using Transport Layer Security (TLS) with mutual authentication. During the establishment of a communication, the TLS

mutual authentication forces each SDC Participant to authenticate each other via X.509 certificates, which includes a cryptographic signature of the issuer of the certificate. When the x.509 certificate of another SDC Participant is received, the issuer is checked against the SDC Participant's internally stored set of trusted issuers. According to [11073-20701], further communication may be restricted based on information from the x.509 Certificate or the certificate chain if necessary to achieve freedom from unacceptable risk.
The information from the x.509 certificate or the certificate chain can be further used to support different levels of trust and interoperability depending on the issuer of a certificate, e.g. external control might be limited.

Based on this method of authentication, an SDC Participant may provide additional measures of security to the Responsible Organization in order to prevent SDC communication with unauthorized SDC Participants, e.g. whitelisting or blacklisting of X.509 certificates based on the common name of the Distinguished Name in the X.509 certificates as defined in [11073-20701]. Alternatively the Responsible Organization may prevent unauthorized network access by means not requiring support by the SDC Participant.

2.3 Types of Data Exchange

Basically there are two types of data exchanges between SDC Participants, as follows:

1. Data disclosing the state of an SDC Service Provider to at least one SDC Service Consumer
2. Data generated by an SDC Service Consumer that is intended to control the state of an SDC Service Provider

The first type of data exchange is initiated by the Service Consumer that intends to consume the data. This type of data exchange is used e.g. for measurements, settings or alerts. The SDC Service Provider providing the data describes the available data and the Services available to retrieve this data by means of the IEEE 11073 SDC Communication Protocol. The SDC Service Consumer requests the data directly or subscribes to reports that convey information about the state of the providing SDC Service Provider.

In the second type of data exchange, the SDC Service Provider that is intended to receive data for a control request describes the available operations by means of the IEEE 11073 SDC Communication Protocol. This data exchange is initiated by the SDC Service Consumer sending the control request data. The control request data includes a handle, which identifies the operation to be executed by the SDC Service Provider. This type of data exchange is used to externally control the settings of other devices, e.g. from an SDC Service Consumer physically located at a remote or at the same location of the SDC Service Provider.

2.4 SDC Protocol Converters

Legacy devices not implementing the IEEE 11073 SDC Communication Protocol by themselves may contribute to an SDC System through a converter. Such a converter translates between the IEEE 11073 SDC Communication Protocol and a proprietary protocol supported by the legacy device. In this case the converter implementing the IEEE 11073 SDC Communication Protocol has to encapsulate the legacy device and represent its System Function Contributions. Even if the IEEE 11073 SDC Communication Protocol is implemented by the converter and not by the legacy device itself, this architecture decision is of no interest to other SDC Participants in the SDC System. It should be noted, that the protocol converter with its converting functionality is not considered to be a Medical Device per se, however it might be a critical component in the Medical IT-Network.

The same principle of encapsulation is applied to subsystems of devices communicating by different communication protocols: The device implementing the IEEE 11073 SDC Communication Protocol encapsulates these subsystems and represents their System Function Contributions.

3 Responsible Parties

The responsibility for Safety and Effectiveness of an SDC System cannot be taken by one device manufacturer alone, but has to be split up and clearly assigned to one of the involved legal parties. The SDC Conformance Principles considers the following to be legal parties:

Manufacturers of SDC Participants place SDC Participants on the market and disclose their System Function Contributions in the accompanying documentation, typically the Instructions for Use (IfU). If the System Function Contributions are only available when the Medical IT-Network satisfies specific preconditions, those preconditions must be disclosed in the accompanying documentation. Furthermore the Manufacturer needs to disclose any residual risks which must be considered by the user or the Responsible Organization operating the SDC Participant..

If a Manufacturer of an SDC Participant gains knowledge about safety and effectiveness related deficiencies in another Manufacturer's SDC Participant, he shall forward the information to the other Manufacturer of the respective SDC Participant. It should be noted that for medical devices each party assess this issue in accordance to the manufacturers established processes for post-market surveillance and vigilance.
Additionally, if a lack of specification within the set of design rules or standards is identified, the information shall be given to the Governance Body. Moreover, if the deficiency cannot be clearly allocated to one SDC Participant, the Manufacturer shall inform the Governance Body (see below).

Responsible Organizations are legal organizations that provide health care to patients, e.g. hospitals. They operate, inspect and maintain healthcare facilities, including buildings, technical equipment, IT-Networks, Medical Devices, and Medical IT-networks including patch management. Furthermore, they manage procedures within their facilities, including workflows, employees' responsibilities and qualification.
Responsible Organizations are responsible for putting Medical Devices into service and operating those Medical Devices in conformance with the Manufacturer's specification, i.e. the Instructions for Use and other accompanying documentation. With regards to an SDC System this specifically means that:

- the Medical IT-Network must fulfill the required network characteristics specified by the accompanying documentation
- tests required by the accompanying documentation must be performed, e.g. when putting the SDC Participant into service or after major modifications of the SDC System
- risk management for the Medical IT-network in accordance with IEC 80001-1 is strongly advised
- users of the SDC System must be informed in accordance with instructions provided in the IfU for each of the SDC Participant's IfUs and additional measures resulting from the risk management for the Medical IT-network

Hospital organizations may outsource some of the related tasks, such as performing an initial risk assessment for the Medical IT-network to third parties, but they are still responsible for these tasks. See [VDE].

System Integrators are organizations that place SDC Systems on the market. Such SDC Systems comprise a Medical IT-Network of at least one SDC Service Provider, one SDC Service Consumer, and both realize at least one complete System Function through their System Function Contributions. System Integrators assume the above mentioned responsibilities of a Responsible Organization and need to provide all information relevant to the user. While System Integrators may emerge in the context of SDC systems, they are not required and are therefore not further considered in this document. System Integrators can only provide partial relief for the responsibilities required of the Responsible Organizations. For Example a System Integrator may help with test and risk management efforts.

