March 2026

DIN SPEC 91509

ICS 35.240.80

Datenmodell für die technische Dokumentation von Medizinprodukten – Release #1: Informationen im Zusammenhang mit der Zweckbestimmung eines Medizinprodukts; Text Englisch

Data model for the technical documentation of medical devices –
Release #1: Information related to the intended purpose of a medical device;
Text in English

Modèle de données pour la documentation technique des dispositifs médicaux –
Version #1: Informations rela-tives à la destination d'un dispositif médical;
Texte en anglais

Gesamtumfang 33 Seiten

Dieses Dokument wurde durch die im Vorwort genannten Verfasser erarbeitet und verabschiedet.

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3670189

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Foreword

This DIN SPEC has been developed according to the PAS procedure. The development of a DIN SPEC according to the PAS procedure is carried out in DIN-SPEC-consortiums and does not require the participation of all stakeholders.

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At present, there are no standards covering this topic in the body of German Standards.

DIN SPECs are not part of the body of German Standards.

A draft of this DIN SPEC has not been published.

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Introduction

Digitization of the technical documentation for medical devices

The increasing complexity of regulatory requirements in the medical technology sector has led to significant challenges in the creation and maintenance of technical documentation (TD) for a medical device. New and more complex requirements introduced by the Medical Device Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR) in the European Union have intensified these challenges, lengthening the conformity assessment procedures and market access, and adding to the administrative burden on manufacturers and notified bodies.

Technical documentation is the collection of information that demonstrates that the medical device complies with the requirements of the Medical Device Regulation (EU) 2017/745. It includes information from design, manufacturing, clinical evaluation, risk management, and post-market activities. Creating and maintaining a TD is a resource-intensive process: the frequent reuse of the same information in different processes and related records creates complex documentation with many relationships that require the involvement of many disciplines and cross-functional subject matter experts. Furthermore, the representation of the documentation in a complete and comprehensive way is needed to ensure that external stakeholders, e.g. notified bodies, can quickly identify relevant information and its context.

The digitalization of regulatory processes and the related documentation offer a great opportunity that would significantly increase the efficiency of manufacturers and notified bodies by

— reducing the need for manual copy & paste activities, completeness checks, and frequent updates of traceability information;

— reducing the number of manual errors and improving consistency, thereby increasing documentation quality.

The benefits of digitalized processes have been well-established in other industries for many years, including the medical device industry. The digitalization of product lifecycle processes for medical devices is still in its infancy, but an increasing number of companies have started with their internal digital transformation.

However, to enable organizations to communicate and exchange information effectively across a digital platform, it is essential to create a common technical language that is clearly documented and accessible.

The use of a standardized, common technical language within a company increases the efficiency of the individual company. However, if a standardized, common technical language would be used by different stakeholders throughout the industry, this would benefit the entire industry ecosystem.

For the medical technology industry in Europe, this would mean faster market access for new or updated medical devices, which would ultimately lead to better patient care.

Unified data model and its benefits

A unified data model provides an unambiguous description of regulatory terms and a structured framework for the organization of the information contained in the TD for medical devices. The unified data model provides two main benefits:

a) standardized language:

   Clear definitions of regulatory terms provide clarity on what is meant by a term or what is expected by notified bodies. Today, terms are sometimes defined differently, misinterpreted or used slightly differently in multiple regulatory documents.

b) acceleration of digitalization:

It would no longer be necessary for companies to develop their own data model for the technical documentation of their products, but they could build on the standardized, unified data model and, if necessary, expand it for their company needs. Data models are the basis for the digitalization of processes, and a unified data model could be used by all industry stakeholders: medical device companies, suppliers, service providers, software providers, notified bodies and other regulatory authorities. That would enable consistency, a digital thread between different stakeholders and most importantly, it would speed up the implementation of software for digitalized processes.

In summary, the application of a unified data model would enable all industry stakeholders to work more efficiently, leading to more innovation and better patient care.

Role of the MDKU e. V.

In 2019, the benefits of a unified data model for medical device documentation were evaluated by a group of industry experts involved in digitalization projects. It was then examined whether there were already organizations working on a corresponding data model for the medical technology industry. Since this was not the case, the concept for the development of such a data model was initially developed in a group of interested parties, which led to the founding of the nonprofit organization Medical Device Knowledge Units (MDKU) e. V.

The goal of the MDKU is the cross-functional development of a unified data model for the content of the technical documentation for medical devices and its continuous maintenance, with a focus on requirements in Europe. The MDKU's goal is to make this data model available to all stakeholders free of charge, promoting wide adoption across the medical technology sector.

The MDKU facilitates collaboration among various stakeholders, ranging from medical device manufacturers and regulatory authorities to software providers. Members of the MDKU are experts from medical device manufacturers, consultancy companies, service providers, software providers, and other organizations in the field with which they cooperate and collaborate. All of them are dealing with the challenges of medical device lifecycle processes and thereby managing and keeping the related technical documentation up-to-date.

The clear mission of the MDKU is to reduce regulatory, administrative burden by facilitating and supporting a clear regulatory language and accelerate digitalization of regulatory processes. This will result in increased efficiency as well as more and faster innovation, in particular in the European medical technology ecosystem, and in the end, will lead to better patient care.

The initial goal of the MDKU is the development of a unified data model for content of the technical documentation as outlined in the European Medical Device Regulation (EU) 2017/745, Annex II and Annex III.

Additional background information on the MDKU project and answers to frequently asked questions are provided in Annex C.

Development of the data model – Initial goal and approach

The initial goal of the MDKU is the development of a unified data model for content of the technical documentation as outlined in the European Medical Device Regulation (EU) 2017/745, Annex II and Annex III.

A standardized data model for the medical technology industry definitely has the potential to be used internationally in other regions of the world, but the initial focus of the MDKU is to reduce the regulatory, administrative burden for the European medical device sector.

Due to the complexity of such a project and the wide range of specialist disciplines, perspectives and dependencies between single data model elements, it was decided that the data model covering an entire TD should be developed iteratively over several releases. It is planned that each release will have a particular content focus and will complement and update the previous release.

When the data model for the MDR technical documentation is complete, the continuous update of the data model, as well as the development of an IVDR specific data model, are planned.

Development of the data model – Identification of data model elements

Step 1: Analysis of regulatory documents: Based on the defined scope of a data model release, the MDKU identifies and screens relevant regulatory documents that provide information on the required content of the TD. In teams ("expert groups"), technical experts analyze the regulatory texts and extract terms that represent specific content that is expected in the technical documentation (data elements known as "knowledge topics" or abbreviated as "KT").

NOTE For the development of the first release of the data model, the focus is on content required by European Medical Device Regulation (EU) 2017/745, Annex II and Annex III. But as details or explanations on certain information in European Medical Device Regulation (EU) 2017/745, Annex II and Annex III, can also be found in other regulatory documents, additional regulatory documents are included in this step – if they contain helpful information for the development of the data model. These can include, for example, international standards and MDCG guidance documents.

Step 2: Development of a clear description: The expert groups develop clear definitions for each of those knowledge topics (KT) and provide additional information, e.g. how the term is used and on which regulatory basis the definition was developed. In case a suitable definition for the KT already exists, it may be possible to adopt it directly from the MDR, a guideline or a standard. When the expert group believes that there is a lack of clarity in the industry, it will work on a better definition. The focus of this work is to create clarity and at the same time to provide important insights for the later application of the KT, which were discussed in the expert groups. The aim: to create the greatest possible added value with the data model provided.

Step 3: Identification of relations between data model elements: Often, elements of the data model are not standalone information, but there is a relationship between other data model elements, e.g. a hierarchical or contextual relationship. Such relations are discussed and documented, helping users to understand the context of a single KT.

Step 4: Collection of feedback from other expert groups: Since many elements of the data model are required in different processes and thus by different experts within a company, feedback is collected from other expert groups within the MDKU. The aim is to describe a data model element so well that it can be used for all applications in different processes. It may become apparent at that point that a more granular structure is required in the data model to meet different regulatory requirements for different processes and records (e.g. one process may require a summary of information and conclusion, whereas another process requires a detailed listing of data and their analysis.)

Step 5: Quality check and finalization of release content: At the end of the MDKU internal process, the content of single KTs and the overall release content is reviewed for completeness and comprehensibility. The results of this step and the first "MDKU internal" release were used as input for this DIN SPEC project.

Development of the data model – Goal of the DIN SPEC project

The aim of the DIN SPEC 91509 project is to have the results of the MDKU's data model development reviewed by other, external, stakeholders of the industry and to discuss and revise data model elements if necessary. Such stakeholders include representatives from companies not involved in the MDKU, representatives from Notified Bodies, academic institutions, or other interested parties.

