Digit(ization/alization)

Technical Documentation

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Mehr Wert.
Mehr Vertrauen.

Add value.
Inspire trust.

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Digitization vs. Digitalization

Digitization

- "…the representation of an object, image, sound, document or signal (usually an analog signal) by generating a series of numbers that describe a discrete set of its points or samples…strictly speaking, digitizing simply means the conversion of analog source material into a numerical format."
  – Wikipedia

Digitalization

- "the use of digital technologies to change a business model and provide new revenue and value-producing opportunities; it is the process of moving to a digital business."
  – Gartner Inc.

Article 4

- Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

Article 8

- Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Annex II - Introduction

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

Main Sections of a Technical Documentation

DEVICE DESCRIPTION

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

INFORMATION SUPPLIED BY THE MANUFACTURER

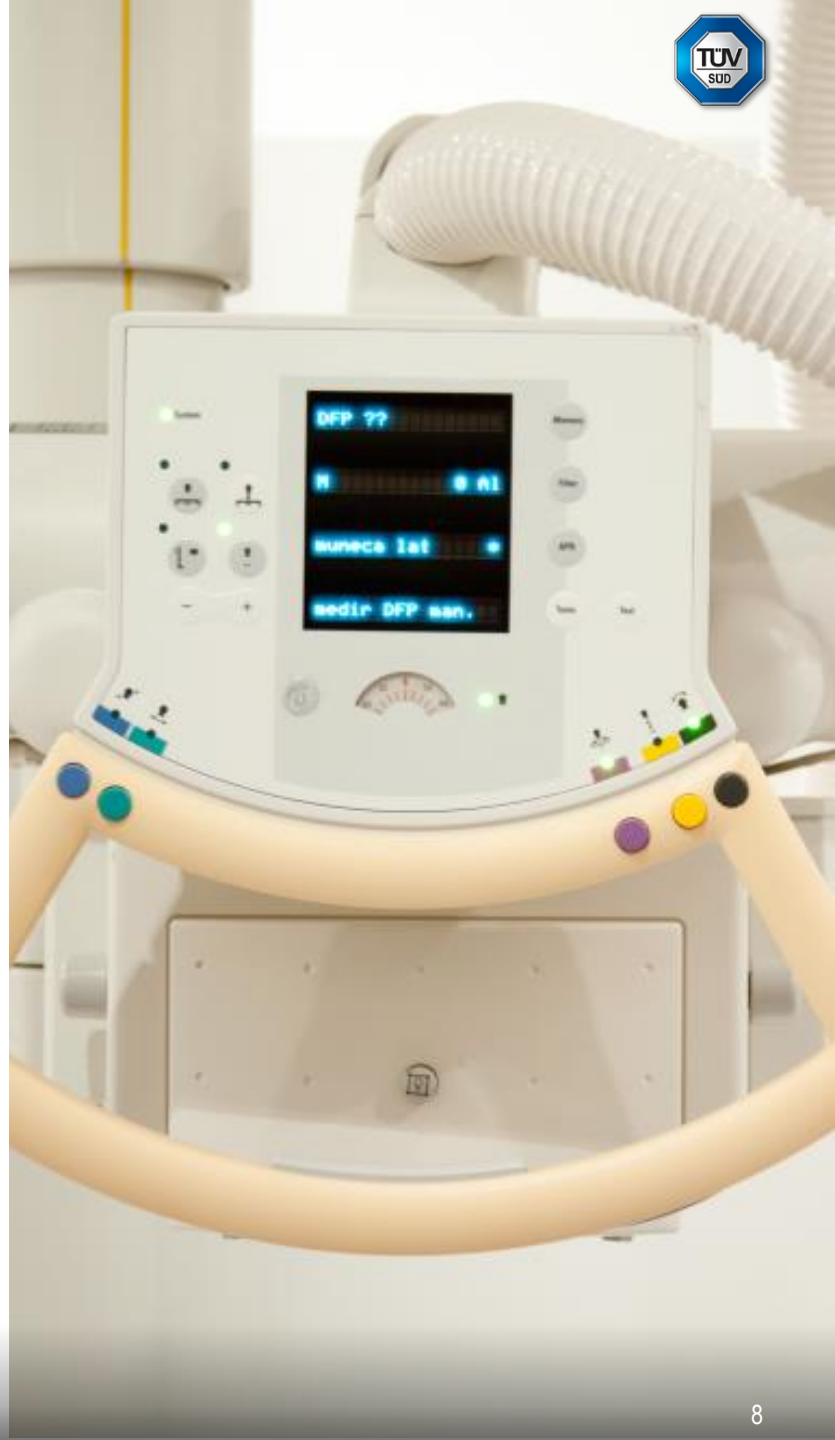
BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