Users of SDC Participants of an SDC system are not directly affected by the principles laid out in this document. Users are made aware of Systems Functions or related risks through accompanying documentation such as the IfU provided with the SDC Participant or they are informed by the Responsible Organization accordingly, e.g. by hospital procedures.

The **Governance Body** is responsible to ensure that the principles laid out in this document are implemented and enforced, and are responsible for managing and maintaining any related system documents. Responsibilities of the Governance Body are to:

- Maintain this document and the related SDC Participant Key Purpose requirements (see Chapter 5.1)
- Allocate complaints that cannot be unambiguously assigned to one SDC Participant by the Manufacturer(s), including evaluation of deficiencies of the SDC Participant Key Purpose requirements
- Ensure needed modification of existing SDC Participant Key Purpose requirements are addressed in the respective standards development bodies, which may include the evaluation of any repercussions on existing systems and devices, and ensuring alignment with SDC Device Manufacturers
- Define how conformance to the SDC Participant Key Purpose requirements shall be demonstrated, including which organizations are eligible to declare conformance.

It should be noted, that currently OR.NET e.V. association is taking the responsibility of a Governance Body, but this responsibility could be also assumed by other legal parties, such as Manufacturers or System Integrators. Where a Manufacturer takes on the role of a Governance Body, its responsibilities required of Governance Body. OR.Net e.V. or a Manufacturer may prospectively transfer responsibility of the Governance Body to an independent third party, e.g. a committee (e.g. IEEE conformity assessment program).

4 Manufacturers Claims and Context of Use

For each SDC Conformant Participant the IfU states the System Function Contributions supported by the SDC Participant.

It is stated that the resulting distributed System Functions will only be available when used together with other SDC Conformant Participants and the related data messages are communicated over the Medical IT-network in an SDC System.

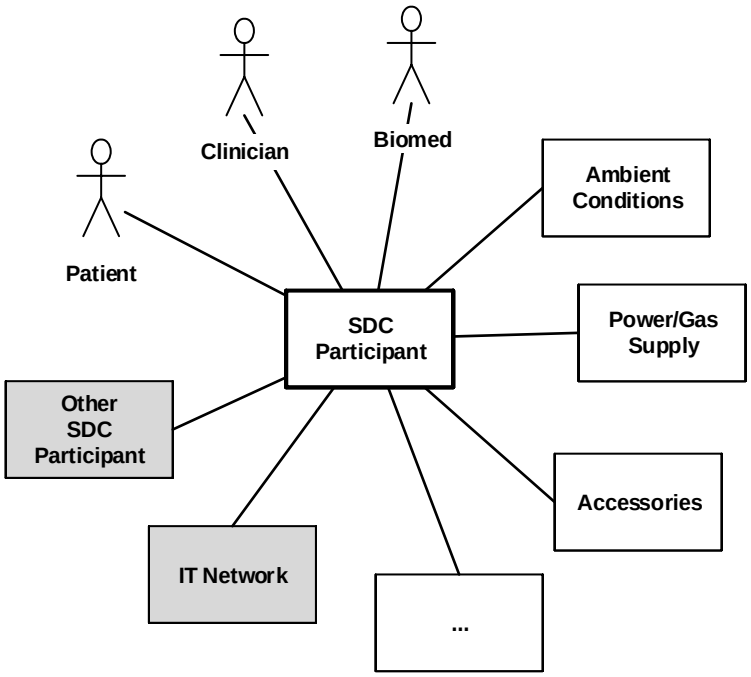

Figure 1: Exemplary system context of an SDC Participant

Based on the claims made, stakeholders depicted in Figure 1 must be anticipated, which are further described below.

4.1.1 Medical IT-Network

A Medical IT-Network encompasses:

- all components that support the IP communication, such as routers, switches, hubs, and network cables,
- the connected devices, such as servers, personal computers, embedded devices, and medical devices.

Each SDC Conformant Participant shall be designed for safe and secure operation in such Medical IT-Networks and does not necessarily require a specific segregated network. Among other requirements, this means that the communication of the SDC Participants is protected such that effects from the Medical IT-Network lead at worst to a loss of the communication and therefore the System Function and the devices other capabilities are to remain unaffected.

The IfU of each SDC Participant shall state the characteristics which must be provided by the Medical IT-network in order to achieve the claimed System Function Contributions and lists hazardous situations which may result from not providing these characteristics. This information is intended to support risk management for the Medical IT-Network performed by the Responsible Organization according to IEC 80001-1.

4.1.2 Other SDC Participants

As described in section 2.2, the communication to other SDC Participants in an SDC System shall be technically restricted to devices providing a valid cryptographic x.509 certificate during the TLS handshake. This x.509 Certificate allows authentication of the individual other SDC Participants and the organization that has issued the certificate. SDC Conformant Participants may restrict the supported System Functions based on the organization that has issued the certificate and the scope of the certicate.

SDC Conformant Participants should consider distinguishing between three types of certificate issuing organizations and the scope of the certificate:

- Manufacturer of the SDC Participant itself

- Organizations having legal obligations with regards to placing SDC Participants on the market
- Other organizations.

If the cryptographic certificate of the other SDC Participant is signed by the Manufacturer of the SDC Participant, the System Function Contributions available to another SDC Participant are not restricted, since the Manufacturer will only place SDC Participants on the market that follow the principles described in this document. If a Responsible Organization or a System Integrator needs to restrict potential communication between SDC Participants for organizational purposes even if they are put on the market from the same manufacturer than they may use the whitelisting or blacklisting mechanism described in section 2.2.