The overall goal of the project is identical to the goals of the MDKU:

The project team wants to establish a standardized, data-based framework for the content of the TD of medical devices, aligning with the regulatory requirements outlined by the MDR, to achieve:

— **Streamlined regulatory compliance:** By creating a common structure for technical documentation, the project aims to simplify and reduce the regulatory burden on manufacturers and notified bodies.

— **Foster innovation and better patient care:** Freeing-up resources that are typically spent on repetitive documentation tasks without any value, allowing manufacturers to focus more on innovation, thus driving advancements in patient care.

— **Promote international consistency:** Further standardization of technical documentation helps ensure that medical devices comply with international regulatory requirements – whether from laws, guidance documents, or international standards – thereby facilitating smoother market access across different regions.

This DIN SPEC project is a crucial step toward ensuring that regulatory compliance supports – rather than hinders – the development of life-saving medical devices, enabling a more efficient, streamlined approach to bringing innovative devices to market.

Development of the data model – Novelty of the data model and its development and review process

This project is unique in terms of both approach and content, and is highly complex. Therefore, the first version of this document and the first data model release should be seen as proof of concept. It is not only about the pure content of the data model, but also about the development of a working method that is suitable for the long-term, continuous development and maintenance of the complex data model.

The results and experiences from the DIN SPEC project are in turn used as input for the MDKU data model development process so that the data model can be continuously improved.

The aim of the MDKU and the DIN SPEC project team and their regular exchange is to develop processes that are as efficient as possible and that allow for a swift expansion and adaptation of the data model. Both the MDKU and the DIN SPEC project team are aware that the data model will need refinement over time with future releases, and that the way the data model is developed, tested, and released will need to be continuously adapted.

1 Scope

This document defines terms, definitions, and general requirements for a data model intended for categorization of information in the technical documentation of medical devices. This includes:

— a provision of general information about the background of the project and expected benefits;

— a description of the data model development procedure;

— information about the data model structure;

— a first collection of data model elements that belong to the “intended purpose information collection” (first release);

— information about the initial application of the data model and feedback collection.

This document establishes a common understanding of elements required in the technical documentation for medical devices – required for a swift and reliable transaction of information between various cross-industry partners. Therefore, the content of this document serves as a facilitator to simplify communication and the exchange of information between different stakeholders in the medical technology sector (e.g. medical device manufacturers, suppliers, notified bodies, certification bodies, regulatory bodies).

This document does not define requirements for other types of data models or specific data formats, nor does it set requirements for the technical infrastructure of industry stakeholders intending to implement and use the data model.

WARNING — As a result of the novelty of this project, no guarantee can be given for the completeness of the published data model. All participants have worked to the best of their knowledge and based on their own expertise and the extensive exchange across various expert groups. Since new regulatory documents are continuously being published, not every regulatory document published yet could be considered in the current release. New documents will be integrated over time with future releases.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

DIN and DKE maintain terminological databases for use in standardization at the following addresses:

— DIN-TERMinologieportal: available at https://www.din.de/go/din-term

— DKE-IEV: available at https://www.dke.de/en/services

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
documentation
continuous and systematic compilation and processing of recorded information for the purpose of storage, classifying, retrieval, utilization, or transmission

Note 1 to entry: Typically, in medical technology the term documentation is understood as collection of documents related to a given subject. That often includes formats like Word, Excel or PDF files. In the context of this document, documentation is understood as a collection of information – independent of the format itself.

[SOURCE: ISO 5127:2017, 3.2.1.22, modified – domain and original note to entry removed and new note to entry added]

3.2
document
collection of selected information, represented in a structured way

Note 1 to entry: Many regulatory documents, such as the MDR, MDCG guidelines or standards, mention documents and list expected content. Nevertheless, the included information can be considered as data that might have a different single source of truth.

3.3
data model
graphical, lexical or combined representation of data, specifying their properties, structure, and interrelationships

[SOURCE: ISO/IEC 11179-1:2023, 3.2.24]

3.4
data element
<organization of data> unit of data that is considered in context to be indivisible

[SOURCE: ISO/IEC 2382:2015, 2121599, modified – all notes to entry removed]

3.5
instance
realization of an abstract concept or specification, e.g., class instance, application instance, information service element instance, virtual medical device instance, operating instance

[SOURCE: DIN EN ISO 11073-10201:2020-09, 3.1.29]

3.6
knowledge topic
KT
(structured) container for information related to a specific topic, subject, or area required in the technical documentation of a medical device, serving as a template to be populated with the specific information for a given medical device

3.7
knowledge unit
KU
instance of a *knowledge topic* (3.6) populated with specific information for a given medical device, serving as a single source of truth, maintained in one place to ensure consistency across documents or sections of the technical documentation

Note 1 to entry: The knowledge unit can be reused as needed but is not duplicated, preserving alignment with its originating *knowledge topic* (3.6) template.

Note 2 to entry: A filled-out *knowledge topic* (3.6) with specific information for a given medical device becomes a knowledge unit.

3.8
single source of truth
SSoT
data management principle where a single, centralized data source is used to ensure consistency and accuracy across an organization, aiming to eliminate data silos and discrepancies by providing all stakeholders with access to the same, up-to-date information

Note 1 to entry: Implementing an SSoT system involves structuring information models and associated data schemas so that every data element is mastered or edited in only one place. This practice provides data normalization to a canonical form, ensuring that all users and systems within the organization rely on the same data source for decision-making.

Note 2 to entry: By adopting an SSoT approach, organizations can improve data quality, reduce redundancy, and enhance trust in the information used for business processes. This is particularly important in complex enterprises where data is sourced from multiple systems and the risk of inconsistencies is high.

4 Data Model Information

4.1 Transformation from documents to data

People that are involved in medical device related lifecycle processes are accustomed to creating and managing extensive documentation, which is part of the technical documentation of a medical device. Up to now, the technical documentation consists of many individual documents, and each document is created and maintained independently according to defined processes. However, this document-centric approach often results in repeated descriptions of the same essential content, such as the device description or information about the intended purpose/intended use which among other is required in the Risk Management Plan (RMP) and in the Clinical Evaluation Plan (CEP) shown in Figure 1.

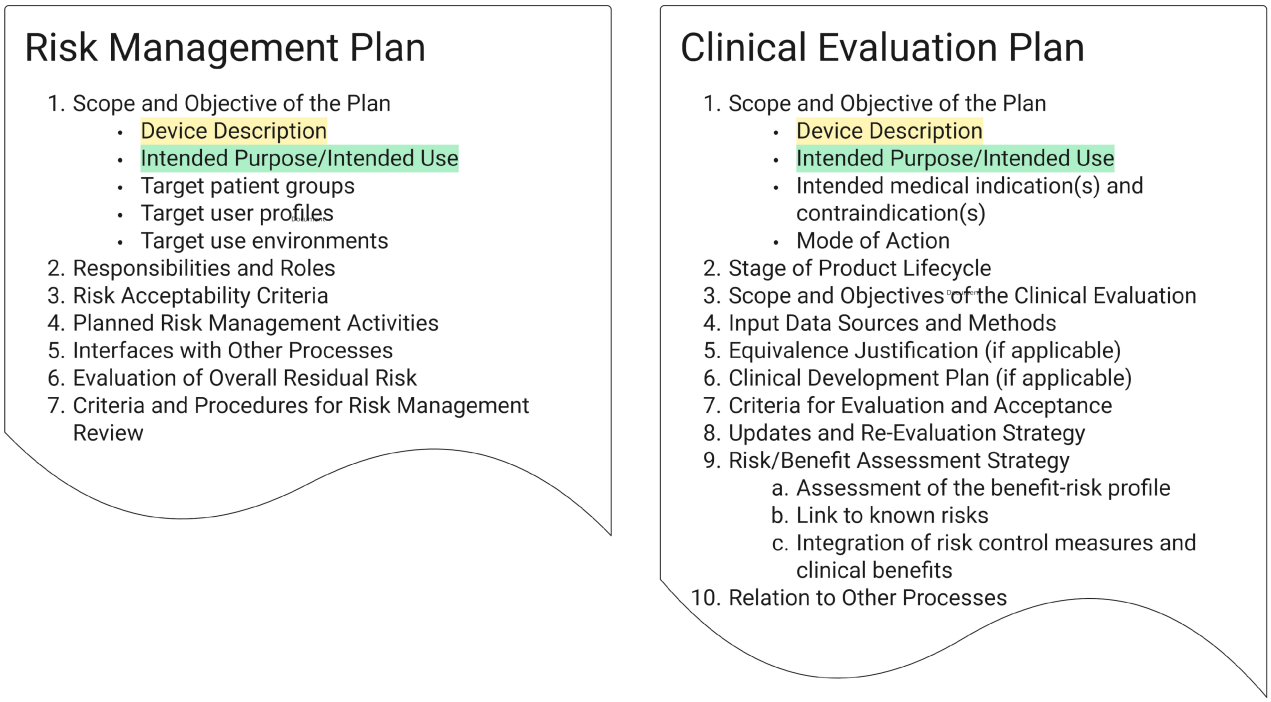

Figure 1 — Repeated content in different documents of a technical documentation for medical devices

This working method creates a risk of inconsistency and redundant effort. Inconsistencies can have far-reaching consequences: for instance, an inconsistency of the target user group, whether a layperson or a healthcare professional, can lead to incomplete risk assessments in risk analysis. Such inconsistencies may also result in clinical data from equivalent medical devices mentioned in the clinical evaluation not being accepted by notified bodies due to different user groups mentioned in different documents of the technical documentation.

