Business plan for a DIN SPEC project according to the PAS procedure on **"Data model for the technical documentation of medical devices"**

Status:
For developing the DIN SPEC after adoption on 2024-01-12

Requests to participate in the project and/or comments on the business plan are to be **submitted by 2024-01-10** to marius.loeffler@din.de[1].

Recipients of this business plan are requested to name **all patent rights** known to them to be relevant to the project and to make available all supporting documents.

Berlin, 2024-03-26 (Version 2)

[1] Applications for participating in the project and comments on the business plan that are not received by the deadline do not need to be taken into consideration. Once constituted, the project workshop will decide whether or not to consider the comments received in good time.

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1. Status/version of the business plan

- **For public commenting (Version 1)**

  This business plan is intended to inform the public of a new DIN SPEC project. Any interested party can take part in this project and/or comment on this business plan. You can register for participation and comment via https://www.din-events.de/ [2] with the log-in code ds91509.

  Once this business plan is published, the Chairman of DIN's Executive Board decides whether or not the project is to be carried out.

  If the project is accepted, all those who have applied for participation or have commented on the business plan by the deadline will be invited to the kick-off meeting of the project consortium.

- **For developing the DIN SPEC after adoption on 2024-01-12**

  Changes to the previous version 1:
  - Frontpage: Updating version of the business plan to version 2;
  - Section 2: Deleted table of organizations that have registered for participation and updated table of organizations that have adopted this business plan (known as consortium members);
  - Section 3.1: Minor adaption of the general objectives of the projects (see point 1);
  - Section 3.2: Minor adaption of the planned scope (deletion of “according to the Medical Device Regulation (MDR), Annex II and III” and replacement of “cross-industry partners” by “stakeholders” as well as change of “medical device developers” to “e.g. medical device manufacturers”;
  - Section 4: Updated information regarding the kick-off meeting;
  - Section 6: Correction of spelling mistake in “Creative Commons Licence CC BY-ND 4.0 (Attribution-No Deriv*ate*s 4.0 International)”
  - Section 7: Updated Information regarding the consortium leader;

[2] If registration or commenting via the link is not technically possible, please send them to Marius.Loeffler@din.de.

2. Initiator and other consortium members

- Initiator:

Person/Organization	Short description
Sarah Panten, MDKU – Medical Device Knowlegde Unit e. V.	The MDKU is a non-profit organization founded in 2021 by a community of people from the med-tech device industry that develops a unified data model for medical device technical documentation content to help accelerate digitalization in the med-tech industry

- Other potential participants:

This DIN SPEC will be developed in a consortium (temporary body) that is open to any interested party. The participation of other experts would be helpful and is desired. It is recommended that

– Notified bodies

– Medical device manufacturers

– Medical associations

– Software providers with industry specific solutions

take part in the development of this DIN SPEC.

- Organizations[3] that have adopted this business plan (consortium members):

Person	Organization
Malin Baumgarten	AstraCon GmbH
Lukas Vogler	avasis solutions GmbH
Dr. Christina Ziegenberg	Bundesverband Medizintechnologie | BVMed e.V.
Dr. Michael Lang Dr. Anja Richter Elena Scheller	KARL STORZ SE & Co.KG
Michael Engler Dr. Holger Brünner Frank Münzinger Michael Röttcher Johannes Walde Sarah Panten Markus Pöttker	MDKU e. V.

[3] Organizations are participating legal entities that send the experts to the DIN SPEC consortium and are assigned to a corporate structure as defined by § 15 of the German Stock Corporation Act or § 271 paragraph 2 of the German Commercial Code.

Person	Organization
Dr. Vincent Castéras Clémentine Conraux	nexialist
Michael Asmalsky Fabian Kühn	Philips Medizin Systeme Böblingen GmbH
Magdalena Heine Dr. Franziska Gumprecht Diana Hohage	qtec Services GmbH
René Schmidt Luisa Wiedenhofer Karin Berndt	seleon GmbH
Sarah Haake-Schaefer Nadine Benad	SPECTARIS e.V.
Dr. Daniel Delfosse	Swiss Medtech
Ozan Aykurt Prof. Dr. Folker Spitzenberger	Technische Hochschule Lübeck
Dr Sarah Tsurkan	TUD Dresden University of Technology/ Else Kröner Fresenius Center for Digital Health
Adam Menzies	TÜV SÜD
Amra Racic	Veeva Systems
Marius Loeffler	DIN e.V.

3. Objectives of the project

3.1. General

The medtech industry is one of the most innovative industries in the world, but the innovative strength of manufacturers is being increasingly slowed down by continuously rising regulatory requirements documented in laws, technical standards, guidelines, etc.