If the certificate is issued by a known and trusted third party, e.g. another manufacturer or a conformance test center appointed by the Governance Body, the available System Function Contributions may be restricted to a subset of all implemented System Function Contributions according to [11073-20701]. Depending on the contractual relation to that third party this may include functions affecting the essential performance of the SDC Participant.

If the certificate is not signed by an organization having a legal relation with the Manufacturer, the Manufacturer of the SDC participant cannot ensure that the SDC Participant of the other organization follows the principles laid down in this document and related requirements. Consequentially the safety and effectiveness of resulting System Functions with such SDC Participants cannot be ensured and SDC Participants from the Manufacturer do not claim to support System Function Contributions to such third-party SDC Participants. The factory default configuration of SDC Participants from the Manufacturer will therefore prevent communication with such SDC Participants.

However, it is recommended that other organizations such as the Responsible Organization or a System Integrator, will be able to activate communication between SDC Participants from organizations that have no established trust relation. If necessary to achieve freedom from unacceptable risk, the available functions might be limited to:

- System Functions not affecting the clinical effectiveness of the SDC Participant and
- display of measurements and settings from other SDC Service Provider.

The accompanying documentation of the SDC Participant shall state that the SDC Participant is not verified and validated for this purpose the organization activating this function therefore assumes full responsibility for the realization of the System Function in the SDC System.

5 Safety, Effectiveness, and Efficiency of SDC Systems

An SDC System provides System Functions by the combination of at least two SDC Participants communicating over the Medical IT-Network. Hence, an instance of System Function is therefore typically not realized by a Manufacturer, but by the Responsible Organization.

However, a Responsible Organization cannot create arbitrary System Functions but only those supported by the System Function Contributions of the SDC Participants. SDC Conformant Devices only support System Functions that are safe and effective when SDC Conformant Devices are used together in a Medical IT-Network.

At first this implies that no System Functions are supported that lead to unacceptable risk when the communication via the Medical IT-Network is lost. Since the communication via the Medical IT-Network cannot be ensured by the System Participant's Manufacturer, the loss of the communication must be acceptable. Typically, this means that supported System Functions can be substituted by the user, hospital workflows, other means, or these functions are dispensable with regards to Safety and Effectiveness.
As a basic principle, SDC Conformant Participants therefore provide a user interface to

control and monitor its own clinical device functions that are not related to the System Functions. Availability, Effectiveness and Efficiency of use of these clinical device functions are thus ensured on the level of the individual SDC Conformant Participant. System Functions often only extend these clinical device functions to support use cases involving more than one SDC Participant even if other devices deriving their intended use out of System Functions.

As mentioned in the previous chapter, other SDC Participants are considered in the context of use of the SDC Conformant Participant. Any characteristics of these other SDC Participants, including technical as well as use related characteristics, are therefore considered in the development of an SDC Conformant Participant. Where Safety and Effectiveness of a supported System Function can only be ensured if the other SDC Participants provides specific characteristics, the SDC Conformant Participant shall only support the System Function Contributions in combination with other SDC Participants assuring these characteristics. This concept is further described in Chapter 5.2.

Due to these design constraints implemented in the SDC Conformant Participant a Responsible Organization will generally not be able to create unsafe System Functions. However, the above described concept implies that it cannot be fully ensured that a provided System Function is highly available, efficient or satisfying to use. These properties should be supported by the Responsible Organization, e.g. by using a highly reliable Medical IT-Network, aligning the UI configuration of the SDC Participants or by choosing SDC Participants with similar interaction concepts.

It should be noted that for a System Function Contribution the application of particular and collateral standards may apply only in part for the SDC Participant and full coverage of the standard can only be achieved by using multiple SDC Participants with their System Function Contributions. The Responsible Organization should carefully review the standard coverage for the System Functions especially as currently used standards are not yet written in a modular structure.

5.1 Requirements Allocation

In general, Safety and Effectiveness of System Function Contributions supported by an SDC Participant requires that the other components of the SDC System, e.g. other SDC Participants and the Medical IT-Network, realize certain characteristics.

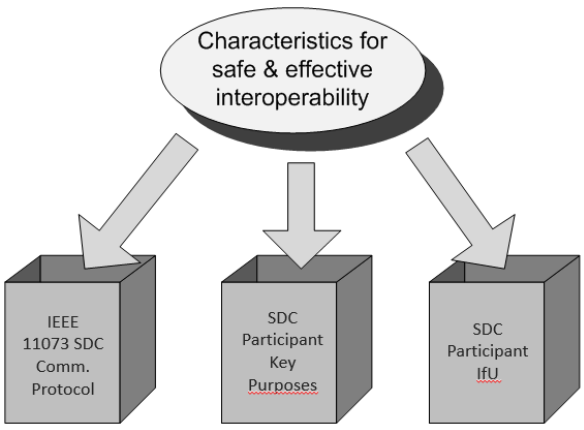

Figure 2: Documents with interoperability related requirements

There are three potential ways to document and communicate such required characteristics:

- The IEEE 11073 SDC Communication Protocol:
  This standard family includes technical requirements on the protocol implementation.
- The SDC Participant Key Purpose specifications. This set of documents comprises:

  - technical requirements detailing and interpreting the SDC standards family for specific SDC Participant Key Purposes,
  - further technical requirements related to the design and behavior of SDC Participants
  - requirements to be considered in the processes of the device manufacturer
- The IfU of an SDC Participant and related accompanying documentation: These documents include requirements on the Responsible Organization and the users. They may include restrictions regarding the creation, operation, and use of an SDC system that includes the SDC Participant. The IfU provided with the SDC Participant only includes requirements related to its SDC Participant Key Purpose, and does not contain general requirements for SDC Systems.

