Software as a Medical Device

Thales Software Monetization

Steffen Rehnig & Prof. Dr. Christian Johner

24.06.2020

Agenda

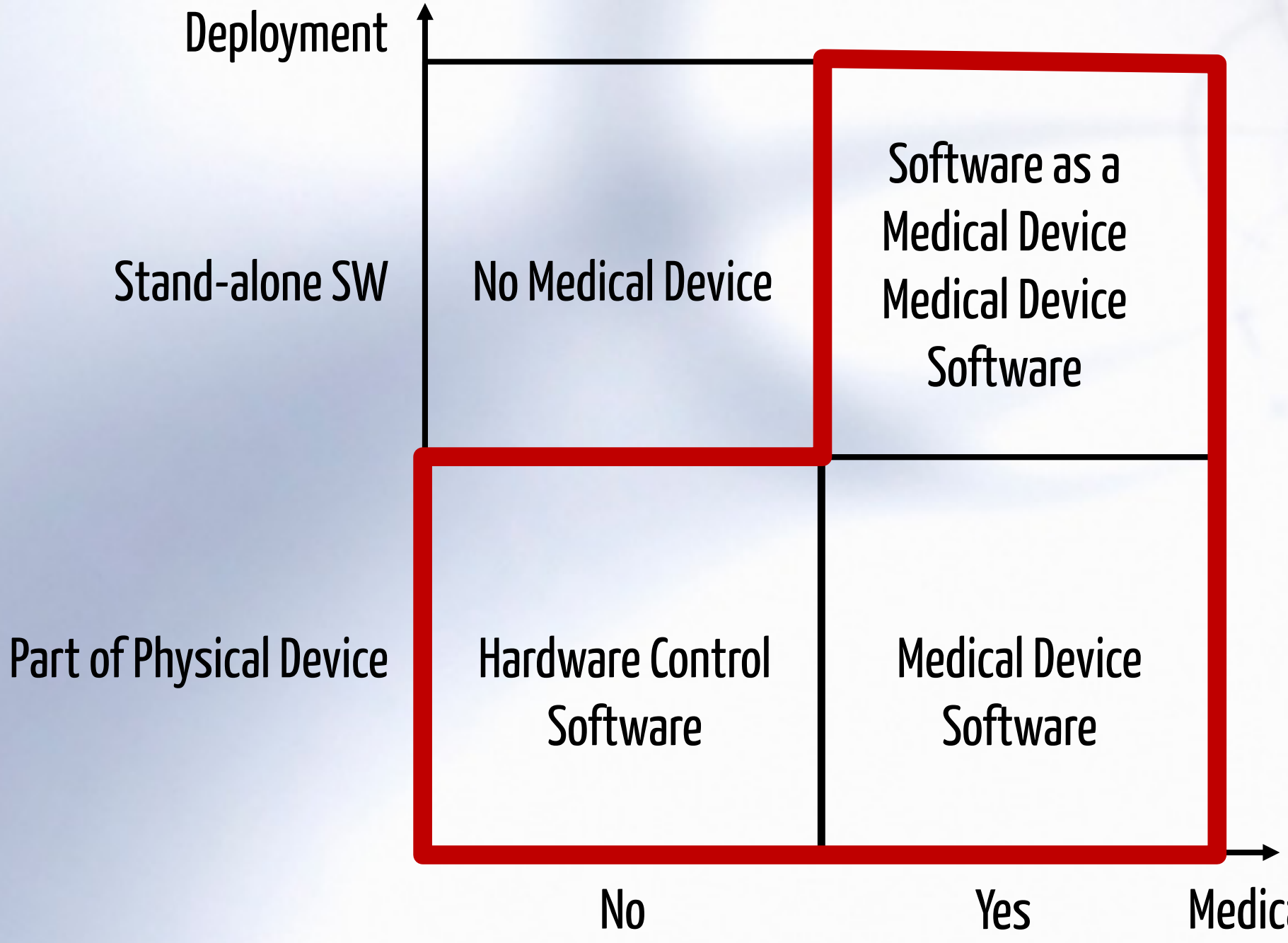
Total: 50 min

Item	Owner/Presenter	Timing
Introduction (recent changes) • What are the recent changes in regards to software	Prof. Dr. Christian Johner	10 min
Requirements & Implications (impact) • What are the legal implications • What is expected from software vendors • How does it translate into requirements for Business&Software	Prof. Dr. Christian Johner	5 min
Solution Approach (overcoming the challenges) • What can be done / how can it be done • What tool chain and which interactions are required	Steffen Rehnig	10 min
Benefits & Side Effects (what´s in it for you) • Business Insights, Version Control, Customer Relationship, New Business Models	Steffen Rehnig	5 min
Closing (Comments) • Closing	Prof. Dr. Christian Johner Steffen Rehnig	3 min
Q&A	All	15 min