To address these challenges effectively, a transformation from a document-centric approach to a data driven documentation practice is needed: Single "elements" of content in documents is captured as structured, interconnected data rather than isolated text. This approach enables the digitalization of processes and the efficient creation and management of technical documentation content with the support of appropriate software. The use of software that allows the "data-driven approach" enables the utilization of the "single source of truth" (SSoT) concept (see Figure 2): The SSoT is typically a database with a user interface in which an element of content is created for the first time. The same content element can then be reused in other documents of the Technical Documentation, but can only be changed in the source. That concept ensures consistency, allows easy cross-referencing, and streamlined updates of different elements of the TD, fostering regulatory compliance and lifecycle management in line with regulatory requirements.

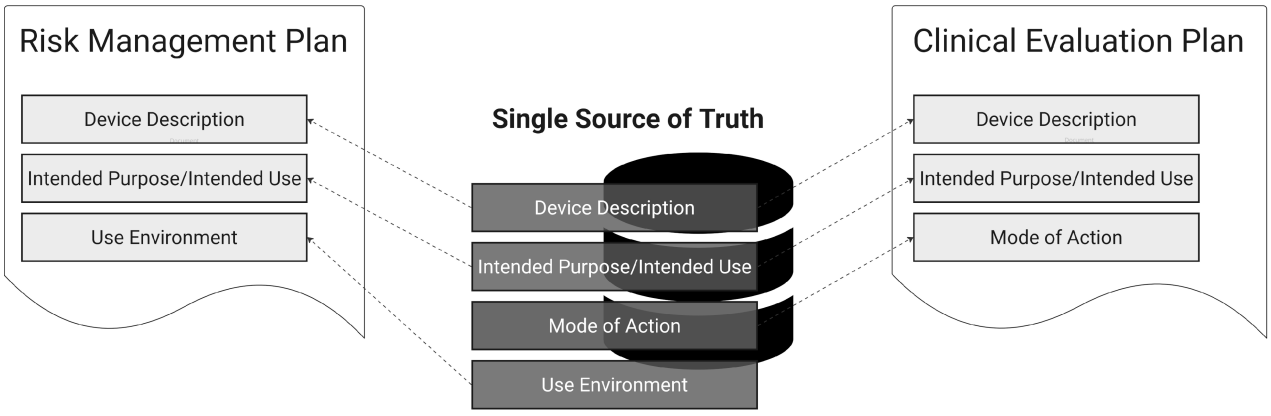

Figure 2 — Single source of truth in a data model

4.2 Data Model Concept

4.2.1 Purpose

The following subclauses explain the concept of the data model and its importance. When creating content or implementing the model itself, reading this chapter should help to understand how data is structured and used. When dealing with more technical aspects, reading additional sections will provide a deeper understanding.

The overarching principles that guided the development of this data model are described in Annex A.

4.2.2 Introduction: Structuring of information

All data has some form of structure. For example, a printed phone book is organized alphabetically and contains a person's name, title, and phone number. Organizing or looking up this information may be difficult: If the name is known, for example, the number is easy to find, but the reverse is much more difficult.

Techniques for accessing data in a more flexible way have been introduced with the advent of computerized data handling, commonly known as database systems, which allow for flexible ways to search and organize information. To make these databases effective, we use data models – structured blueprints for how information should be stored, retrieved, and managed (see Figure 3).

RFC 3444:2003 gives some baseline definitions of the terms and usage thereof and was used to derive the following definitions.

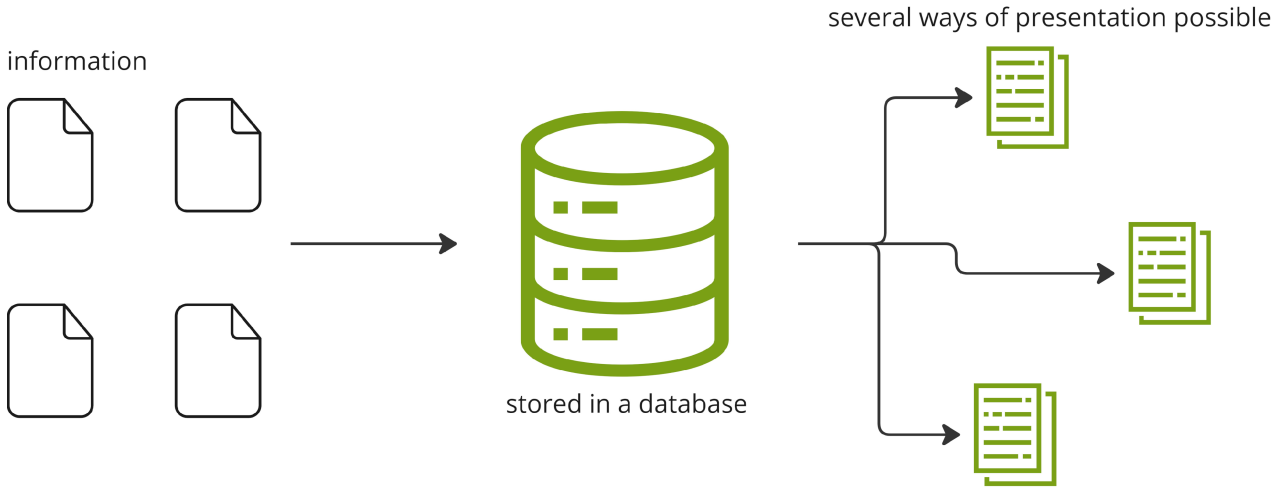

Figure 3 — Raw information can be stored in a database, enabling flexible and multiple ways of presentation

4.2.3 Information Model (IM)

An Information Model (IM), often also named “conceptual model” or “abstract”, defines a broad, conceptual way to organize data and to add context to the data.

It outlines

— the types of data being used,

— how different pieces of data relate to each other,

— the rules for structuring data.

Information models are independent of specific technologies, allowing them to be implemented in various forms such as diagrams, digital databases, or software applications designed to manage this type of information. They serve as a bridge between technical and non-technical stakeholders, ensuring clear communication and shared understanding. Typically, IMs are tool agnostic, meaning they are not restricted to a certain technology or even protocol, but may be realized in many ways, such as pictorial, plain text or other drafting tools (see Figure 4).

Analogy: Think of an Information Model as a recipe – it tells you what ingredients (data) you need and how they should be combined.