5.1.1 User Experience

Additionally a Manufacturer may maintain a set of internal requirements that are intended to optimize interoperability between SDC Participants of that Manufacturer. These requirements are intended to ensure efficient and satisfying use of System Functions realized by SDC Participant combinations or to support the maintenance of SDC Systems including multiple SDC Participants of the Manufacturer.

5.2 Key Purpose Concept

Above mentioned SDC Participant Key Purpose specifications are organized by the Key Purpose concept outlined in this chapter.

An SDC Participant Key Purpose might be for example a set of requirements that guarantees safe and effective communication with SDC Participants for a System Function Contribution, e.g. external control of a Medical Device. Alternatively, an SDC Participant Key Purpose might be, for example, a set of requirements that guarantees Safe and Effective communication with SDC Service Providers that represent clinical Medical Device specializations contributing to System Functions. It should be noted that an SDC Participant Key Purpose can be interpreted as a role of the SDC Participant that correlates to the System Function Contribution of the SDC Participant.

In any case, if an SDC Participant has more than one SDC Participant Key Purpose, then those SDC Participant Key Purposes cannot contradict as the SDC Participant has to conform to the superset of the set of requirements defined for each SDC Participant Key Purpose in order to be an SDC Conformant Participant.

Any SDC Conformant Participant realizing a specific SDC Participant Key Purpose satisfies all requirements related to that SDC Participant Key Purpose. These SDC Participant Key Purpose requirements are not limited to technical requirements, but also specify which Intended Purpose an SDC Participant needs to consider during development and how this shall be reflected in the development processes.

This Key Purpose concept clearly allocates the overall responsibility for a System Function to one of the contributing SDC Participants and allows this SDC Participant to rely on the other contributing SDC Participants to take over a clearly defined subset of this responsibility.

The following basic SDC Participant Key Purposes are defined:

- ‘SDC Participant‘ is any network node that is part of an SDC System and exchanges data according to the types defined in section 2.3 and adheres to the mandatory requirements of the IEEE 11073 SDC Communication Protocol [11073-20701]. It should be noted that a Medical Device can not implement only the SDC Participant Key Purpose ‘SDC Participant’, but needs to implement at least one of the SDC Participant Key Purposes ‘SDC Service Provider’ or ‘SDC Service Consumer’ or another SDC Participant Key Purpose derived from ‘SDC Service Provider’ or ‘SDC Service Consumer’.

- ‘SDC Service Provider‘ exposes its own state and its provided Services to the SDC System and adheres to the mandatory requirements of the IEEE 11073 SDC Communication Protocol [11073-20701].
- ‘SDC Service Consumer‘ requires state information or Services from an SDC Service Provider to perform its System Functions and adheres to the mandatory requirements of the IEEE 11073 SDC Communication Protocol [11073-20701].
- ‘SDC Metric Provider‘ provides metrics, e.g. measurement and settings, to other SDC Participants. Examples are patient monitors, ventilators, insufflators, surgical pumps, etc.
- ‘SDC Metric Consumer‘ requires metrics from other contributing SDC Participants with the SDC Participant Key Purpose of SDC Metric Provider to realize its System Function Contribution. The SDC Participant having the ‘SDC Metric Consumer’ SDC Participant Key Purpose has the overall responsibility for the System Function. An example is a Central Station displaying measurement and settings from Medical Devices like patient monitors or ventilators or to configure parameters of surgical devices.
- ‘SDC Operation Consumer‘ is intended to control the state of an SDC Operation Provider by sending request control data to the SDC Operation Provider. An Example is a central stations that allows the user to de/activate alarms on remote patient monitors or an insufflator providing SDC Operations to configure parameters like pressures.
- ‘SDC Operation Provider‘ provides at least one function to be externally controlled by another SDC Participant by means of receiving control request data. The SDC Participant having the ‘SDC Operation Consumer’ SDC Participant Key Purpose has the overall responsibility for the System Function. An example is a Patient Monitors providing an SDC operation to de/activate specific alarms.
- ‘SDC Alert Provider‘ provides data about alert conditions and/or alert signals to other SDC Participants. Examples are patient monitors and ventilators.
- ‘SDC Alert Consumer‘ requires data about alert conditions and/or alert signals from other contributing SDC Participants with the SDC Participant Key Purpose of SDC Alert Provider to realize its System Function Contribution. An Example is a central station annunciating alarms from a remote patient monitor. The SDC Participant having the ‘SDC Alert Consumer’ SDC Participant Key Purpose has the overall responsibility for the System Function.

The actual requirements on these basic SDC Participant Key Purposes and requirements on derived more specific SDC Participant Key Purposes are contained in the SDC Participant Key Purpose specifications. These documents have to be maintained by the Governance Body described in Chapter 3, which is currently OR.NET e.V. but in future will be maintained by a workgroup of standards development organization.