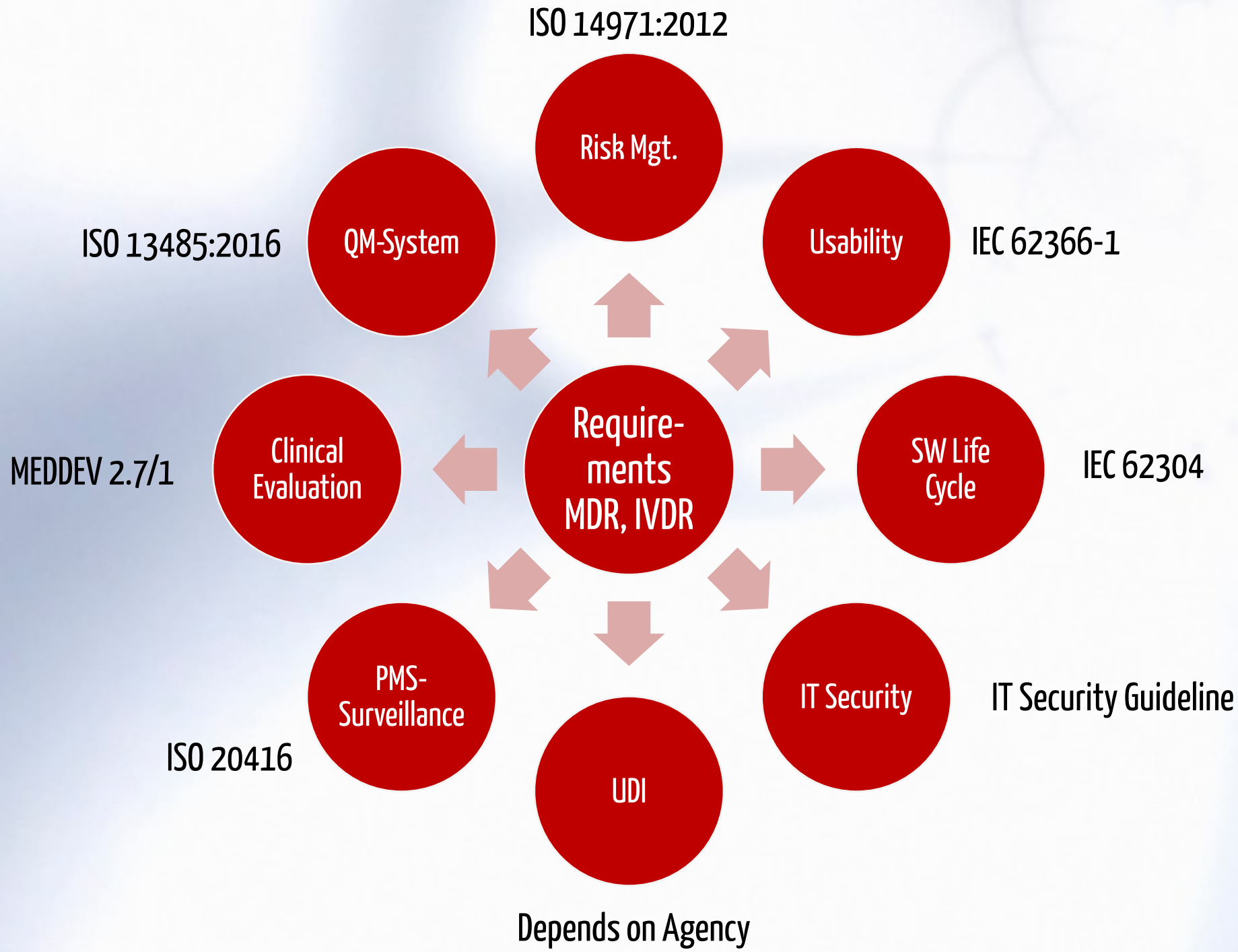
Johner Institut

Medical Device Software

Prof. Dr. Christian Johner

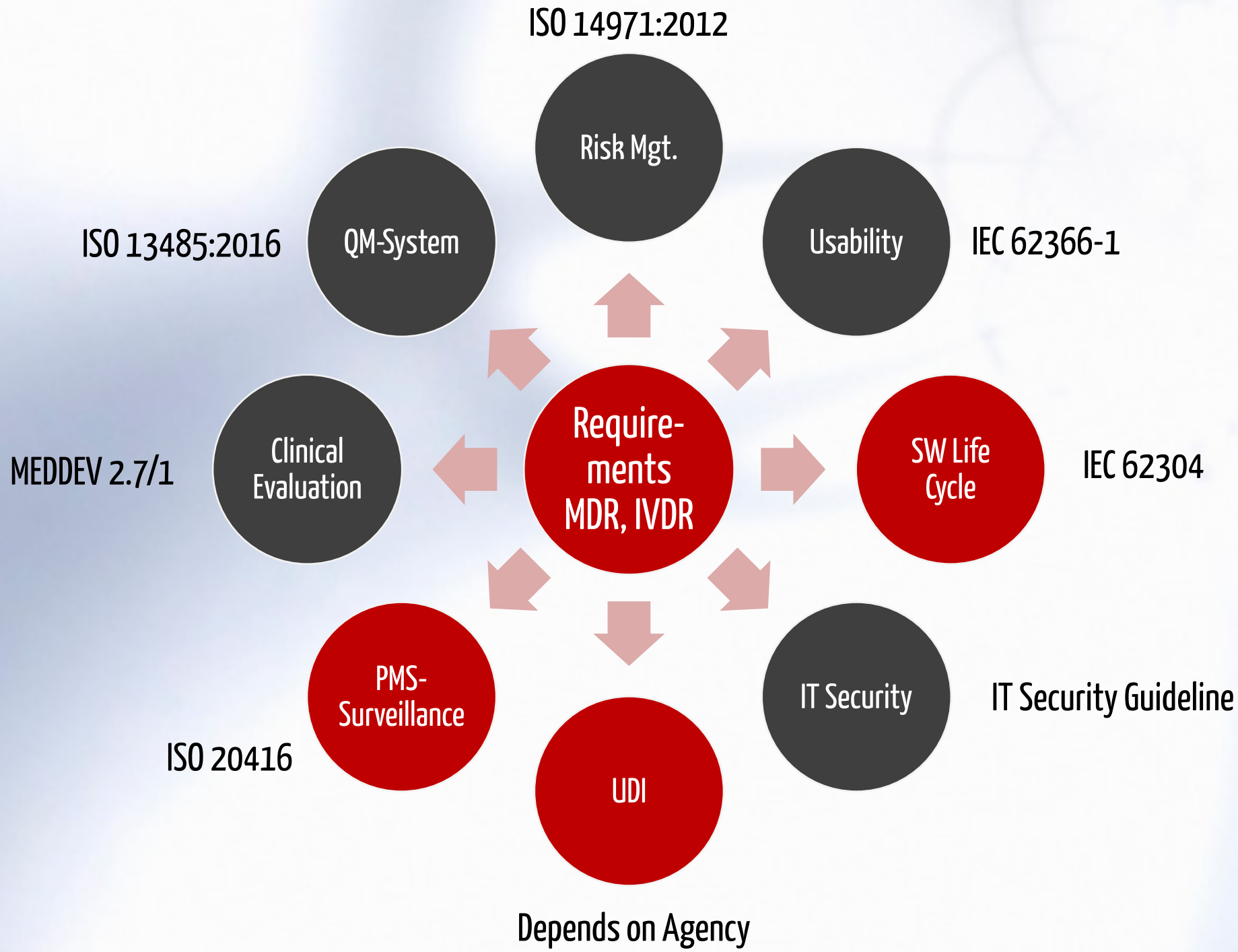


Regulations Apply (MDR, IVDR)


ISO 14971:2012
Risk Mgt.
ISO 13485:2016
QM-System
Usability
IEC 62366-1
MEDDEV 2.7/1
Clinical Evaluation
Require-ments MDR, IVDR
SW Life Cycle
IEC 62304
PMS-Surveillance
ISO 20416
IT Security
IT Security Guideline
UDI
Depends on Agency

Devices which are in conformity with the CS shall be presumed to be in conformity with the requirements of this Regulation [...]

Manufacturers shall comply with the CS [...] unless they can duly justify that they have adopted solutions that [...]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UDI


987654-A1234B5678-20220930
Company
Product
Product Instance
UDI-DI
UDI-PI

Trace medical devices

Enhance post-market safety

Reduce medical errors

Fight against counterfeit devices

Improve waste disposal policies

Motivation

Registration (EUDAMED)

Declaration of Conformity

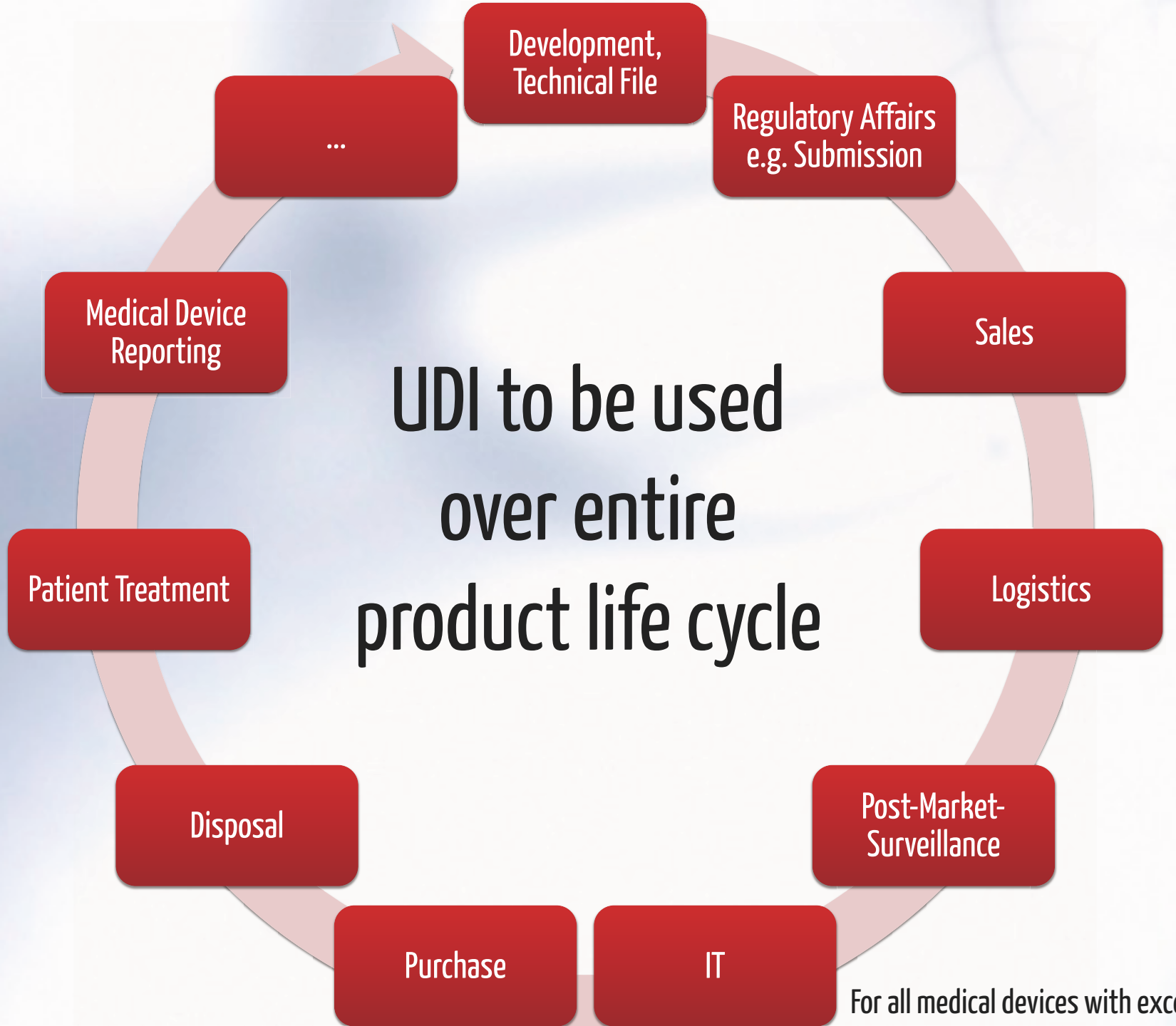
SSCP

Technical Documentation

Free Sales Certificates

UDI-DI

Summary of Safety and Clinical Performance
Kurzbericht über Sicherheit & klinischen Leistung



For all medical devices with exception of custom-made devices

Manufacturers

Economic Operators

Health Institutions

Health Professionals

Logistics

MDR affects ...