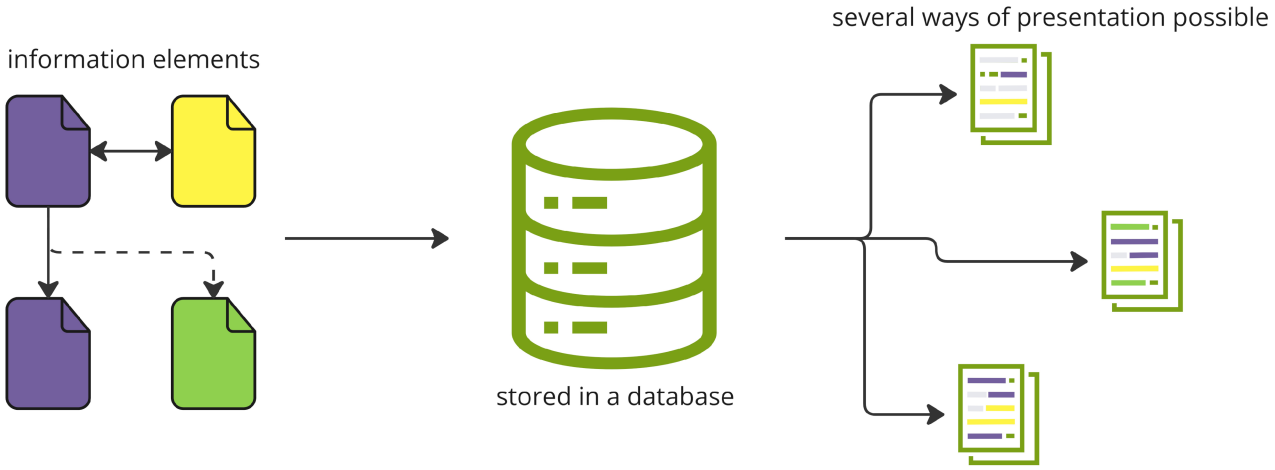

Figure 4 — An Information Model defines structures of abstract data that can be implemented in a Data Model

4.2.4 Data Model (DM)

A Data Model (DM) is a more detailed version of an Information Model. It provides the technical structure necessary to implement the model in software systems (see Figure 5).

Unlike an IM, a Data Model:

— defines how data is stored in databases or applications;

— specifies software rules and constraints;

— converts abstract concepts into a usable format.

Analogy: If an Information Model is a recipe, then a Data Model is the actual dish, i.e. what is served as a result of application of the recipe.

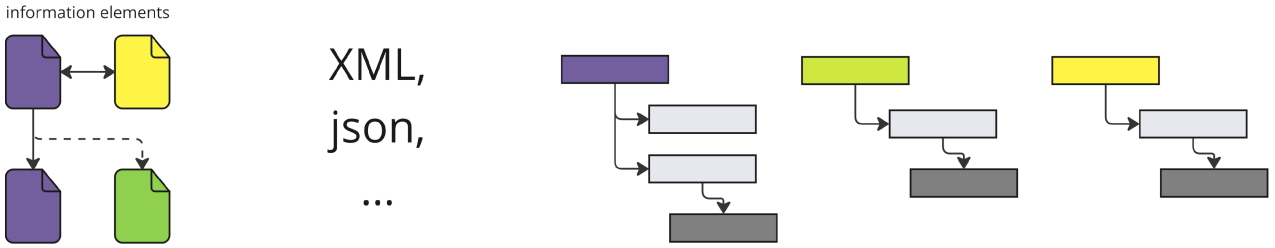

Figure 5 — A Data Model realizes the defined structure from the Information Model.

4.2.5 Application of IM and DM for the MDKU

For the MDKU the Information Model is implemented using XML-based definitions (XSD schemas). These structures are designed to be simple yet comprehensive, ensuring that regulatory requirements and solutions are clearly documented. The names used in the definition are aligned with the ongoing work in the IDiS consortium for the international establishment of Digital Standards.[1]

1 IDiS – Smart Standards, https://www.dke.de/idis

Relations between entities (in the sense of entity relationship modelling) are enclosed as list-valued entries in the elements for the moment but shall be externalized into separate entities within the system in the future work[2]. This model may be implemented in any valid way, preserving the overall structure, and therefore may be exported to other formats such as Excel or Word files – albeit this will be accompanied by the loss of at least some information.

The key structure of a knowledge topic can be visualized as shown in Figure 6:

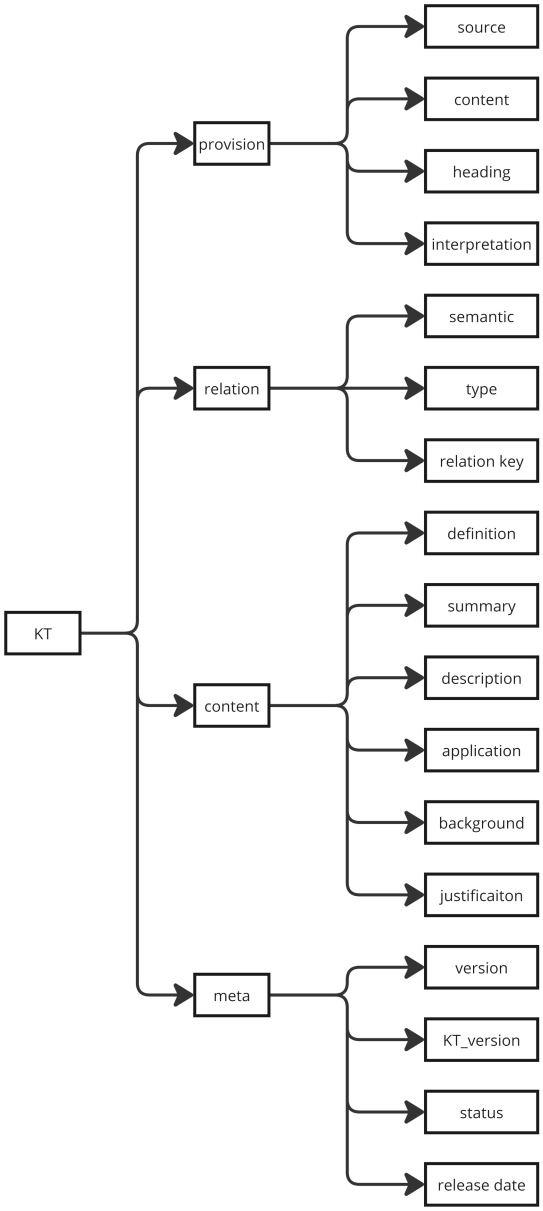

Figure 6 — Key structure of a knowledge topic (KT)

The key structure consists of:

— **KT**: MDKU knowledge topic, the main element in our model:

2 This is due to limitations in the current workflow, which does not support normalized relations.

- **Provision:** identifies legal or regulatory requirements:
  - Source: identifies the origin of the regulatory requirement.
- Content: is the original text from the source, may not be available due to licensing issues.
- Heading: heading or chapter name of the provision if applicable.
- Interpretation: povides background information on the regulatory requirement with a practical, industry-oriented perspective.
- **Relation**: defines the relationship of this element to other elements:
  - Semantic: comment or explanation of relation, i. e. the semantic relation to another topic(s).
  - Type: type of relation: “contributes”, “is mentioned in”, “is defined in”, “is child of”, “in collection.”
  - Relation key: points to the unique identifier of another MDKU knowledge topic (KT)[3].
- **Content**: is the main content and the definition of the data necessary to fulfil the identified provisions:
  - Definition: definition of the meaning of the knowledge topic in the Information model. Note: The Definition is derived from the provisions.
  - Summary: summary/abstract/catchphrase of this content. This is the abbreviated text “chunk” which is included in the output when compiling units into larger structures.
  - Description: description of the content.
  - Application: explains the intent behind the definition, distinguishes the KT from other knowledge topics, and describes how it should be applied within the Technical Documentation.
  - Background: provides relevant context on why and how the knowledge topic (KT) was defined.
  - Justification: explains the rationale behind the selected Evidence Level (clarifying whether the KT definition is reused from a regulatory source (e.g., law, international standard, or guidance) or uniquely defined by MDKU, and why that choice was made.
- **Meta**: represents the metadata of this KT:
  - Version: version of this KT.
  - KT_Version: version Number of this KT.
  - Status: status of this KT.
  - Release date: date of the release of this KT.

Applying the information model helps create specific data model instances, prepared by the MDKU. For example, when identifying a regulatory requirement such as “We need a definition for the content of the Intended Use statement,” various sources are collected to form the “provision.” This provision can be addressed

3 Technically this should be a separate entity as a n:m relation, therefore this is a workaround until new workflow has been realized. For reasons of self-containment of KTs the relation entries shall be included in the actual KTs rather than in a separate file, which is a violation of normalization principles – but this way they are easily parseable by any application program.

by defining the relevant "Content." When applied in a real-world case, this results in a "unit" containing specific content. A collection of these knowledge units (KU) makes up the "Technical Documentation" for a medical product (see Figure 7).