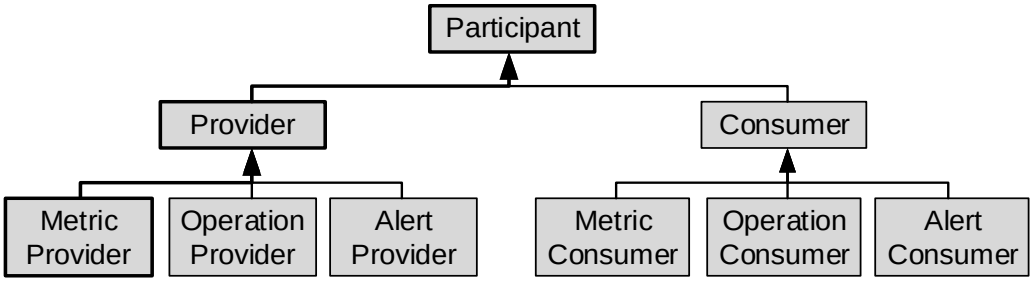

Figure 3: Hierarchy of basic SDC Participant Key Purposes

SDC Participant Key Purposes are hierarchically structured: For example, an SDC Conformant Participant assuming the SDC Participant Key Purpose ‘SDC Metric Provider’ likewise assumes the SDC Participant Key Purposes ‘SDC Service Provider’ and ‘SDC Participant’. Therefore, requirements applicable to all SDC Participant Key Purposes are only specified once in the SDC Participant Key Purpose ‘SDC Participant’. More specific SDC Participant Key Purposes may be derived from these basic SDC Participant Key Purposes to address specific System Functions as necessary.

Since an SDC Conformant Participant will generally contribute to multiple System Functions, each SDC Conformant Participant will typically assume multiple SDC Participant Key Purpose. Some SDC Participant Key Purposes postulate that another SDC Participant Key Purpose is implemented, e.g. an ‘SDC Operation Consumer’ typically needs to know the current settings of the controlled SDC Operation Provider and therefore assumes also the SDC Participant Key Purpose ‘SDC Metric Consumer’.

The SDC Participant Key Purpose that an SDC Conformant Participant assumes is transmitted in the SDC protocol and results from the System Functions it contributes to either by consuming and/or providing data, e.g. using metrics from other devices or invoking certain operations on other SDC Participants.

In order to foster extensible open systems this SDC Participant Key Purpose concept is strongly tied to the different types of data exchange described in Chapter 2.3. Hereby, metrics and alerts disclose the state of an SDC Service Provider, while operations are intended to control the state of an SDC Service Provider. Where it is technically possible to provide new System Functions based on Services from existing SDC Service Providers, it should also e possible to fulfill the assumed responsibility for these new System Functions, potentially leveraging the responsibility already taken by the SDC Service Provider.

For some System Functions it may technically not matter if they are implemented by either metrics or operations. However, the chosen solution may significantly affect the SDC Participant Key Purposes assumed by the involved SDC Conformant Participant and therefore the responsibilities of the Manufacturer of the SDC Conformant Participant. For example, a Patient Monitor may prefer to provide measurements to a therapy device instead of controlling the therapy device.

5.2.1 Metrics

Metrics disclosed by an SDC Metric Provider, convey the current state of a Medical Device to SDC Service Consumers. Therefore, a metric at first does not generally have a specific Intended Purpose, i.e. the SDC Metric Provider does not know what it will be used for. Nevertheless, the provision of data by means of a metric is part of the Intended Use of the SDC Metric Provider as (part of) its System Function Contribution. An SDC Metric Provider may declare that a metric is intended for a specific clinical purpose.

The IEEE 11073 SDC Communication Protocol provides an attribute that allows to declare metrics, as well as other elements, to be intended for display to support diagnostic and therapeutic decisions. When using this attribute the SDC Metric Provider takes the responsibility to provide the metric with a suitable quality to support this System Function.

Since the SDC Metric Provider does not know the System Function actually implemented by the SDC Service Consumer, the SDC Metric Provider does not take further responsibilities beyond providing the metric in the quality for displaying to support diagnostic and therapeutic decisions.

On the other hand, the SDC Metric Consumer realizes a System Function based on the metric. The SDC Metric Consumer can therefore assess the overall System Function and takes full responsibility for the System Function in the first place. If it only displays metrics from other devices, it can fully rely on the quality of the received data and only needs to ensure that the data is appropriately displayed. If it provides any further functions based on the data, the SDC Metric Consumer needs to consider if the received data is appropriate for that function.

The Manufacturer of the SDC Metric Consumer thus takes the responsibility for the System Function excluding the responsibility already taken by the SDC Participant Key Purpose ‘SDC Metric Provider’.

5.2.1.1 Specific Metrics

An SDC Metric Provider may assume a more specific SDC Participant Key Purpose derived from the SDC Participant Key Purpose ‘SDC Metric Provider’, if a metric is intended for a specific clinical function, e.g. closed-loop-control. This more specific SDC Participant Key Purpose will comprise additional requirements for the contributing SDC Participant to ensure essential performance. This metric will be marked in the SDC protocol by the attribute “SafetyClassification” and the assumed SDC Participant Key Purpose will be conveyed.

5.2.2 Alerts

Alerts follow the same concepts as metrics: An SDC Alert Provider only exposes the internal state of a Medical Device to SDC Participants in the SDC System. The System Function of generating the alert signals is realized by the SDC Alert Consumer. However, typically alerts will be marked in the SDC protocol by the attribute “SafetyClassification” to show that they are intended to notify the user about a patient or device state requiring user intervention.

5.2.3 Operations

Control request data exchanged for operations in contrast to metrics and alerts is intended to control the state of the receiving Medical Device through the SDC Operation Provider. Such control request data has a specific purpose. This purpose is defined by the SDC Operation Provider. The SDC Operation Provider assumes full responsibility for the related System Function by default. However, the responsibility can be shared by specifying a related SDC Participant Key Purpose ‘SDC Operation Consumer’ and requirements allocated to that SDC Participant Key Purpose.

The IEEE 11073 SDC Communication Protocol provides the attribute “SafetyClassification” that allows an SDC Operation Provider to mark operations that will affect the device’s clinical functions and to what extent. When invoking such a marked operation the SDC Operations Consumer takes all responsibilities specified for the related SDC Participant Key Purpose.

6 Product Lifecycle Processes

Safety and Effectiveness of Medical Devices are ensured by proper design, manufacturing, and lifecycle processes of the Manufacturer.