The developmental time of medical devices is being prolonged due to overly complicated and convoluted approval and market monitoring procedures. Procedures that are of course necessary to guarantee the safe implementation and use of these devices.

However, the primarily manual screening of relevant regulatory documents pertaining to each individual device, as well as the implementation during product development and creation of required technical documentation, is prone to errors and slows down the approval process significantly. Capacities of highly qualified employees are tied up procedural activities, leaving less time developmental activities that may add economic value, which in turn increases the developmental time of new, innovative diagnostic or treatment options.

Evidence for regulatory compliance of a medical device is provided based on its technical documentation. Regulatory requirements may differ depending on the market as well as regional or national requirements. Manufacturers must meet all the regulatory requirements applicable to the markets they wish to enter. If regulatory requirements are not met, manufacturers will not be able to sell their products and thus fail economically.

The assessment of the vast majority of products requires the involvement of a notified body. Due to capacity bottlenecks and the effects of the general shortage of specialists both at manufacturers and at Notified Bodies, the scheduled transition periods of the regulations are rarely met, resulting in a shortage of medical devices, and - downstream, in a lack of innovation in the European medical market.

When creating the technical documentation for a medical device, there are three main challenges having an impact on the time and effort required to create the documentation:

1) Reuse of information, including consistency of data and absence of data ambiguity

2) Cross-process and cross-document linking of information

3) Completeness of information

If processes and associated documents are digitalized with the help of software solutions, the effort required to create the technical documentation can be significantly reduced and the subsequent approval of the product accelerated.

Thus, new diagnostic or therapeutic procedures are available to patients more quickly. Likewise, improvements to approved products are implemented more quickly and are available to patients sooner. Resources at manufacturers and notified bodies are freed up and can be used for development.

There is currently a lack of a uniform language to which manufacturers and Notified Bodies can refer to in communication. Regulatory terms are often misinterpreted or interpreted differently by different stakeholders and might differ from country to country.

These challenges could be solved by establishing a uniform data model and a uniform language accessible to all stakeholders developed by all stakeholders.

This document will help establish a consistent, end-to-end digital continuity.

3.2. Planned 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 document establishes a foundation for an expedited approval process for medical devices. The document also serves as a facilitator to improve communication and the exchange of information between stakeholders (e.g.

medical device manufacturers, suppliers, notified bodies, certification bodies, regulatory bodies).

This document does not provide requirements for other type of data models or specific data formats; nor does it establish requirements for the technical infrastructure of industry participants.

This document establishes a common understanding of the technical documentation that is required for a swift and reliable transaction of information between various cross-industry partners.

3.3. Related activities

The subject of the planned DIN SPEC is not at present the subject of a standard. However, there are committees, standards and/or other technical rules that deal with related subjects and thus need to be taken into account - and involved or incorporated, where necessary - in this project:

- DIN Standards Committee Health Technologies

4. Work programme

The aim of the project is to develop a DIN SPEC according to the PAS procedure (see www.din.de/go/din-spec-en). The DIN SPEC shall be consistent with the body of German standards and shall not be in conflict with any DIN Standard.

The kick-off meeting is planned to take place on 2024-01-12 in Berlin. The project duration will be about 4 months.

At this kick-off meeting, the consortium for developing the DIN SPEC will be constituted, further organizational issues will be decided on and clarified, and, where possible, work on the subject matter will be begun.

A draft for public commenting will not be published.

A total of 2 project meetings (kick-off meeting and work meeting) and 1 web conference will be held, during which the content of the DIN SPEC will be presented, discussed and approved. The content of the DIN SPEC can be drawn up by individual consortium members or in working groups.

Dates of further meetings and/or web conferences are to be agreed on within the consortium in consultation with DIN.

The DIN SPEC will be drawn up in English (language of meetings, minutes, etc.). The DIN SPEC will be written in English.

NOTE The calculation covers only one language version. Please keep in mind the fact that other language versions involve additional expenses; for this reason, they shall be agreed on

separately. If another language version is desired, Beuth/DIN can provide a translation. Requests for translations are to be submitted after the DIN SPEC manuscript has been approved for publication.

5. Resource planning

Each consortium member shall bear the expenses he/she incurs as a result of participation in the project.

If the DIN Executive Board approves the project, the initiator of the project will then conclude a contract with DIN.

The performance of this project as set out in the programme of work will result in DIN incurring costs to a total of 31.934 euros, excluding VAT. Additional services give rise to additional costs.

Sharing the burden of these costs is a prerequisite for membership in the consortium.