DESIGN AND MANUFACTURING INFORMATION

PRODUCT VERIFICATION AND VALIDATION

1. Devices Description

1. Product, trade name, general description
2. Intended purpose, users, patient population, patient selection criteria
3. Indications, contra-indications, warnings, risk class
4. Principle of operation
5. Novel features
6. Accessories
7. Variants and/or configurations
8. Raw materials
9. Technical specifications



2. Information supplied by Manufacturer

- A complete set of:
  - the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and
  - the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. Design & Manufacturing Information

Identification of all sites, suppliers, sub-contractors

04

03

Data fully incl. into TD

Manufacturing processes

- Process validation
- Adjuvants
- Continuous monitoring
- Final product testing

02

01

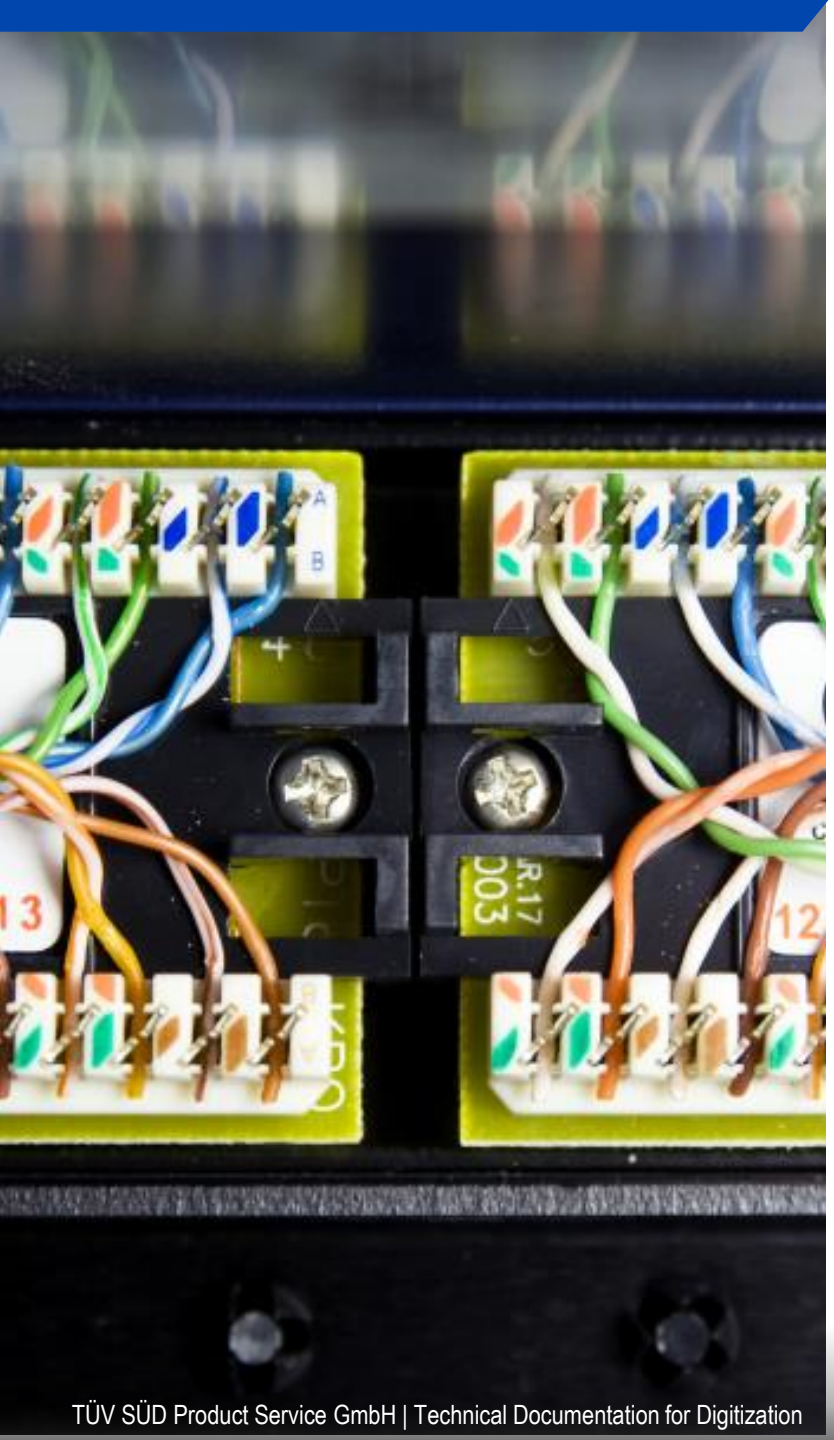
Applied design stages

3. Design & Manufacturing Information

a) information to allow the design stages applied to the device to be understood;