This chapter describes how the Key Purpose concept as described in section 5.2 is used to ensure that these aspects are considered consistently in the product lifecycle processes of the SDC Participant contributing to a System Function.

6.1 User and Customer Requirements

The top level user and customer requirements typically identify which System Functions are supported by an SDC Participant, in particular the System Function Contributions of the SDC Participant.

During subsequent development the manufacturer needs to evaluate, if an intended System Function can be realized by leveraging the existing general SDC Participant Key Purpose definitions, e.g. SDC Metric Provider and SDC Metric Consumer. Such System Functions do not require additional documentation on the SDC System level. However, some System Functions, e.g. synchronization behavior, require that multiple SDC Participants share a common understanding of the specific desired System Function and its Intended Use. Such System Functions will be described in the SDC Participant Key Purpose specifications to achieve this common understanding.

It is recommended that the clear definition of an SDC Participant System Function Contribution is done by the Manufacturer in the product requirements, to subsequently identify the SDC Participants Key Purposes assumed by the device and to promote the adherence of the related requirements in all product development related processes. Additionally, it is recommended to maintain user and customer requirements that describe the intended overall System Functions and the System Function Contributions of the SDC Participant beyond what is already stated in the SDC Participant Key Purposes. Hence, these may support the definition of new Key Purposes where necessary and the allocation of SDC Participant Key Purposes to SDC Participants. The content of the additional user and customer requirements can be found in the accompanying documentation of the SDC Participant (see section 6.2).

6.2 Documentation

The accompanying documentation of the SDC Participant, primarily the IfU, will state the System Functions Contributions of the device. This documentation must disclose all conditions that must be met so that the System Functions are actually available. This includes required characteristics of the Medical IT-Network as well as required characteristics of other SDC Participants, e.g. some System Functions may only be available in combination with certain other SDC Participant implementing complementary System Function Contributions. These required characteristics must correspond with the conditions considered during verification of the SDC Participant.

In any case, the Responsible Organization shall be able to determine which System Functions can be expected from a combination of SDC Participants by the information given in the IfUs or accompanying technical documentation.

Furthermore, the documentation shall disclose relevant residual hazards related to the Medical IT-Network so that the Responsible Organization can consider these hazards during its risk management process for the Medical IT-network according to IEC 80001-1.

6.3 Technical Design

Whereas the IEEE 11073 SDC Communication Protocol is designed to support semantic interoperability of SDC Participants it cannot guarantee interoperability for all System Functions. The IEEE 11073 SDC Communication Protocol allows for sufficient freedom for two SDC Participants, although being semantically interoperable being unable to realize a System Function when combined, e.g. one SDC Service Consumer may require information that is not mandatorily required by the IEEE 11073 SDC Communication Protocol and therefore not provided by the SDC Service Provider.

The technical requirements in the SDC Participant Key Purposes shall restrict the use of the IEEE 11073 SDC Communication Protocol in such a way that all SDC Service Providers in the SDC System provide their Services in the way expected by the respective SDC Service

Consumers. Thus when two complementing SDC Participants satisfy all requirements on their realized SDC Participant Key Purposes they are designed to be contributing to a System Function in a safe and effective manner and therefore allow the practical realization of the System Function in the SDC System.

Furthermore, the IEEE 11073 SDC Communication Protocol alone cannot fully describe the semantics of all types of data, such as specific device states or device related measurements. Where it is necessary that such data is created or used in a predefined way, this needs to be specified in the technical requirements on related specific SDC Participant Key Purposes.

Each SDC Service Consumer must consider if the technical requirements on the related SDC Service Provider are sufficient to reliably realize a System Function. If this is not the case the SDC Service Consumer shall disclose additional constraints in its IfU.

Besides supporting interoperability of SDC Participants, technical requirements can support the alignment of the expected environment of use, e.g. that devices do not have contradicting demands on the required characteristics of the Medical IT-Network.

6.4 Risk Management

Each SDC Participant Manufacturer shall consider the risks related to the SDC Participant's System Function contribution in its risk management process. In general the Manufacturer shall consider:

- that the Medical IT-Network may lead to a detected loss of communication,
- that data provided to other SDC Participants may contribute to risks of the other SDC Participant,
- that data received from other SDC Participants may contribute to its own risk,
- that supported System Function Contributions may contribute to risks by affecting the use of the SDC Participant itself as well as the use of other SDC Participants.

This assessment cannot be entirely performed by a Manufacturer of one SDC Participant alone, but the Manufacturer of an SDC Participant must make assumptions about the other SDC Participants contributing to a System Function. For this purpose the Manufacturer of the SDC Participant can rely on the risk management related the other SDC Participant Key Purposes requirements.

Any risk related considerations made during the definition of SDC Participant Key Purposes requirements do not relieve the Manufacturer of an SDC Participant from any risk management responsibilities. Each SDC Participant must decide if the SDC Participant Key Purposes requirements are sufficient to accept the residual risks related to its supported System Functions.

6.5 Verification

In addition to the verification of the stand-alone SDC Participant functionality, the verification of the System Function of each SDC Conformant Participant aims to achieve that the SDC Participant works as intended in the expected context of use. As described in Chapter 4, this context of use comprises the Medical IT-Network as well as other SDC Participants.

To this end, tests at different test levels are required.