Not only Manufacturer!

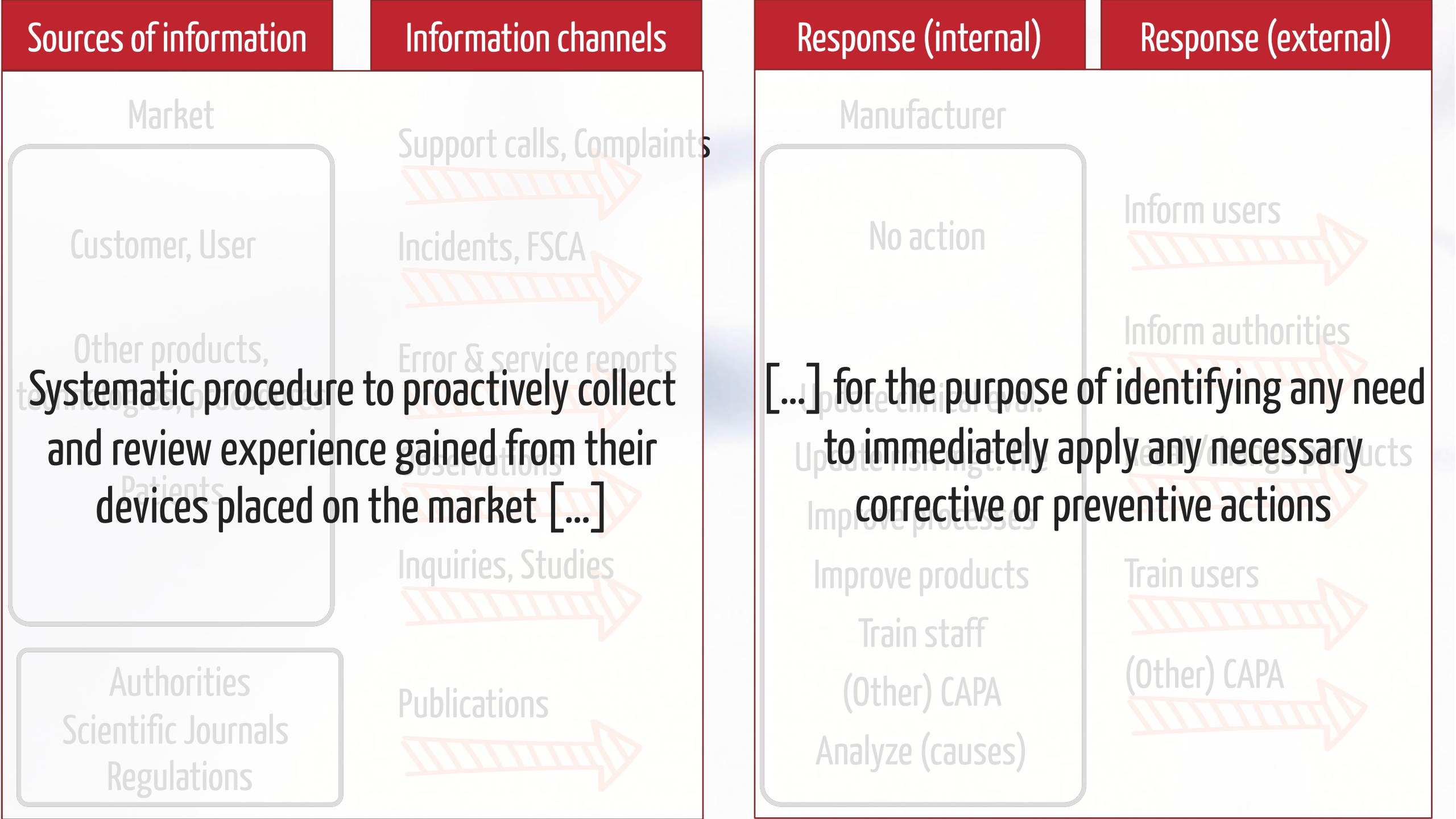
PMS

Post-Market Surveillance

"all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;"

MDR

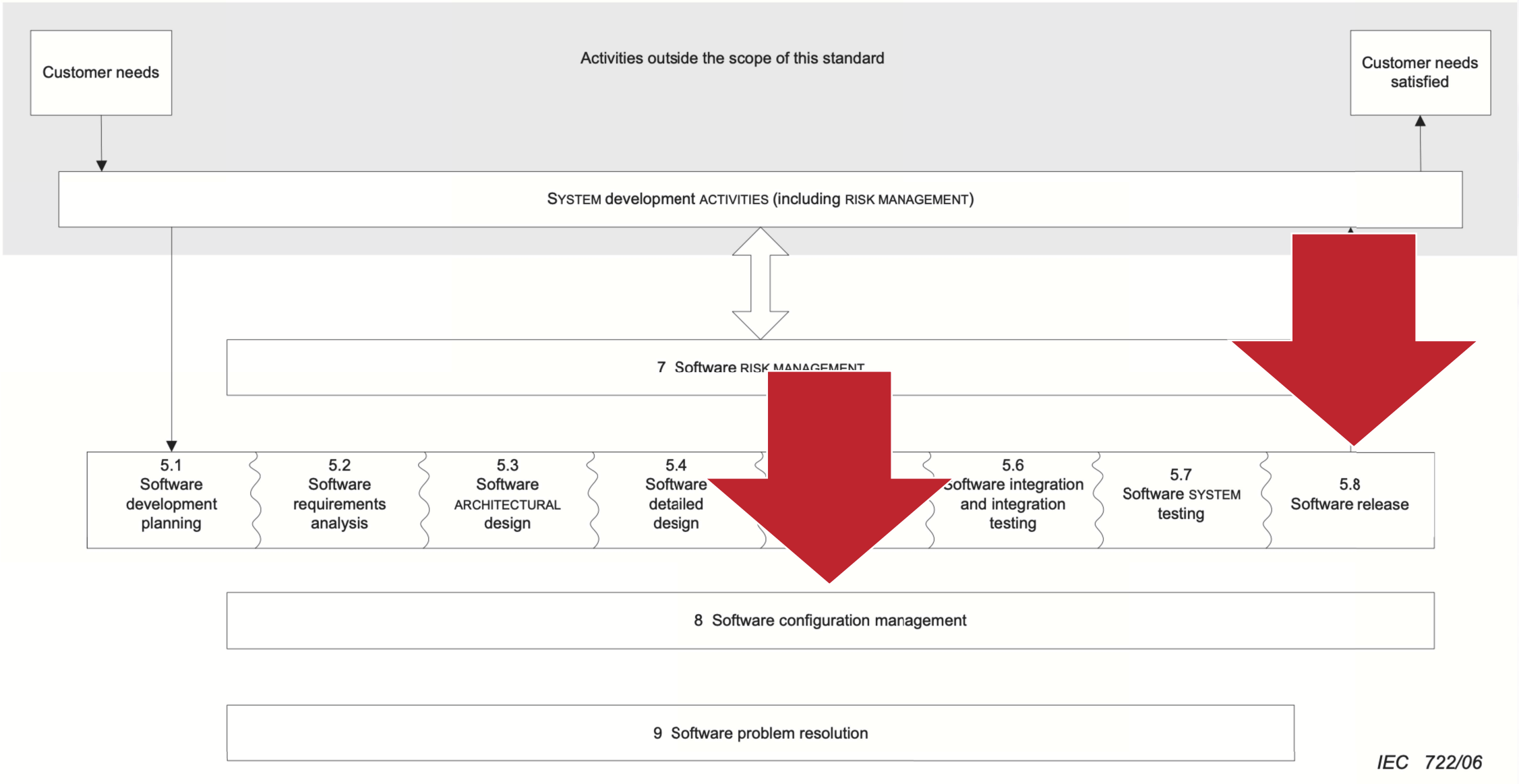
Definition


Sources of information
Information channels
Response (internal)
Response (external)
Market
Customer, User
Other products,
Patients
Authorities
Scientific Journals
Regulations
Support calls, Complaints
Incidents, FSCA
Error & service reports
Inquiries, Studies
Publications
Manufacturer
No action
Improve processes
Improve products
Train staff
(Other) CAPA
Analyze (causes)
Inform users
Inform authorities
Train users
(Other) CAPA
Systematic procedure to proactively collect and review experience gained from their devices placed on the market [...]
[...] for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions

- 1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).
- 2. The post-market surveillance system shall be suited to actively and systema[illegible] gathering, recording and analysing relevant data on the quality, performance and safety of a device throughou[illegible]time, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive a[illegible]tions.3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
  - (a) to update the benefit-risk determination and to improve the risk management a[illegible]hapter I of Annex I;
  - (b) to update the design and manufacturing information, the instructions for use and the[illegible]
  - (c) to update the clinical evaluation;
  - (d) to update the summary of safety and clinical performance referred to in Article 32;
  - (e) for the identification of needs for preventive, corrective or field safety corrective action;
  - (f) for the identification of options to improve the usability, performance and safety of the device;
  - (g) when relevant, to contribute to the post-market surveillance of other devices; and
  - (h) to detect and report trends in accordance with Article 88.The technical documentation shall be updated accordingly.
- 4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

Too much text

IEC 62304


Customer needs
Activities outside the scope of this standard
Customer needs satisfied
SYSTEM development ACTIVITIES (including RISK MANAGEMENT)
7 Software RISK MANAGEMENT
5.1 Software development planning
5.2 Software requirements analysis
5.3 Software ARCHITECTURAL design
5.4 Software detailed design
5.6 Software integration and integration testing
5.7 Software SYSTEM testing
5.8 Software release
8 Software configuration management
9 Software problem resolution
IEC 722/06

IEC 62304

Document version of software

Archive configuration items

Ensure SW reliably delivered

Document version tested

Versions to be controlled

IEC 62304

5.8 * Software RELEASE for utilization at a SYSTEM level

5.8.1 Ensure software VERIFICATION is complete

The MANUFACTURER shall ensure that all software VERIFICATION ACTIVITIES have been completed and the results have been EVALUATED before the software is released. [Class A, B, C]

5.8.2 Document known residual ANOMALIES

The MANUFACTURER shall document all known residual ANOMALIES. [Class A, B, C]

5.8.3 EVALUATE known residual ANOMALIES

The MANUFACTURER shall ensure that all known residual ANOMALIES have been EVALUATED to ensure that they do not contribute to an unacceptable RISK. [Class B, C]

5.8.4 Document released VERSIONS

The MANUFACTURER shall document the VERSION of the MEDICAL DEVICE SOFTWARE ~~PRODUCT~~ that is being released. [Class A, B, C]

5.8.5 Document how released software was created

The MANUFACTURER shall document the procedure and environment used to create the released software. [Class B, C]

5.8.6 Ensure activities and tasks are complete

The MANUFACTURER shall ensure that all software development plan (or maintenance plan) ACTIVITIES and TASKS are complete along with ~~all~~ the associated documentation. [Class B, C]

NOTE See 5.1.3.b).

5.8.7 Archive software

The MANUFACTURER shall archive:

a) the MEDICAL DEVICE SOFTWARE ~~PRODUCT~~ and CONFIGURATION ITEMS; and

b) the documentation

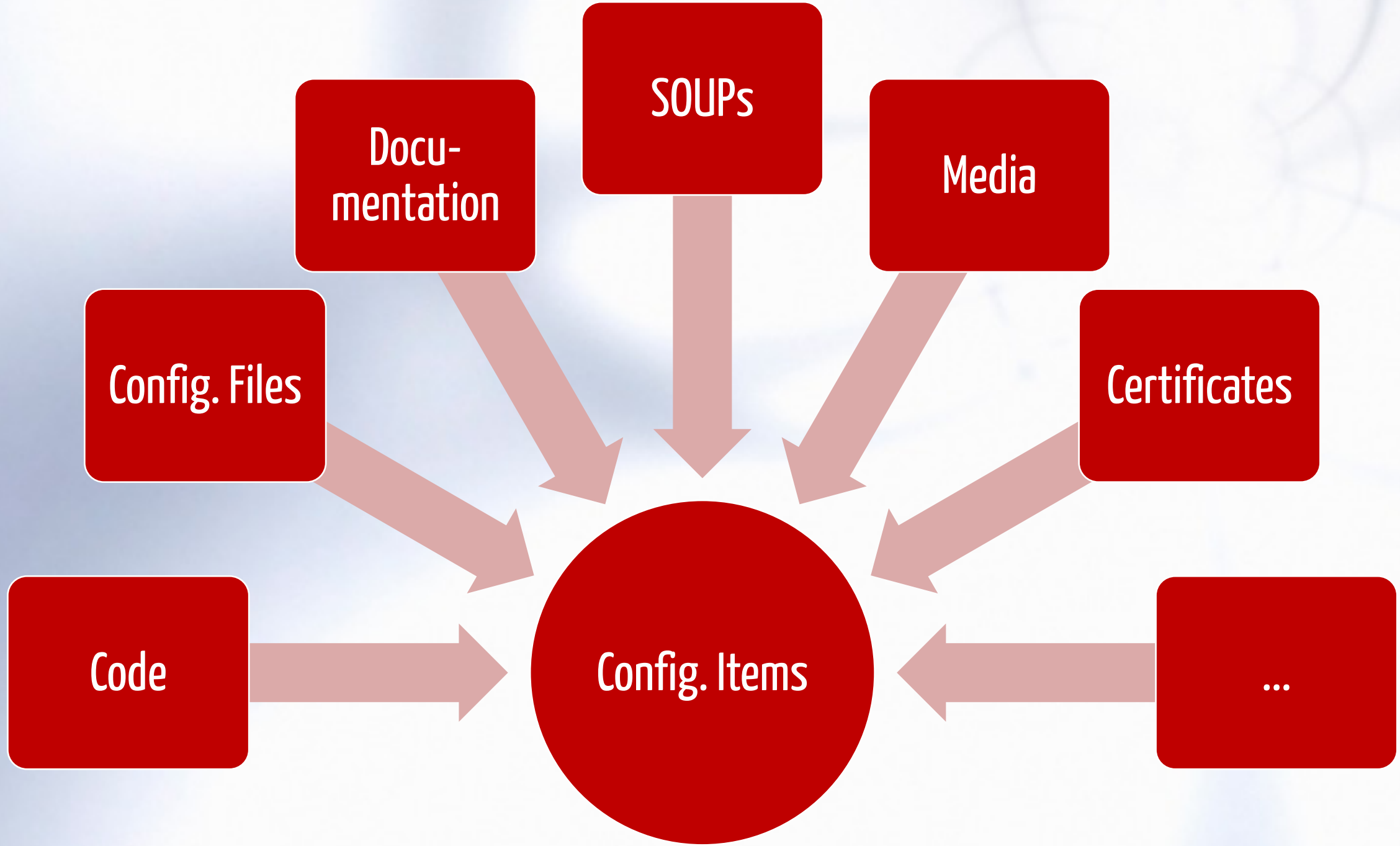
for at least a period of time determined as the longer of: the life time of the ~~device~~ MEDICAL DEVICE SOFTWARE as defined by the MANUFACTURER or a time specified by relevant regulatory requirements. [Class A, B, C]

5.8.8 Assure ~~repeatability of software release~~ reliable delivery of released software

The MANUFACTURER shall establish procedures to ensure that the released MEDICAL DEVICE SOFTWARE ~~PRODUCT~~ can be reliably delivered to the point of use without corruption or unauthorised change. These procedures shall address the production and handling of media containing the MEDICAL DEVICE SOFTWARE ~~PRODUCT~~ including as appropriate:

– replication,
– media labelling,
– packaging,
– protection,
– storage, and
– delivery.