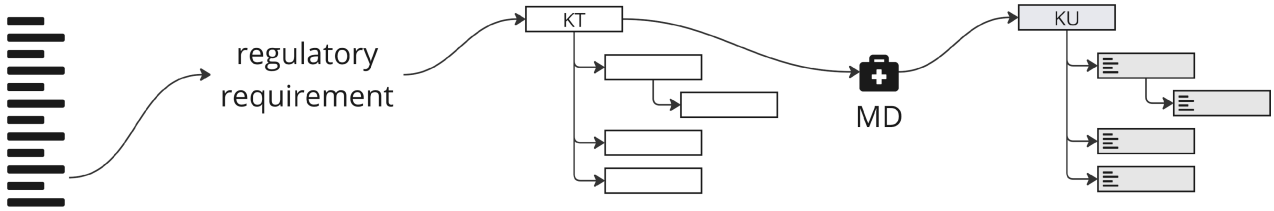

Figure 7 — Application process of knowledge topics (KT) to a specific medical device (MD) in order to generate corresponding knowledge units (KU), which fulfills the regulatory requirement addressed by the KT

4.2.6 Benefits

This approach offers two key benefits:

a) **Standardized Information Exchange:**

Having a widely accepted information model enables software architects to design programs that efficiently handle data model content. Think of this as a common standard for sharing information, similar to exchange formats like ReqIF™. While the model presented here can be easily converted into ReqIF™, it provides a unique set of features tailored for specific needs.

b) **A Reliable Source of Truth:**

The data model, which consists of predefined "knowledge topics," serves as a validated, single source of truth. To create a complete dataset, users only need to add specific information related to a particular device, manufacturer, or project. These datasets, called "knowledge units," inherit their structure from the corresponding knowledge topic and remain traceable back to the original regulatory requirement, ensuring full compliance and closing the loop.

4.3 Data Model Application Example

4.3.1 General

Beyond the theory of information and data models, the following subclauses will provide a practical understanding of how a data model can be implemented.

4.3.2 Understanding knowledge topics (KT) and their instances

A knowledge topic (KT) can exist in different ways:

— Exactly one instance → This KT is mandatory and must always be present.

— Zero or one instance → This KT is optional and may or may not be included.

— Zero to multiple instances (0 to n) → This KT can appear multiple times as needed.

Each KT has a predefined specification that determines how many instances are required. One medical device might be used by one or more intended user(s), therefore the KT "Intended User" can exist in one or more instances. In contrast, each medical device has exactly one intended purpose/intended use. Therefore, the KT "Intended Purpose/Intended Use" exists only in a single instance.

4.3.3 Grouping knowledge topics with “Topic Collection”

Beyond the predefined KTs of the MDKU data model, users can extend the provided data model with own company-specific KTs if needed for the application within the company and for the specific product portfolio. The following sections provide examples of how the provided data model might be used within a company. To accommodate different approaches to structuring technical documentation, KTs can be grouped under broader categories, called “Topic Collection” (see Figure 8).

Topic Collection serves as a mechanism for thematically organizing knowledge topics (KTs) without altering their original structure or duplicating content. Each KT exists as a single, uniquely defined data object within the overall data model.

To illustrate the principle, consider the analogy of a music streaming service. Each song in such a service exists only once in the central music database. However, users can create playlists by referencing individual songs, thereby grouping them by mood, activity, or personal preference. Songs can appear on multiple playlists or in none at all.

In the same way, a Topic Collection groups context-specific KTs based on thematic, functional, or regulatory criteria. A Topic Collection constitutes a KT by its structure; same data elements to describe the Topic Collection’s content are applicable. Each KT may be associated with multiple Topic Collections or remain unassigned.

This structuring principle supports flexibility in documentation and reuse across different contexts, while maintaining consistency and integrity of the underlying data model.

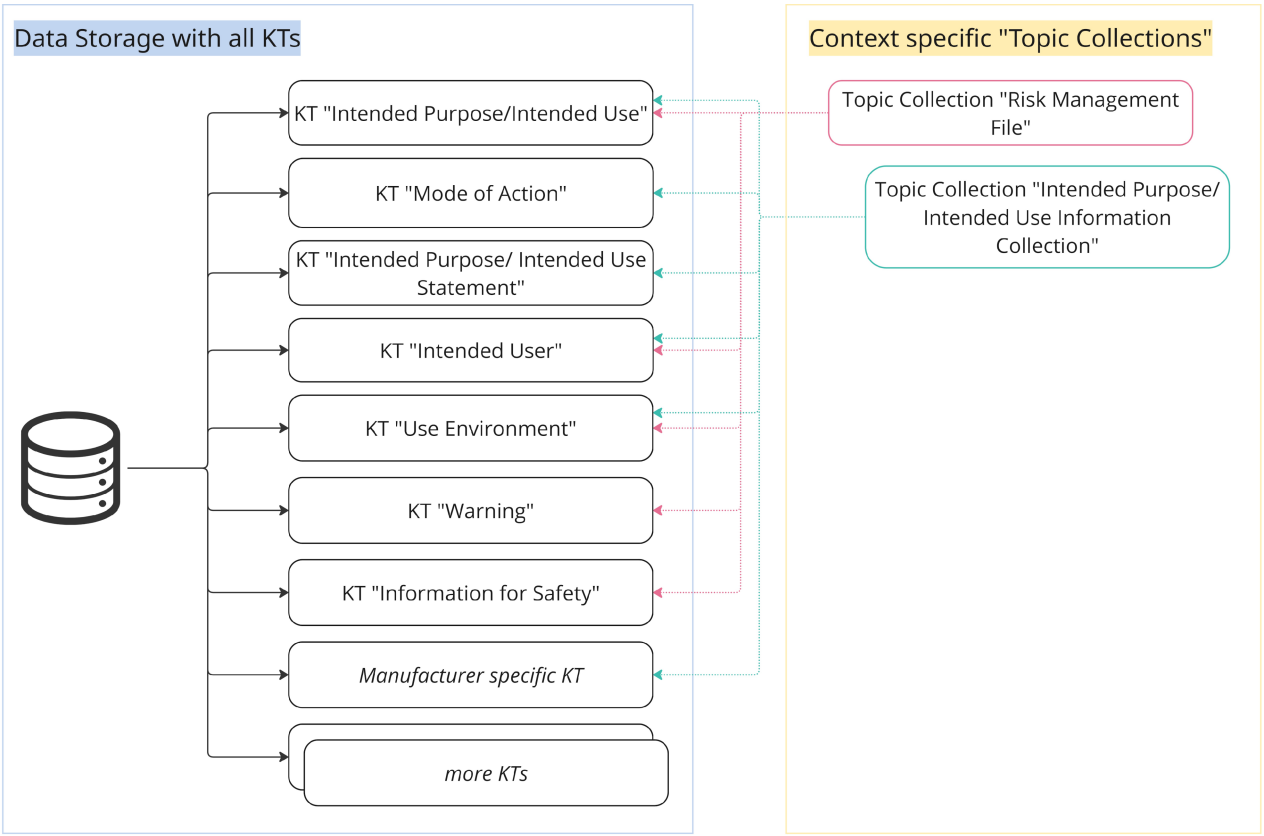

Figure 8 — Topic Collections can be used to group KTs context specific

The following applies:

— A “Topic Collection” represents a set of KTs (by structure).

— Regardless of their assignment to a Topic Collection, every KT can have contextual relationships with other KTs, establishing meaningful connections within the data model.

— A Topic Collection can be created as needed for the data model application.

— There is no limit to the number of Topic Collections.

4.3.4 Different representation of data model's flexibility of application

Various interpretations of the topic "Intended Purpose/Intended Use" can be realized by using the concept "Topic Collection". The need for a flexible data model to enable use of the two terms "Intended Purpose" and "Intended Use" is outlined in a publication provided by this DIN-SPEC-consortium and published at https://mdku.digital.

The following examples (see Figure 9, Figure 10 and Figure 11) show the data model's flexibility and are not limited to these.