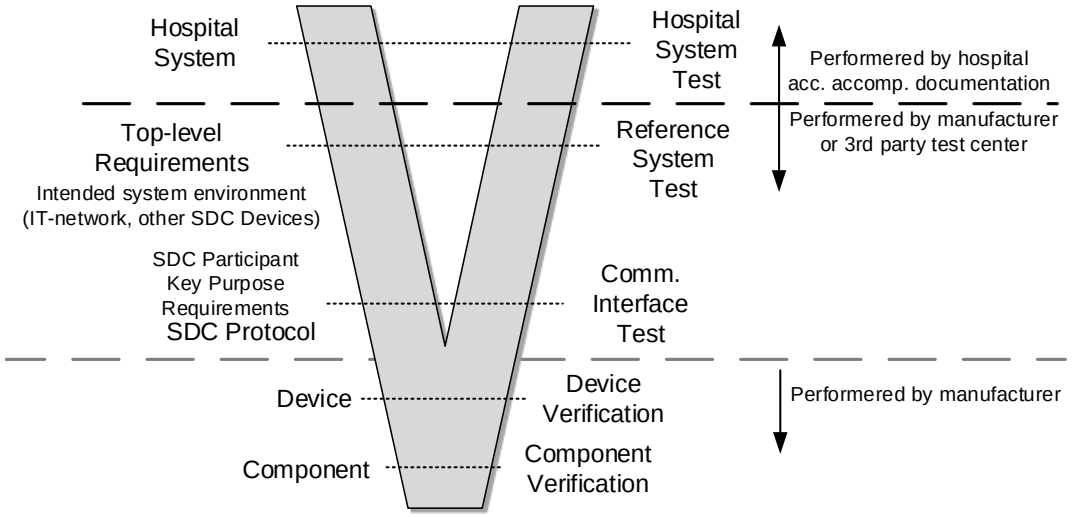

Figure 4: Levels of SDC Participants and SDC System tests

The verification against the specification of the System Function Contributions of the communication interface comprises that the SDC Participant under test has to prove that it's IEEE 11073 SDC Communication Protocol interface is conformant to the IEEE 11073 SDC Communication Protocol as well as to all requirements of its SDC Participant Key Purpose. Showing conformance to IEEE 11073 SDC Communication Protocol is done by proving that either the SDC Service Provider or the SDC Service Consumer or both is implemented. The SDC Participant Key Purposes also specify how an SDC Participant shall behave under inopportune conditions, e.g. high load scenarios, loss or delay of data messages, data corruption, combinations with SDC Participants that perform according to their specification, but at the extremes of the acceptable SDC Participant behavior. Furthermore, the SDC Participant Key Purposes also specify how an SDC Participant shall behave under conditions outside the specification, e.g. extreme load scenario or undue request, shall demonstrate that such conditions do not result in hazardous situations. Verification of those requirements thus automatically results in showing that the SDC Participant is robust against network-related extreme or error scenarios that might occur during real-world usage of the Medical Device.

In addition to this, the SDC Participant has to demonstrate its capability to perform its System Functions and System Function Contributions in a Reference System (Reference System Test). This Reference System is made up of real SDC Participants which complement the SDC Participants System Function as well as a simulated SDC System to emulate a realistic use scenario. The Medical IT-network of the Reference System as well as the amount of simulated data traffic is chosen in accordance with the Medical IT-Network characteristics specified in the SDC Participants IfU. In addition to the functional tests, the verification of the SDC Participant shall include tests in which those network requirements are violated. In these cases the SDC Participant has to go into a safe state where a potential loss of System Functions does not affect the SDC Participant's stand-alone essential performance.

In order to ensure that the intended System Function and System Functions Contribution is available in a specific SDC System, the verification by the SDC Participant's Manufacturer must be complemented by verification activities of the Responsible Organization. These verification activities are specified in the accompanying documentation of the SDC Participants and may for example be required, during the system integration, periodically while the SDC Participant is in operation, following software updates, or following major changes of the Medical IT-Network.

6.6 Validation

The validation process for Medical Devices is intended to demonstrate that the Medical Device conforms to defined user needs and intended uses. This may be done by means of clinical evaluation, direct validation, usability evaluation or translation into technical requirements and subsequent verification. The intended use environment is taken into account as part of the product requirements as well as in the derived technical system requirements. As a consequence, environmental conditions are simulated as required for verification..

For SDC Conformant Participants the intended use environment includes the Medical IT-Network and other SDC Conformant Participants. As described in the previous chapters, these aspects are primarily handled by verification as well.

If the System Function Contribution of an SDC Conformant Participant to a System Function satisfies a user need, it should be considered for usability evaluation. Such usability evaluation should be focused on the System Function Contribution of the device rather than on the overall System Function. The validation process of each SDC Participant will require this activity independently from the principles described in this document. However, the SDC Participant Key Purposes requirements related to usability evaluation will ensure that the evaluation of the overall System Function is appropriately covered by the evaluation of the contributions of the devices.

Usability evaluation is furthermore required to support the risk management process in the identification of potential use errors and the verification of use related risk control measures.

As described in Chapter 6.4, the risk management process needs to consider that System Functions can be lost due failures of the Medical IT-Network. Considering that a low availability of these functions is acceptable, their low efficiency of use cannot lead to unacceptable risks as well. Consequently, the usability process does not need to demonstrate that System Functions are efficient to use.

For the identification and mitigation of potential use errors the usability process of the SDC Participant responsible for the overall System Function (see definitions in Chapter 5.2) needs to evaluate the complete System Function. With regards to the mitigation of use errors this SDC Participant can rely on the SDC Participant Key Purpose requirements for the other contributing SDC Participants, but must not make any further assumptions about the other SDC Participants.

6.7 Regulatory

The System Functions supported by an SDC Participant may not be reflected in the intended use statement of the SDC Participant. The purpose of the communication interface may be required or not in the intended use depending on the significance the interface plays within the clinical context. However, these System Functions and the SDC Participant Key Purposes assumed to support these System Functions still affect the intended use of the SDC Participant as expressed by the IfU and further accompanying documentation or Manufacturer documentation. Consequentially, the System Functions need to be considered in the context of the regulatory classification of the SDC Participant as well as other regulatory processes such as premarket evaluation by agencies.