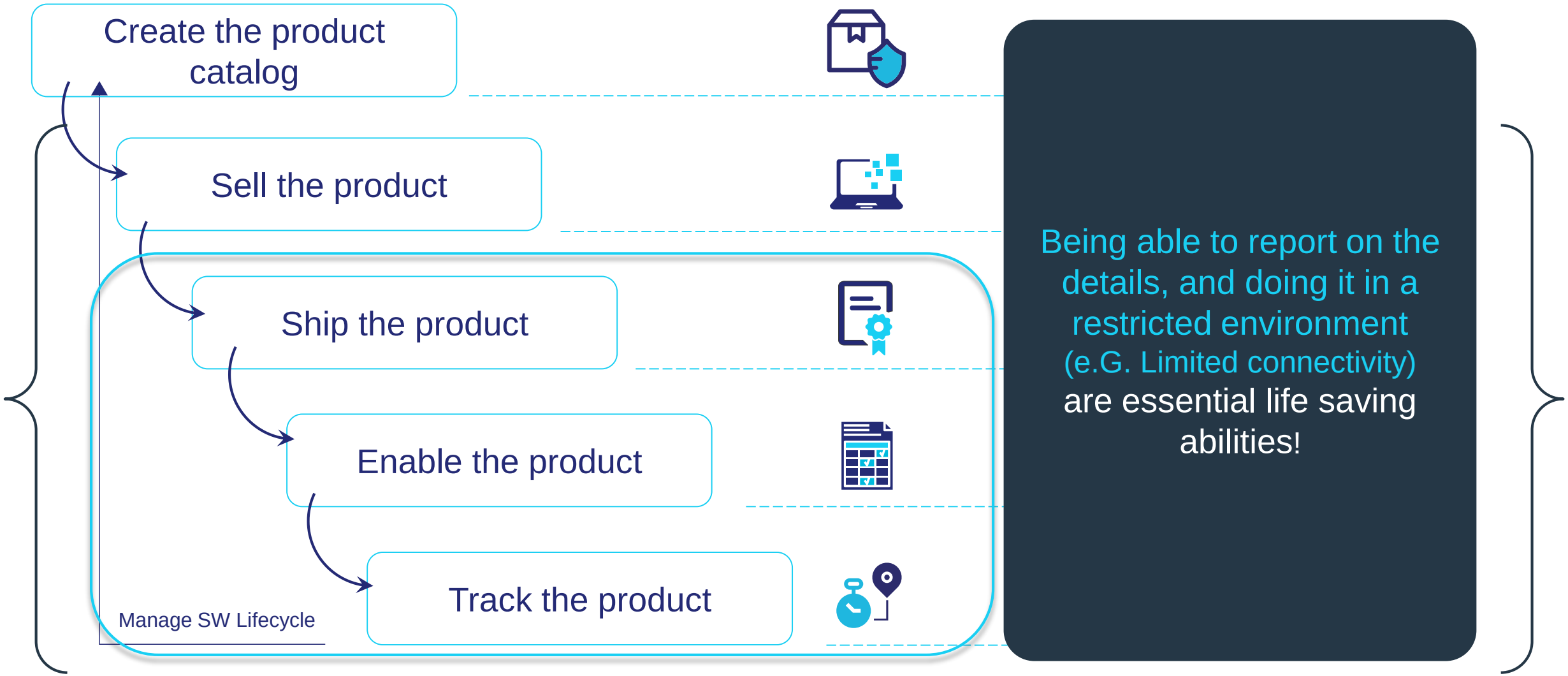
[Class A, B, C]


SOUPs
Docu-
mentation
Media
Config. Files
Certificates
Code
Config. Items
...

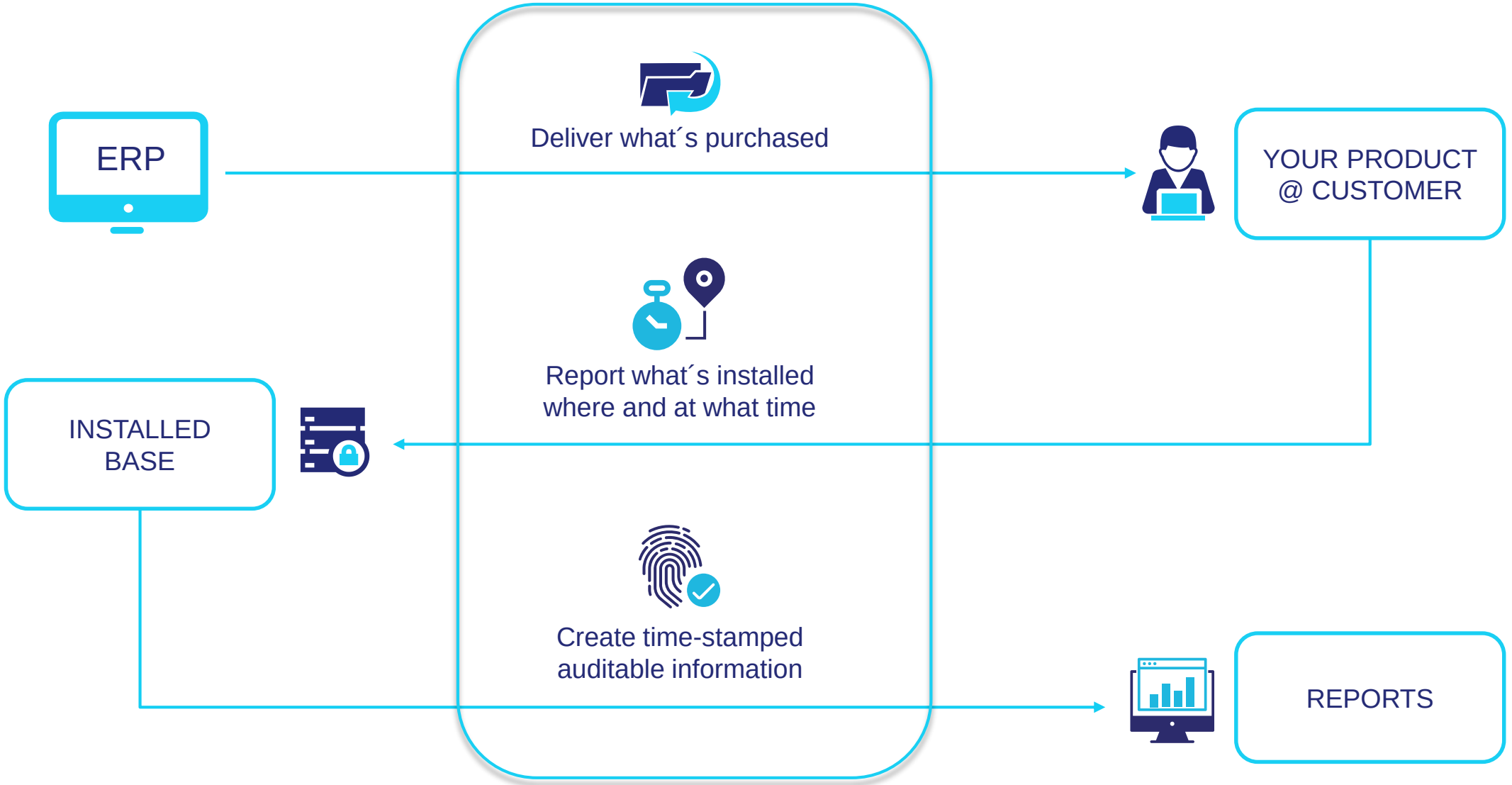
Summary

You need to know	In order to
Which medical device software	remove it
- in which version	recall it
- contains which artifacts	analyze problems
- with which version of artifacts	fix it
is located / used where	report it

Typical Product Lifecycle & Challenges



How it works



Technical bits and pieces supporting the lifecycle

Management

- Something that **is integrated with my back-Office** to enable an auditable digital supply chain
- Something in my Back Office that **collects information from the field** on my installed base and how it´s being used
- Something flexible **that maps my commercial product catalog** to a consistent technical product catalogue
- Something that allows me to **deliver my products digitally** in a secure and consistent way

Enforcement

- Something that **enforces my commercial** contract with the customer and helps my customers to be compliant
- Something that **reports back** my installed base and how it´s being used
- Something that is able to **work in restricted environments** (like hospitals) as well as in highly connected environments in a similar way

Lifecycle

- Something that **provides SW updates** based on rules I set and contracts that are in place
- Something that empowers my end customers to more **self service** without scarifying auditable information consistency
- Something that helps me to **control the lifecycle** of a product in the field

Thales **Sentinel** Solutions

Sentinel EMS (Management)

- Connect to your back office (make sure you deliver the right thing)
- Manage technical interpretation of a commercial contract
- Collect information on installed base and usage
- Ensure consistent product catalogue while providing flexibility (evolving business models / packaging)
- Connect to ESD to reliably provide SW packages

Sentinel Enforcement (Enforcement)