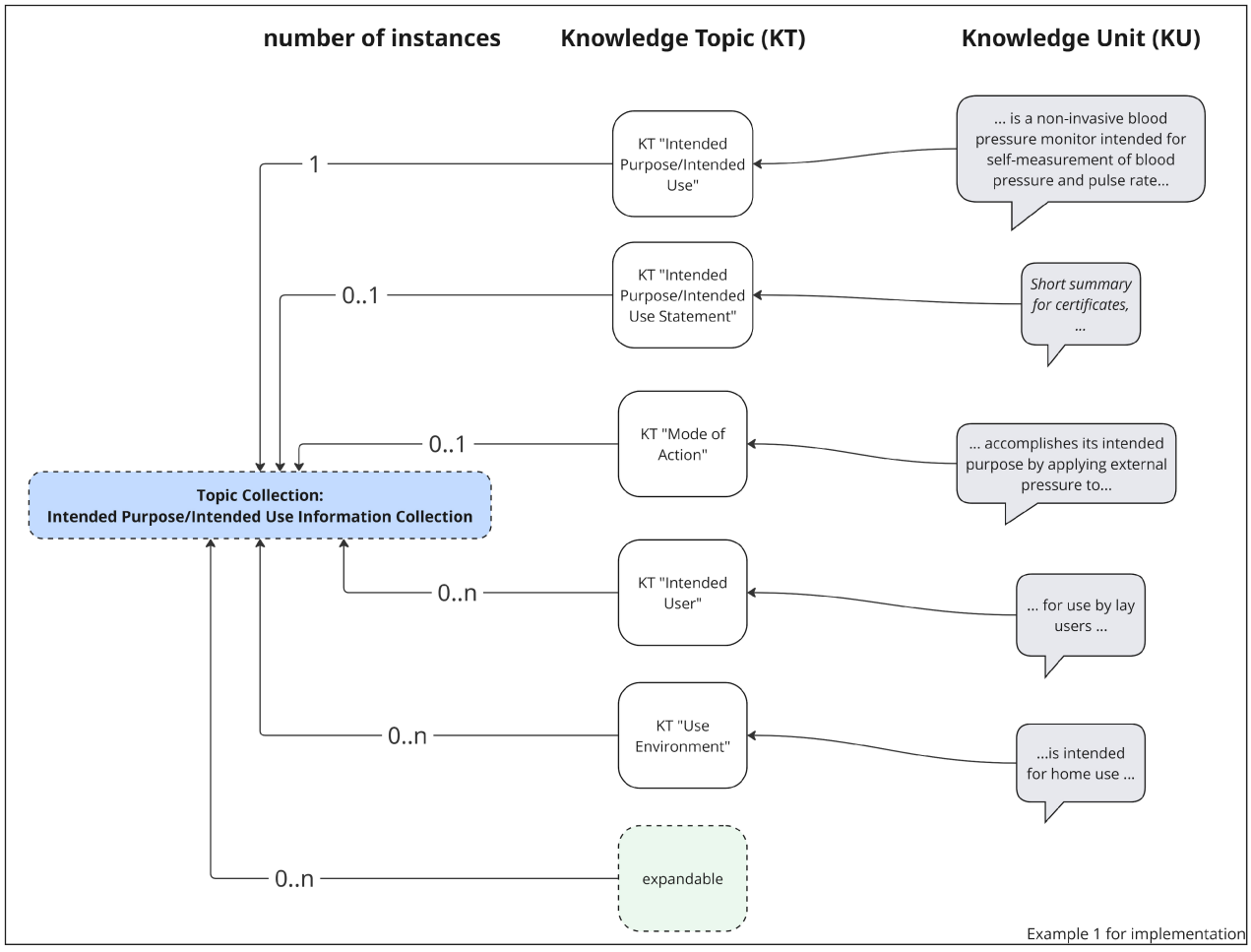

Figure 9 — Example 1 highlights two application rules: A Topic Collection can be used to group KTs in the context "Intended Purpose/Intended Use" and the field "expandable" emphasizes the individual selection of KTs

4.3.5 Realization Example 1

Document Title: Intended Purpose/Intended Use Information Collection

1) ***KT: Intended Purpose/Intended Use***

KU: "Blood Pressure Monitor" is a non-invasive blood pressure monitor intended for self-measurement of blood pressure and pulse rate in adult individuals at home.

2) ***KT: Intended Purpose/Intended Use Statement***

KU: The "Blood Pressure Monitor" is intended to measure diastolic and systolic blood pressure, as well as pulse rate to detect hypertension or hypertension for all patients with the necessary upper arm cuff diameter between 22 cm and 42 cm. This device is intended to be used by individuals who use automated BP monitors for self-monitoring at home. This medical device is contraindicated for cardiac arrhythmias.

3) ***KT: Mode of Action***

KU: The blood pressure monitor accomplishes its intended purpose – measuring arterial blood pressure – by applying external pressure to the wrist via an inflatable cuff to temporarily restrict blood flow, and then detecting changes in the arterial wall during gradual cuff deflation.

4) ***KT: Intended User***

KU: The device is intended for the use by individuals who use automated BP monitors for self-monitoring at home. There is no age restriction, but the user must be able to read and understand the user manual and the built-in digital measurement monitor.

5) ***KT: Use Environment***

KU: The device is intended for home use in an environment with 10 °C to 25 °C and a maximum humidity of 80 %.

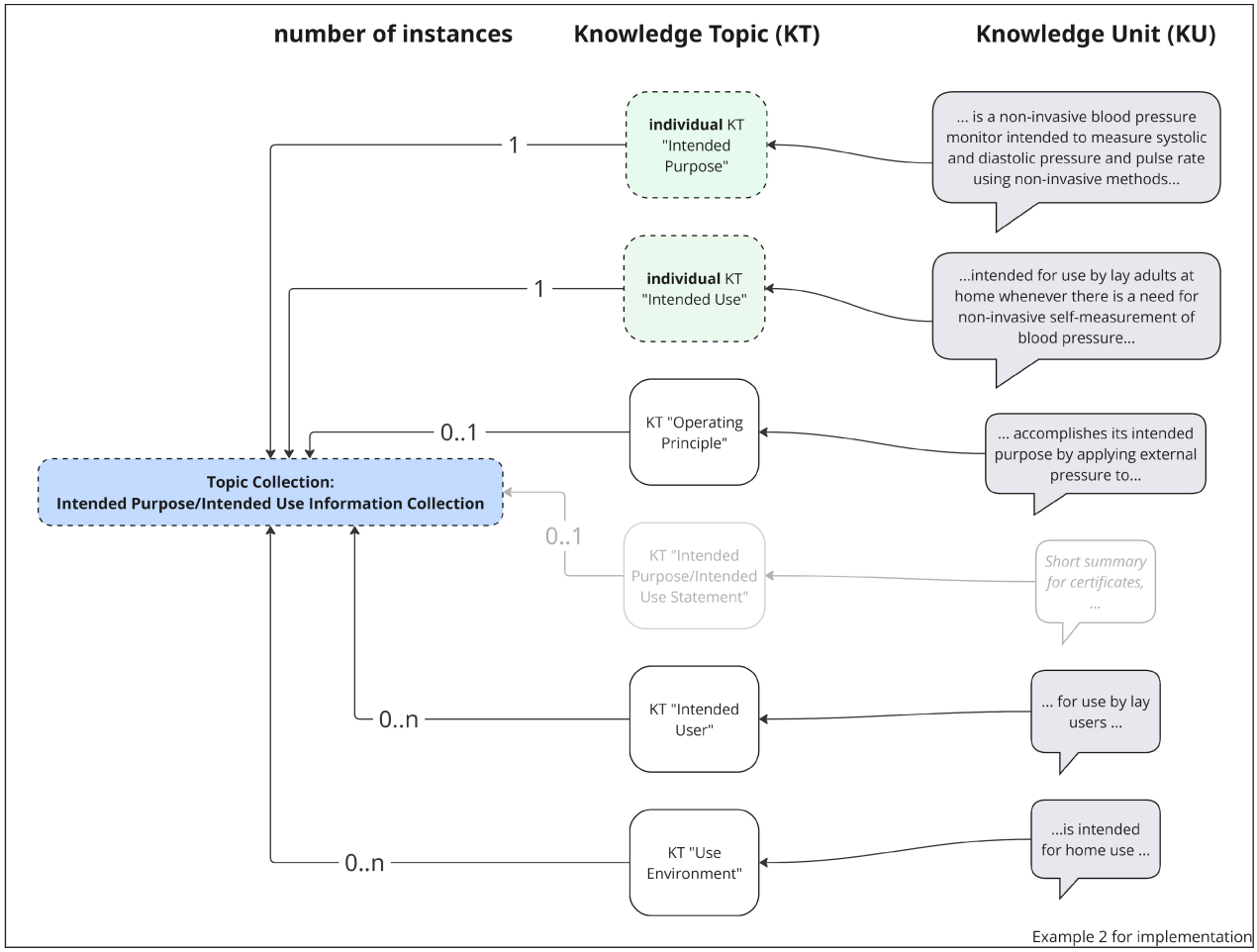

Figure 10 — Example 2 accentuates the feature to create individual, company-specific KTs that can, similar to predefined KTs, be connected to a Topic Collection as well

4.3.6 Realization Example 2

Document Title: Intended Purpose/Intended Use Information Collection

1) ***KT: Intended Purpose***

KU: In accordance with the European Medical Device Regulation 2017/745, the "Blood Pressure Monitor" is part of the device group Z120302, "Vital Signs Monitoring Instruments."