By adopting this business plan, consortium members declare their willingness to bear their share of the project costs, which is based on the number of consortium members.

Each consortium member is to declare this willingness to take on his/her share of costs.

If the consortium is expanded later, the additional consortium members shall pay the same fee to cover costs as the original consortium members.

6. Rules of cooperation in the DIN SPEC consortium

This project is governed by the PAS procedural rules. All interested parties and consortium members are to inform themselves of these procedures by going to www.din.de/go/din-spec-en.

The consortium will be constituted during the course of the kick-off meeting. The kick-off meeting will not take place until the business plan has been published and approved by DIN's Management Board. The consortium shall comprise at least three members from different organizations[4]. It is not necessary that these members come from different areas and represent different stakeholders. By approving this business plan, the interested parties declare their willingness to participate in the consortium and will be formally named as consortium members, with the associated rights and duties. Participants at the kick-off meeting who do not approve the business plan are not given the status of a consortium member and are thus excluded from further

[4] Organizations are participating legal entities that send the experts to the DIN SPEC consortium and are assigned to a corporate structure as defined by § 15 of the German Stock Corporation Act or § 271 paragraph 2 of the German Commercial Code.

decisions made during the kick-off meeting and from any other decisions regarding the project.

If an organization (e.g. an association) sends someone who is not an employee to the consortium, this person shall be authorized by the organization, who shall provide proof of this to DIN.

Each consortium member is entitled to vote and has one vote. If an organization sends several experts to the consortium, that organization has only one vote, regardless of how many consortium participants it sends. Transferring voting rights to other consortium members is not permitted. During voting procedures, decisions are passed by simple majority; abstentions never count.

As a rule, the consortium is closed once it is constituted. The current consortium members shall decide whether any additional members will be accepted or not.

During the kick-off meeting, the consortium members shall elect a consortium leader, who is responsible for content management and any decision-making and voting procedures. The leader is supported by the responsible DIN Project Manager, whereby DIN will always remain neutral regarding the content of the DIN SPEC. Furthermore, the DIN Project Manager shall ensure that DIN's rules of procedure, rules of presentation, and the principles governing the publication of DIN SPEC have been observed. Should a consortium leader no longer be able to carry out his/her duties, the DIN Project Manager shall initiate the election of a new leader.

The DIN Project Manager is responsible for organizing and leading the kick-off meeting, in consultation with the initiator. Further project meetings and/or web conferences shall be organized by the DIN Project Manager in consultation with the consortium leader.

If consortium members cannot be present when the DIN SPEC or its draft is approved, an alternative means of including them in the voting procedure shall be used (e.g. in writing, electronically).

All consortium members who voted for the publication of the DIN SPEC or its draft will be named as authors in the Foreword, including the organizations which they represent. All consortium members who voted against the publication of the DIN SPEC or its draft, or who have abstained, will not be named in the Foreword.

Any expansion of the consortium at a later date is decided on by the members making up the consortium at that time. It is particularly important to consider these aspects:

a) expansion would be conducive to shortening the duration of the project or to avoiding or averting an impending delay in the planned duration of the project;
b) the expansion would not result in the project taking longer to complete;

c) the new consortium member would not address any new or complementary issues beyond the scope defined and approved in the business plan;
d) the new consortium member would bring complementary expertise into the consortium in order to incorporate the latest scientific findings and state-of-the-art knowledge;
e) the new consortium member would actively participate in the drafting of the manuscript by submitting concrete, not abstract, proposals and contributions;
f) the new consortium member would ensure wider application of the DIN SPEC.

The DIN SPEC and its content will be published under a Creative Commons Licence CC BY-ND 4.0 (Attribution-No Derivates 4.0 International) by DIN and MDKU respectively.
Consortium members are requested to inform DIN of all patent rights known to them to be relevant to this DIN SPEC project.
Subsequent changes to the scope (Section 3.2) or to the resource planning (Section 5) require, in addition to a two-thirds majority of all votes cast, the approval of DIN.

7. Contacts

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Annex: Project schedule

DIN SPEC project	2023												2024											
	Jul		Aug		Sep		Oct		Nov		Dec		Jan		Feb		Mar		Apr		May		Jun		Jul	
Initiation																								
1. Request and review																								
2. Business plan drawn up																								
3. Publication of business plan																								
Development phase																								
4. Kick-off meeting/consortium constituted																								
5. DIN SPEC drawn up																								
6. DIN SPEC approved by consortium																								
Publication																								
7. Review and release by DIN																								
8. Publication of DIN SPEC																								
Milestones													**K**					**M**		**M / A**				

K Kick-off
M Project meeting
W Web conference
A Adoption of DIN SPEC