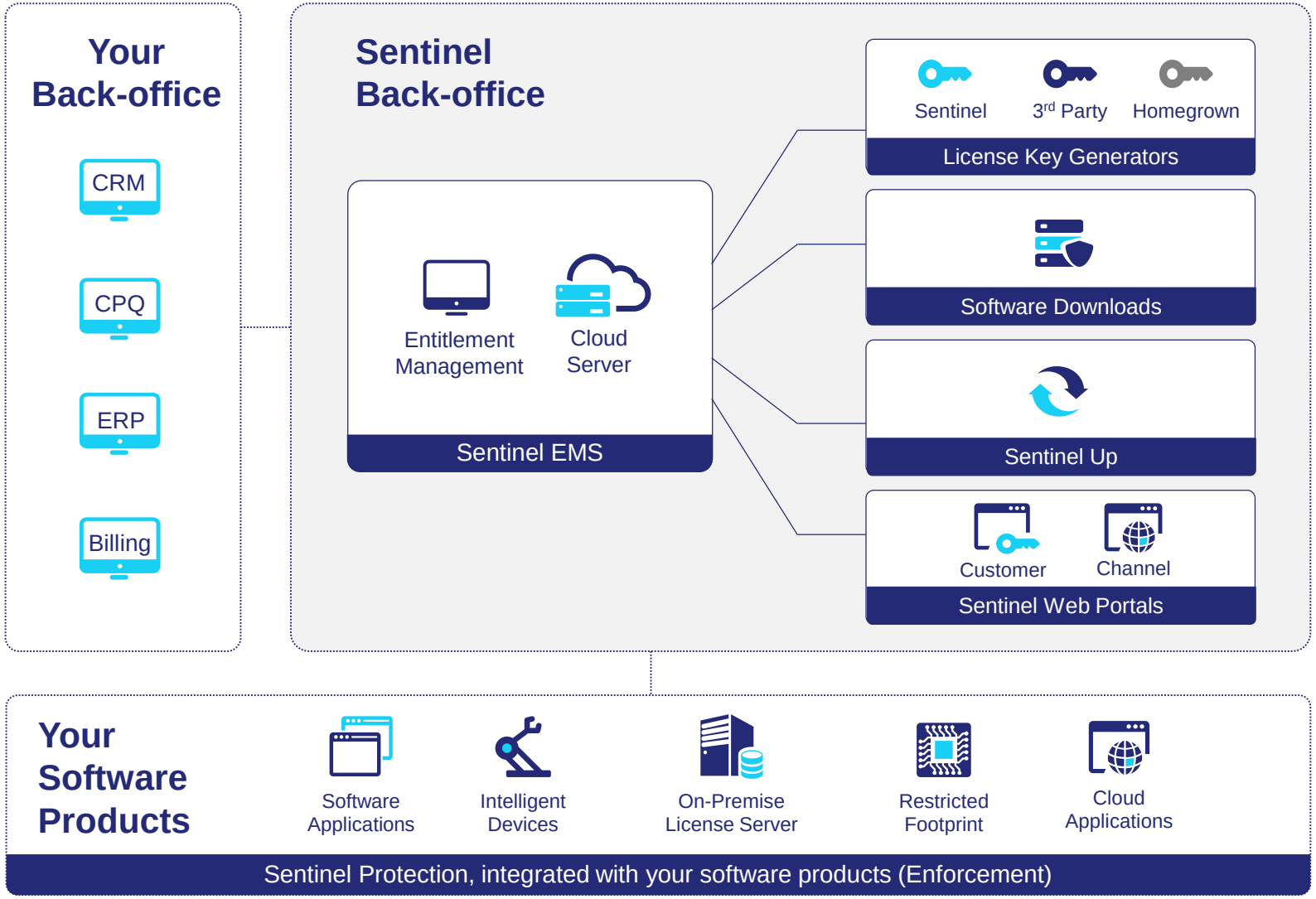
- Integrated with your software
- Enforce rules set by Sentinel EMS
- Supports your customers to be compliant
- Report installed base and usage
- The more connectivity, the better. But not required

Sentinel UP & EMS (Lifecycle Management)

- Control Lifecycle in the field
- *Provide SW updates based on rules set in Sentinel EMS automatically
- *Report installed base and location

*Requires connectivity for seamless operation & best customer experience

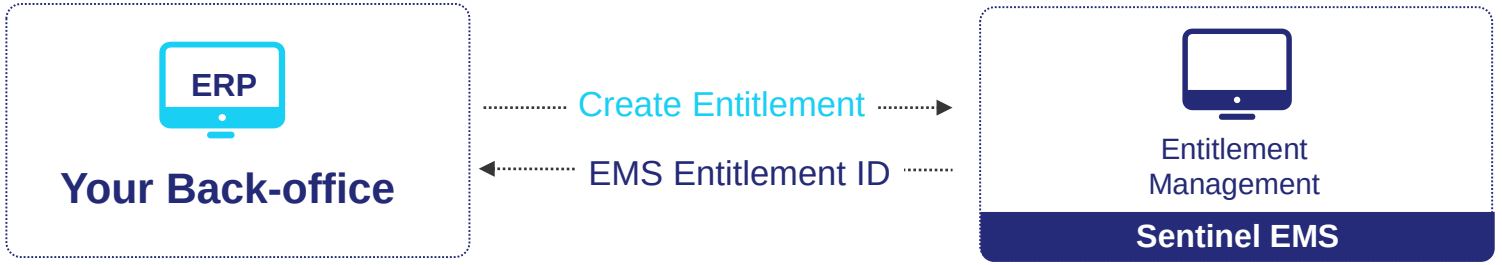
Toolchain - Sentinel Platform Overview



Solution Highlights

- **Integrated**
  The Sentinel EMS back- office can be tightly integrated into your back-office systems
- **Automated**
  EMS integration with ordering systems allows for automatic entitlement creation and customer notification
- **Flexible**
  EMS enhanced web portals have fully customizable workflows and look and feel
- **Secure**
  Sentinel offers application license enforcement across varying license models including IP protection

End to End – Sales Order to Entitlement



Sales Order Details

Sales Order	2077672770	
Customer	Ocean Waters Hospitals	
Ship-to	techadmin@acme	
Partner	ABC Reseller	
Distributor	Ingram Micro	
Product	**Quantity**	**Expiration**
ScanSuite	100	None
ScanSuite Pro	30	Jan 1, 2020