The intended purpose of the "Blood Pressure Monitor" is to measure systolic and diastolic pressure and pulse rate using non-invasive methods.

2) ***KT: Intended Use***

KU: "Blood Pressure Monitor" is intended for use by lay adults at home whenever there is a need for non-invasive self-measurement of blood pressure and pulse rate.

3) ***KT: Operating Principle***

KU: The "blood pressure monitor" measures arterial blood pressure and pulse rate by applying external pressure to the wrist via an inflatable cuff to temporarily restrict blood flow, and then detecting changes in the arterial wall during gradual cuff deflation.

4) ***KT: Intended User***

KU: The device is intended for the use by individuals who use automated BP monitors for self-monitoring at home. There is no age restriction, but the user must be able to read and understand the user manual and the built-in digital measurement monitor.

5) ***KT: Use Environment***

KU: The device is intended for home use in an environment with 10 °C to 25 °C and a maximum humidity of 80 %.

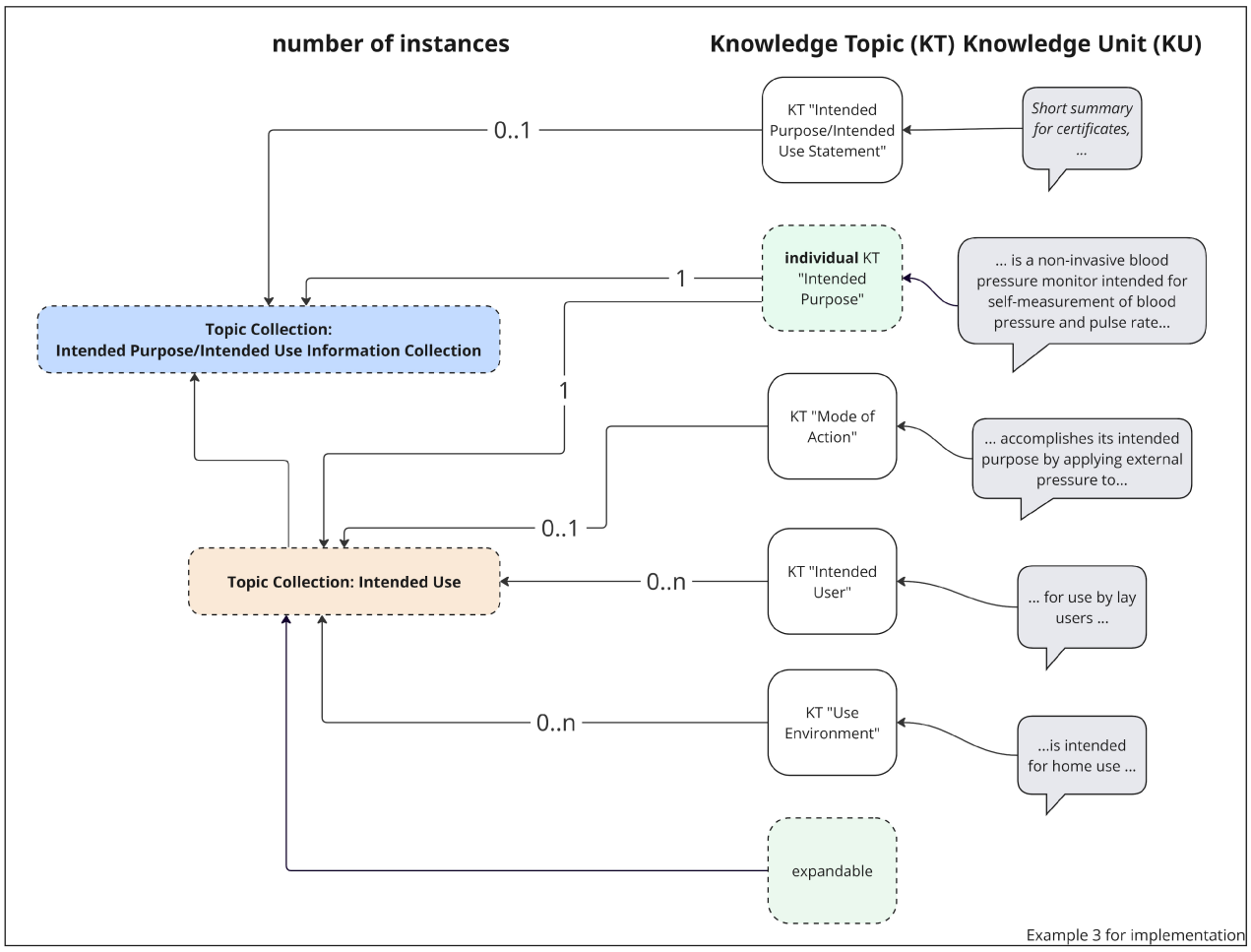

Figure 11 — Example 3 emphasizes the possibility to set relationships to more than one Topic Collection

4.3.7 Realization Example 3

Document Title: Intended Purpose/Intended Use Information Collection

1) ***KT: Intended Purpose/Intended Use Statement***

KU: The "Blood Pressure Monitor" is intended to measure diastolic and systolic blood pressure, as well as pulse rate to detect hypertension or hypertension for all patients with the necessary upper arm cuff diameter between 22 cm and 42 cm. This device is intended to be used by individuals who use automated BP monitors for self-monitoring at home. This medical device is contraindicated for cardiac arrhythmias.

2) ***KT: Intended Purpose***

KU: "Blood Pressure Monitor" is a non-invasive blood pressure monitor intended for measurement of blood pressure and pulse rate.

3) ***Topic Collection: Intended Use***

   a) ***KT: Intended Purpose***

      KU: "Blood Pressure Monitor" is a non-invasive blood pressure monitor intended for measurement of blood pressure and pulse rate.

   b) ***KT: Mode of Action***

      KU: The blood pressure monitor accomplishes its intended purpose – measuring arterial blood pressure – by applying external pressure to the wrist via an inflatable cuff to temporarily restrict blood flow, and then detecting changes in the arterial wall during gradual cuff deflation.

   c) ***KT: Intended User***

      KU: The device is intended for the use by individuals who use automated BP monitors for self-monitoring at home. There is no age restriction, but the user must be able to read and understand the user manual and the built-in digital measurement monitor.

   d) ***KT: Use Environment***

      KU: The device is intended for home use an environment with 10 °C to 25 °C and a maximum humidity of 80 %.

5 Information about the published data model

5.1 Accompanying documents to DIN SPEC 91509

This document is supplemented by two accompanying documents which are available as digital annexes to this document:

Supporting document 1: Data Model Schema

This document defines the data model in the form of an XML Schema Definition (XSD). It provides the formal structure and syntax for the consistent representation of the data elements specified in this document.

Supporting document 2: Data Element Detailed Description

This document contains detailed information for each data model element, serves to simplify readability and includes the following information:

— **Public ID**: unique identification of an individual data model element.

— **Title**: name of the knowledge topic (KT).

— **Description**: descriptive text providing the meaning and intended use of the KT.

— **Attributes**: list of associated attributes to the KT.

— **Information for KT Application**: provides additional information about how the KT is used later within the technical documentation.

— **Binding Force**: specifies whether the KT is required by legislation, standards, or guidance documents, or if its application is based on established best practices.

— **Limitations**: constraints regarding the applicability of the KT.

— **Description of Limitations**: detailed explanation of identified limitations.

— **Source of KT Definition**: origin or reference(s) used for the KT definition.

— **Justification of KT Definition**: rationale supporting the selected KT definition.

— **Existing Regulatory Definitions**: overview of related definitions from applicable regulatory frameworks.

Note on Referenced Sources and Regulatory Definitions: The information provided under "Source of KT Definition" and "Existing Regulatory Definitions" is based on the regulatory and normative references available at the time of compilation of this specification. Due to the time required for the preparation, review, and publication of this document, it cannot be ensured that the cited sources reflect the most current state at the time of use. Users of this specification are advised to verify the current validity and applicability of referenced sources and regulatory definitions prior to implementation.

These accompanying documents serve to enhance clarity, interoperability, and alignment in the application of this document.

For information on the initial application of the data model and the structured feedback process, see Annex B.