Applying these set of rules to the design input of the communication interfaces, will result in Safe and performant functionality as a design output for the system context. The IfU of an SDC Conformant Participant shall clearly indicate that the SDC Participant is intended to be integrated into an SDC System by a Medical IT-Network and will state all related requirements for the Responsible Organization. The Responsible Organization or System Integrator reviews the individual provided System Function Contribution in the Labelling, and utilizes the SDC Participant in accordance to the Manufacturer’s disclosures. Hence, by

integrating an SDC Participant into an SDC System, the Responsible Organization does not assume the responsibilities of a Manufacturer of an SDC Participant.

Only if an SDC Conformant Participant is combined with another SDC Participants or software that does not conform to these principles, the Responsible Organization creating that combination takes the responsibilities of a Manufacturer for that combination (see Chapter 4.1.2).

6.8 Complaint Management / Post Market Surveillance

Deficiencies of System Functions may be related to a deficiency of one of the contributing SDC Conformant Participants or to deficiencies in requirements on their SDC Participant Key Purposes.

In order to assign occurred events to the correct responsible party each SDC Conformant Participant and its Manufacturer must support the analysis of events related to System Functions. The technical SDC Participant Key Purpose requirements therefore include which data from the IEEE 11073 SDC Communication Protocol data exchange needs to be logged. Furthermore the Manufacturers of an SDC Conformant Participant must oblige themselves to report revealed deficiencies of other SDC Participants to the respective Manufacturers.

Where an event cannot be clearly attributed to one SDC Participant the event shall be reported to the Governance Body (see Chapter 3). The Governance Body will evaluate if the event resulted from deficiencies in the SDC Participant Key Purpose requirements and will initiate a modification of the SDC Participant Key Purpose requirements, if necessary. For this purpose, the Governance Body will set up a focal point for System Function complaints. This focal point shall be informed whenever deficiencies of the SDC Participant Key Purpose requirements are revealed.

6.9 Change Management

There exists two types of changes in an SDC System:

- Changes of an SDC System itself
- Changes of an SDC Participant

6.9.1 Changes of the SDC System

For any change on the SDC System (e.g. replacement of devices, architectural changes, up- or downscaling) the Responsible Organization shall evaluate via the risk management process for the Medical IT-Network, if additional verification or validation measures are necessary and if the Intended Use remains unchanged. New System Functions shall be integrated in the SDC System according to the System Function Contributions and in line of the declared conformity of the relevant Manufacturers.

6.9.1.1 Maintenance of SDC System

A Manufacturer shall inform the Responsible Organization regarding mandatory and optional bugfixes, patches (including cybersecurity vulnerabilities) and repair activities. The Responsible Organization should not role out changes on the SDC Participant without seeking advice and recommendations from the Manufacturer.

6.9.2 Significant Changes of SDC Participants

Changes of an SDC Conformant Participant are in the responsibility of the Manufacturer. The Manufacturer must ensure that its SDC Participant Key Purpose after modification meets the applicable SDC Participant Key Purpose requirements. Furthermore, the Manufacturer must evaluate if the change is covered by the scope of its SDC conformance assessment, e.g. if the SDC Participant provides new System Functions or System Function Contributions and thereby assumes new SDC Participant Key Purpose not previously considered.

Changes of the SDC Participant Key Purpose requirements are managed by the Governance Body for these requirements. Additions of new SDC Participant Key Purposes or SDC

Participant Key Purpose requirements as well as editorial modifications of existing requirements may be performed using the normal approach of standard bodies like corrigenda or amendments or new projects.
However if existing SDC Participant Key Purpose based requirements are significantly modified or deleted the proposed change will be evaluated if it may affect safety and effectiveness of existing SDC Conformant Participants. The proposal and its evaluation will be distributed to all Manufacturers of SDC Conformant Participants for comment.

The Manufacturer shall not role out significant changes in the SDC Participant without permission of the Responsible Organization.

7 SDC Conformance

SDC Conformant Participants are only intended to support System Functions in an SDC System with other SDC Conformant Participants that have been developed following these principles and that satisfy all applicable SDC Participant Key Purpose requirements. As described in Chapter 4.1.2, it is therefore recommended that SDC Conformant Participants technically limit the supported System Functions depending on the information of x.509 certificate or the information from the certificate chain of the other SDC Participant.

Organizations that obligate themselves to follow these principles declare that their SDC Participant and its design conforms to all applicable SDC Participant Key Purpose requirements by equipping their SDC Participant with such an x.509 certificate. It is in the responsibility of the respective organizations to ensure conformance.

7.1 Declaration of Conformance and System Governance

The conformance of an SDC Participant and its design process shall be checked and declared by an organization independent of the actual SDC Participant development project. This organization will:

- check if an SDC Participant is conformant with the principles of this document and the SDC Participant Key Purposes it declares to support and
- check the documentation provided by the SDC Participant to show conformance.

7.1.1 Conformance Documentation

In order to show conformance to these principles and related SDC Participant Key Purpose requirements the Manufacturer of an SDC Participant needs to provide the following artefacts:

- IfU and accompanying documentation
- if applicable, maximal content of the MDIB (SDC data structure representing the SDC Participant in an SDC System)
- List of supported SDC Participant Key Purposes and System Function Contributions
- Results from Risk Management
- Results from Verification and Validation
- List of known non-conformities related to the IEEE 11073 SDC Communication Protocol or the supported SDC Participant Key Purposes and rationales
- IEEE 11073 SDC Communication Protocol related change description