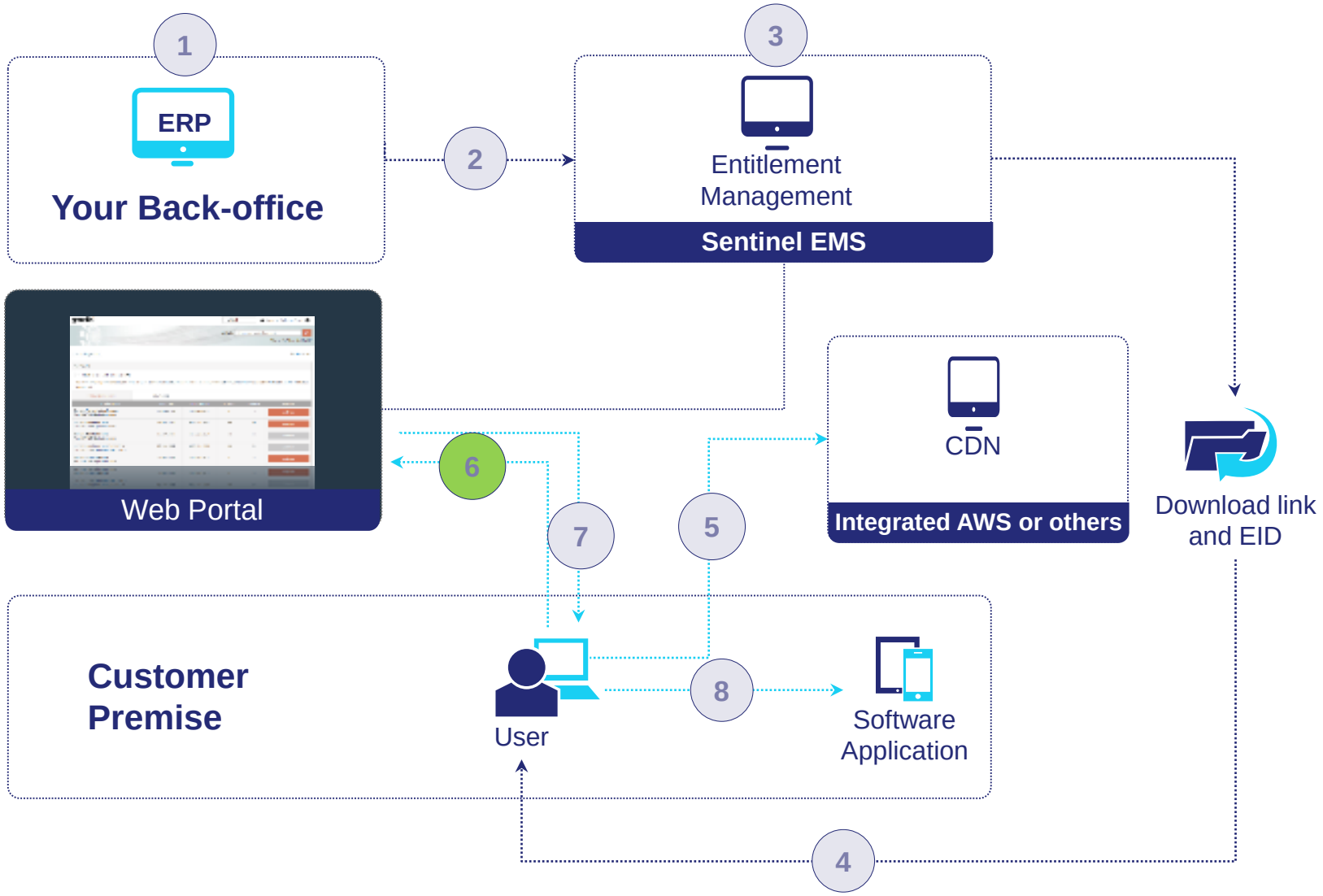
EMS Entitlement Details

EID	**asd-as1274-288434-ceda8iafa**	
Sales Order	2077672770	
Customer	ACME Engineering	
Contact	techadmin@acme	
Partner 1	ABC Reseller	
Partner 2	Ingram Micro	
Product	**Quantity**	**Expiration**
ScanSuite *{Metadata}*	100	None
ScanSuite Pro *{Metadata}*	30	Jan 1, 2020

Details

- **EMS Entitlements**
  Common configuration is to have a 1:1 relationship between sales orders and EMS entitlements
- **Common Data Elements**
  - Customer
  - Partners
  - Contact email
  - Order number
  - Line items
  - Quantities
  - End dates
- **Unique Identifiers**
  Each EMS entitlement has unique identifier (EID) and unique line item identifiers (product keys)
- **Entitlement Attributes**
  EMS entitlements support attributes for holding custom vendor information
- **Product Attributes**
  EMS products support attributes for holding custom vendor information

Activation Using Web Portal (target offline)



Workflow

1. New order placed in ERP

2. Order details flow to EMS

3. EMS creates new entitlement with unique EID
>> locked to specific SW version

4. EMS sends email to contact on entitlement. Email includes correct download link and EID

5. User downloads & installs SW

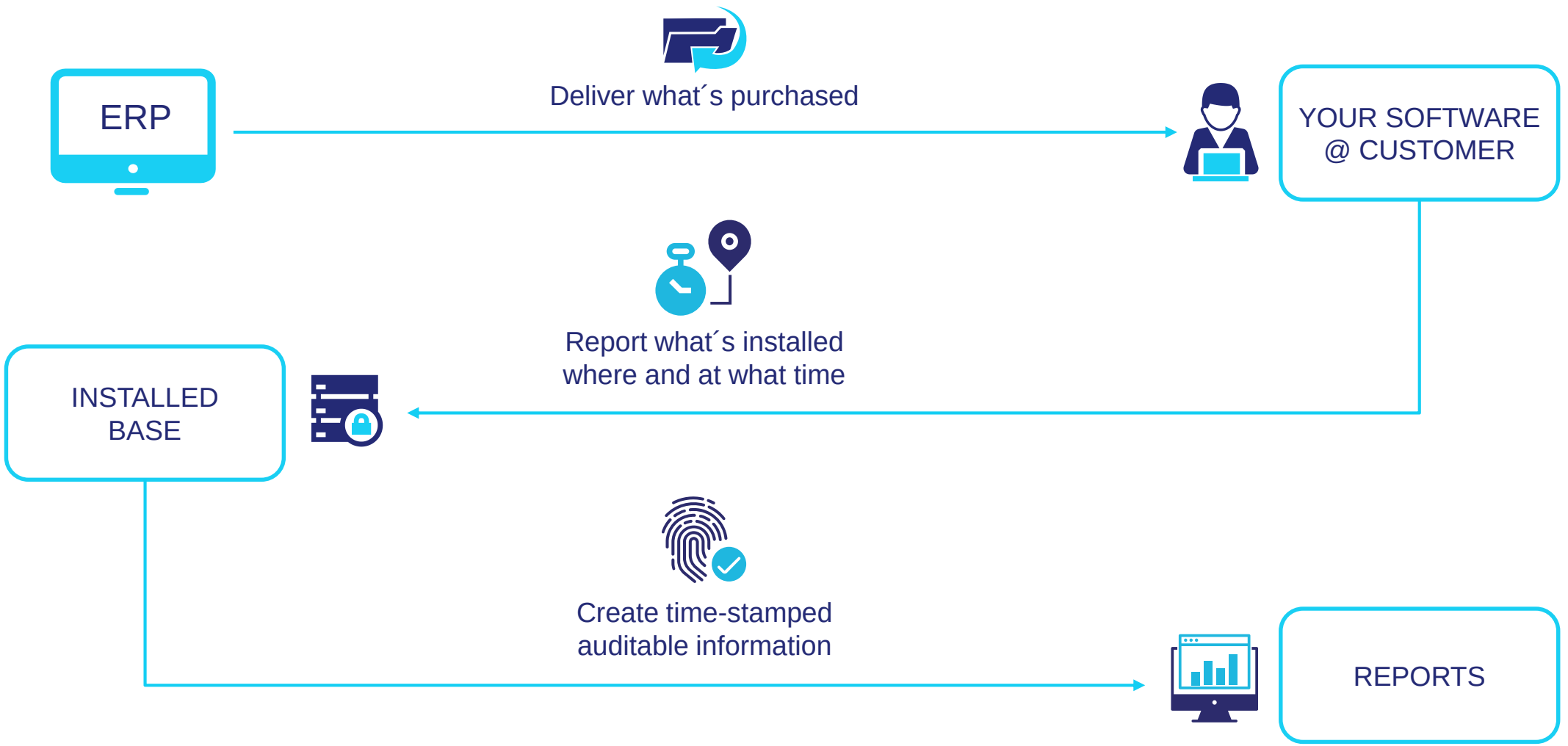
6. User logs into customer web portal and activates the license using the **locking ID of the target system + custom data (e.g. installed base information)**

7. User downloads the license file

8. User installs the license file on the target system

Alternative: Provide Entitlement with unlocked version and lock version at activation time

How it works



Benefits of using THALES Licensing solutions

SOFTWARE VERSIONS

- Know which SW version operates on which system at a certain time
- Know the history: which version was active at what moment
- Know the details: Which features have been active when and where)

REPORTING

- Report that information for each UDI
- If the audit is about a bug in a specific version of a function, know which customers have licensed it and could be affected

USAGE*

- Know which features have been used and when
- If the audit is about a bug in a specific version of a function, know which customers are really affected

* works better with online connectivity

Additional Benefits of using THALES Licensing solutions

COMPLIANCE

- Ensure your customers are compliant

BUSINESS INSIGHTS

- Marketing / Product Management insights

FLEXIBILITY

- Flexible product packaging
- Business Model flexibility
- Upgrade/Downgrade/Upsell
- Version Control (e.g. for Maintenance Contracts)

CUSTOMER RELATIONSHIP

- React to market quickly
- Subscription / PayPerUse
- Improve Software Support Efficiency

Q&A

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https://cpl.thalesgroup.com/software-monetization

Any Questions?

Johner Institut

Johner Institute

Getting your medical device approved in Europe and the US

The Johner Institute will help you navigate the medical device approval process in Europe (CE-mark) and in the US (FDA) getting your device to market as quickly, easily, and safely as possible

The Mission

The Johner Institute's mission is to help manufacturers market active medical devices quickly and successfully in the European and US markets by fulfilling regulatory requirements, passing audits and inspections, and preparing successful submissions.

The Johner Institute's ambition is to make sure that the innovative potential of medical device manufacturers is not limited by quality management bureaucracy nor mis-understood regulations.

The Team

The Johner Institute employs auditors (at notified bodies), computer scientists, physicists, physicians, engineers, members of standard committees, quality management and regulatory affairs experts.

Its founder is professor Christian Johner, PhD. The Institute has a strategic alliance with UserWorks, Inc., a US firm specializing in user experience design and human factors/usability engineering.