5.2 Included data model elements (KTs)

The first data model release focuses on or associated with information related to the **intended purpose/intended use of a medical device**. The following data model elements are incorporated in the first release:

1) intended purpose/intended use;

2) intended purpose/intended use statement;

3) medical device accessory;

4) compatible device;

5) mode of action;

6) operating principle;

7) information for safety;

8) precaution;

9) warning;

10) restriction for use;

11) limitation of use;

12) intended user;

13) user group;

14) user profile;

15) normal condition of use;

16) use environment;

17) medical purpose;

18) medical condition;

19) medical procedure;

20) indication;

21) contra-indication;

22) complication;

23) undesirable side-effect;

24) intended patient population;

25) size of patient population;

26) part of the body or type of tissue interacted with;

27) type of application;

28) Clinical Benefit;

29) Clinical Performance.

Details for each data model element are provided with separate accompanying documents.

For the listed terms, we have analyzed on a legislative level the MDR, on a guidance document level several MDCG guidance documents, a number of harmonized standards together with further international standards and guidelines from medical societies (e.g. the same that are contributing to MDCG documents). Information extracted from these documents has been incorporated directly or indirectly into the description of the data model elements.

5.3 Terms excluded from the data model

5.3.1 Necessity for exclusion

Similar terms frequently appear across various regulatory documents. However, clear definitions that distinguish or would indicate the difference of these terms are often lacking, making it unclear whether the terms are intended to refer to the same concept or if different wording was deliberately chosen by the authors.

This ambiguity creates room for interpretation, which can lead to confusion and inefficiencies – particularly when working with data or developing technical documentation.

To support unambiguous regulatory language – an essential foundation for a clear data model and the efficient digitalization of technical documentation – the following is recommended:

a) **Development of clear definitions for similar term**s, ensuring that any distinctions between them are meaningful and well-documented; or

b) **Agree on a single, consistent term** to be used across all relevant regulatory documents.

Terms in the next chapter have been excluded from the data model, and they should not be used – unless a clear benefit for a separate definition of the term is evident and a definition available.

5.3.2 Excluded terms and justification

The following terms have been identified by the MDKU in different regulatory documents and are considered as similar to elements in the data model that have been listed in Clause 4. A justification is provided for each excluded term:

— **Clinical condition**

There is no clear definition and differentiation between “medical condition” and “clinical condition” available in regulatory documents for medical devices. MDCG 2020-7 and MDCG 2020-8, Section B (8), include a footnote with a mixture of “clinical condition” and “medical condition”.

— **Field of application**

This term is an umbrella (general) term above a specific indication, related to the medical purpose, but without a precise definition and clear use of the term within the TD. It is only mentioned in the European Medical Device Regulation (EU) 2017/745, Annex XV, Chapter II, 3.2 (Clinical Investigation Plan).

— **Medical discipline**

This term is an umbrella (general) term above a specific indication, related to the medical purpose, but it lacks a precise definition or clear usage within the TD. It is only mentioned once in the European Medical Device Regulation (EU) 2017/745, Article 2 (38), under the definition of “Lay Person.”

— **Principle of device operation**

This term is used synonymously with operating principle. No separate term is recommended to ensure a clear, precise regulatory language.

NOTE If you are interested in joining the “Data Model Application” working group and want to provide detailed feedback on the data model, please contact the MDKU at info@mdku.digital.

Annex A
(informative)

Data Model Principles for Medical Device Regulatory Information Exchange

NOTE The following principles were considered when developing the data model.

A.1 Simplicity

This principle ensures the data model serves as a solution rather than adding complexity. By focusing on regulatory essentials from the Medical Device Regulation (EU) 2017/745, MDCG guidance documents, and relevant standards, the model streamlines compliance processes. Stakeholders won't face additional administrative burden beyond what regulations already require. The model is designed to make regulatory compliance more straightforward by organizing requirements in a logical, accessible structure that facilitates efficient information exchange between manufacturers, notified bodies, and competent authorities.

A.2 Clarity

The model creates a common language around regulatory requirements, establishing a shared understanding across the medical device sector. By providing a clear structure for required compliance information, it eliminates ambiguity in regulatory interpretations. This standardized approach ensures that manufacturers know exactly what information to provide, notified bodies know what to assess, and competent authorities know what to monitor – significantly reducing confusion, miscommunication, and compliance gaps in the regulatory process.

A.3 Independence

This principle emphasizes that the data model is system-agnostic, focusing on conceptual organization of regulatory information rather than technical implementation. By remaining independent from specific software solutions, the model allows organizations to implement it through their existing systems or preferred technologies. This flexibility ensures that stakeholders are not forced to adopt particular software platforms, allowing for integration into various IT environments while maintaining the integrity of the regulatory information structure.

A.4 Scalability

The model provides a standardized core while allowing for customization to meet specific organizational needs and product variations. Companies can extend the base model to accommodate their unique product portfolios, quality management systems, and internal processes. This flexibility ensures the model works equally well for small manufacturers with limited product lines and large enterprises with diverse portfolios, while maintaining regulatory compliance and information exchange capabilities.

A.5 Sustainability

Long-term viability is critical for regulatory frameworks. The model is designed with stability and robustness to avoid frequent, disruptive changes while incorporating mechanisms for regular updates as regulations evolve. By clearly identifying the life cycle status of different model elements, stakeholders can easily track which components are current, which are being phased out, and which are newly introduced. This approach ensures the model remains relevant and compliant with evolving regulatory requirements over time.

A.6 Commitment

The collaborative development approach involving manufacturers, notified bodies, and competent authorities creates shared ownership of the model. By incorporating diverse perspectives during development, the model addresses the needs and concerns of all stakeholders, increasing the likelihood of widespread adoption. This inclusive approach, combined with the open-source, free-of-charge distribution model, fosters a regulatory ecosystem where all parties are invested in the model's success and consistent application.

Annex B
(informative)

Application of the data model and feedback collection

At present, there is no practical experience with the application of the data model.

Feedback on the data model content is welcome, and everyone is encouraged to submit their input directly via the feedback form available on the website at https://mdku.digital. This approach enables a structured process for collecting, evaluating, and integrating feedback efficiently into the data model.

Annex C
(informative)

Frequently Asked Questions

C.1 Who commissioned the project?

This project is not commissioned by any national authority, notified body, industry association or company.

It was initiated by a group of industry experts on their own initiative. At the start of the data model development initiative in 2019, none of the existing regulatory organizations were working on a concept for a unified data model for the medical technology industry. As result, members of the industry community decided to start the development of such a data model themselves.

It is important for all involved parties that no commercial interests are pursued, and that the data model is made available as easy as possible for all stakeholders in the industry to ensure broad application.

It is not the goal of involved parties to develop a dedicated software for the application of the unified data model, but it will be ensured that the data model can be used by all common software solutions for the digitization of regulatory processes.

C.2 How is it ensured that the data model is also continuously maintained and further developed?

To make the data model available as open source, the initiators of this project have established a non-profit organization with limited resources. The long-term maintenance and further development of the data model can only be ensured if a wide community of manufacturers and notified bodies recognizes its value and is willing to support the initiative. In this way, the data model will be developed by the community, for the community.

C.3 What long-term costs will users of the model incur?

Everyone involved in the development of the data model has an interest in exploiting the potential of digitalization to save costs. The creation of necessary documentation represents a major cost factor for companies in the medical technology sector. A data model that continuously derives the necessary information from the processes in the company and makes it available for exchange, e.g. with notified bodies, streamlines existing procedures and will therefore also reduce costs. Therefore, long-term costs are expected to decrease rather than increase.

Furthermore, the initiators of the data model do not intend to charge license fees. Efforts have been undertaken to make the data model available as open source.

Each company decides for itself to what extent it wants to apply and integrate the data model. However, the resulting internal costs will lead to significant savings in the medium term, as the effort required to provide information for regulatory purposes will be reduced.

C.4 How is it ensured that Notified Bodies also support the data model and its objectives?

Currently, notified bodies invest significant time in reviewing technical documentation for product approvals. A considerable portion of this time is spent verifying both the completeness of the documentation and its consistency and alignment with the manufacturer's information. Consequently, notified bodies have a strong interest in exchanging structured and clear information to reduce approval times for medical devices, ensuring the delivery of safe and effective products for the benefits of patients.

From the outset, the initiators of this project have prioritized the perspective of notified bodies, involving them directly to ensure their needs and insights are addressed.

C.5 When will the complete data model be published?

Developing a data model that fully reflects all regulatory requirements is a comprehensive and responsible task, currently being undertaken on a purely voluntary basis. Additionally, the initiators of this document are not aware of any similar projects to use as a benchmark for setting a specific timeline. As a result, the data model is developed across multiple releases, allowing for its parallel implementation within companies.

The generation of valuable feedback will help to support the development of future releases. The more engagement is received from the community, the faster the data model can evolve.

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4 Available at https://www.rfc-editor.org/rfc/rfc3444.html