The Specialization

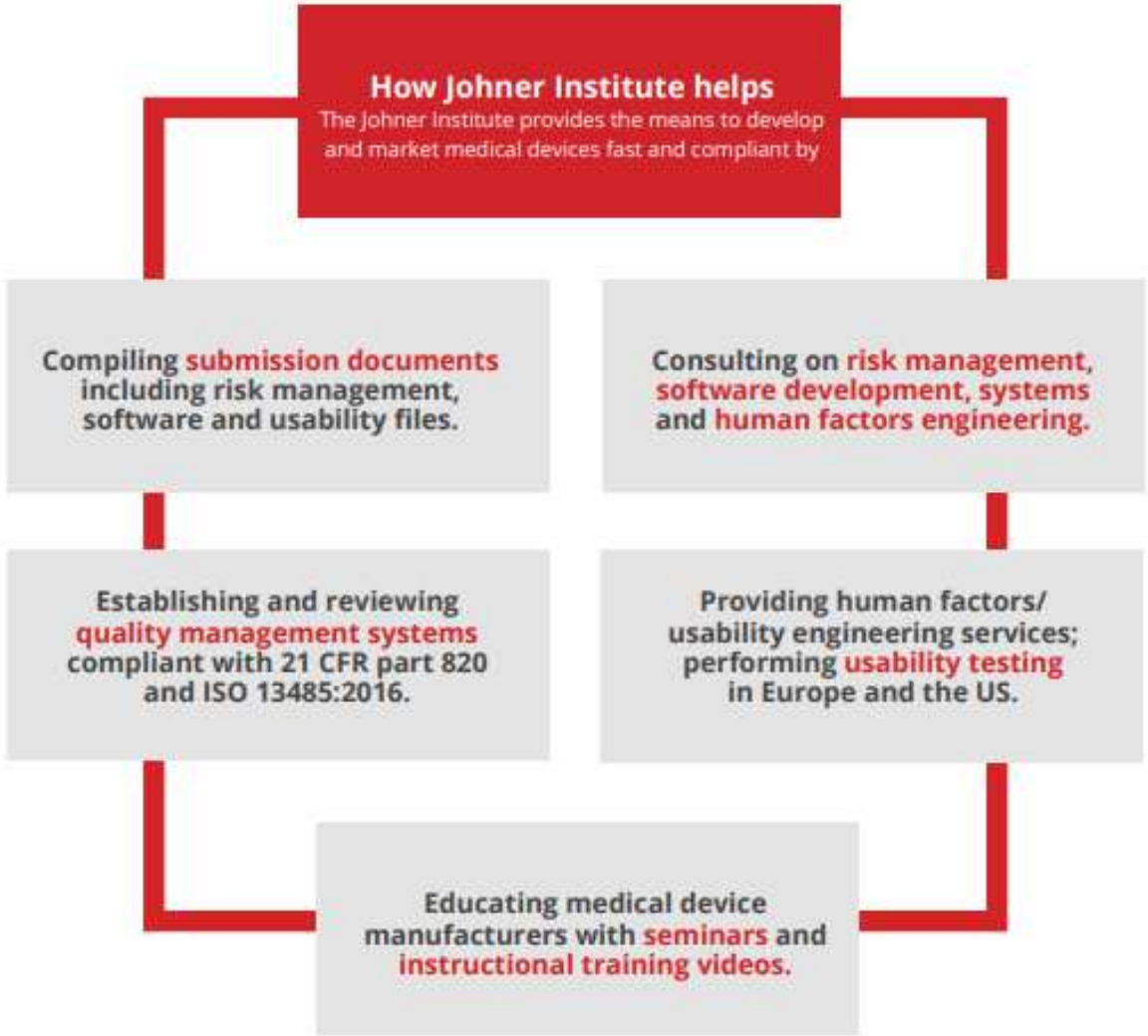
The Johner Institute supports manufacturers of medical devices, in particular of devices with embedded and of stand-alone software.

In this domain Johner Institute is the leading consultancy firm in the largest European market -- the German speaking countries.

With no exception, all of Johner Institute's customers (several hundred) passed audits, inspections and submissions successfully.

The Customers

When it comes to regulatory affairs, medical device software, risk management and human factors engineering, the Johner Institute is **the** consultancy and training provider for medical device manufacturers, engineering service providers, and most of the German notified bodies.



We help you to pass audits and approvals safely with lean files:

- Review, compile, improve **technical documentation** to achieve MDR/IVDR conformity
- Create, revise and prepare **submission files** for registration
- Establish, improve and audit **QM systems**
- Perform **usability tests** (e.g. in USA, Germany)
- Assess **biocompatibility**
- Compile **clinical evaluations**
- Planning and conducting **clinical investigations**
- Acting as your **Importer, Legal Manufacturer** and **"QM roof"**
- Monitor the market for you (regulations, **post-market surveillance**)
- Educate and qualify your team

Johner Institut

We do help!

www.johner-institute.com/contact

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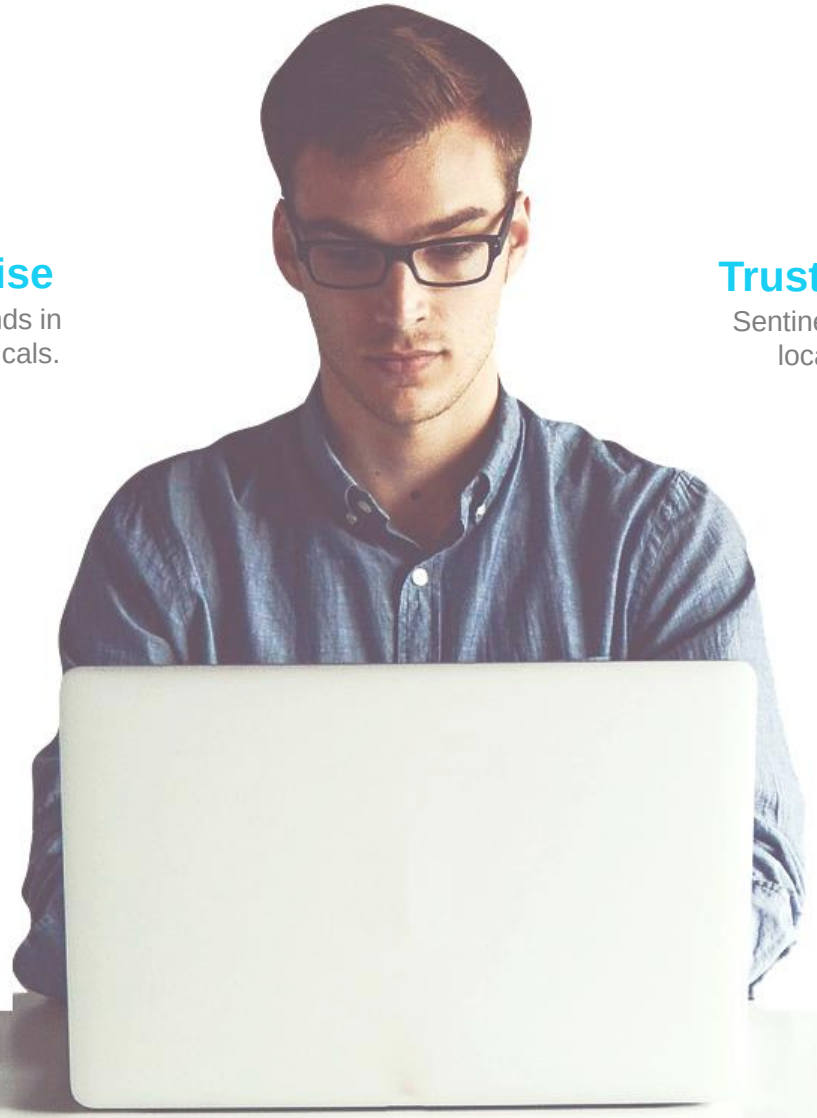
About Sentinel: Know the Facts



Proven Industry Expertise

Sentinel is used by leading global brands in 32 different industries and market verticals.

Trusted Global Supplier

Sentinel has over 10,000 customers located in over 100 countries

Market Leadership

Sentinel has 51% market share in the licensing and software protection market.

Technology Innovation

Frost & Sullivan Best Practices Award for innovation in emerging software monetization use cases.

Decades of Experience

Sentinel has over 30 years of experience and the Sentinel brand is recognized worldwide.

Q&A

Reach out to us:

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Any Questions?