b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed

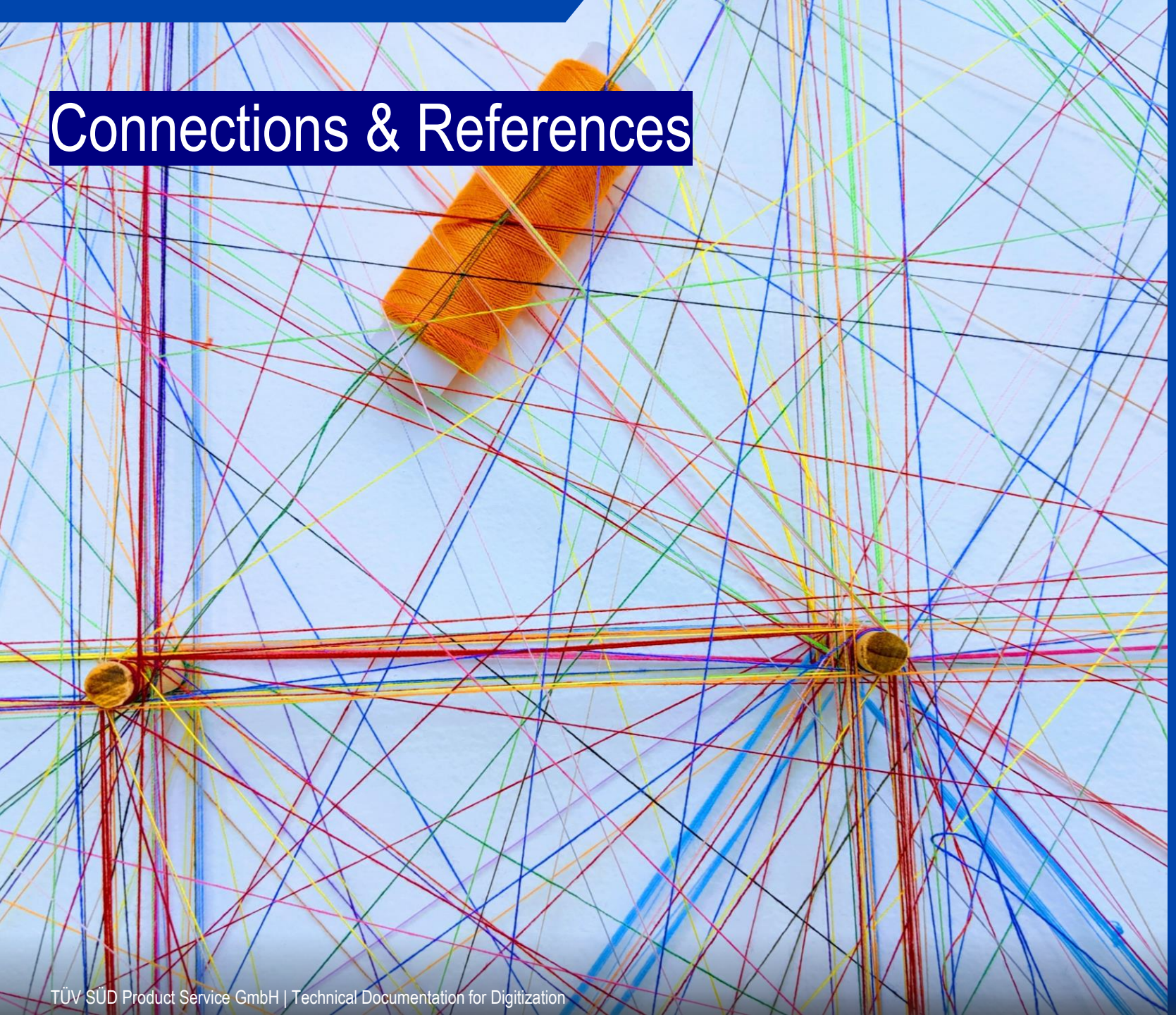


4. GS&PR

The documentation shall contain information for the demonstration of conformity …

- the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;
- the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;
- the harmonised standards, CS or other solutions applied; and
- the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

Connections & References



MDR Annex II

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

– The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. […]

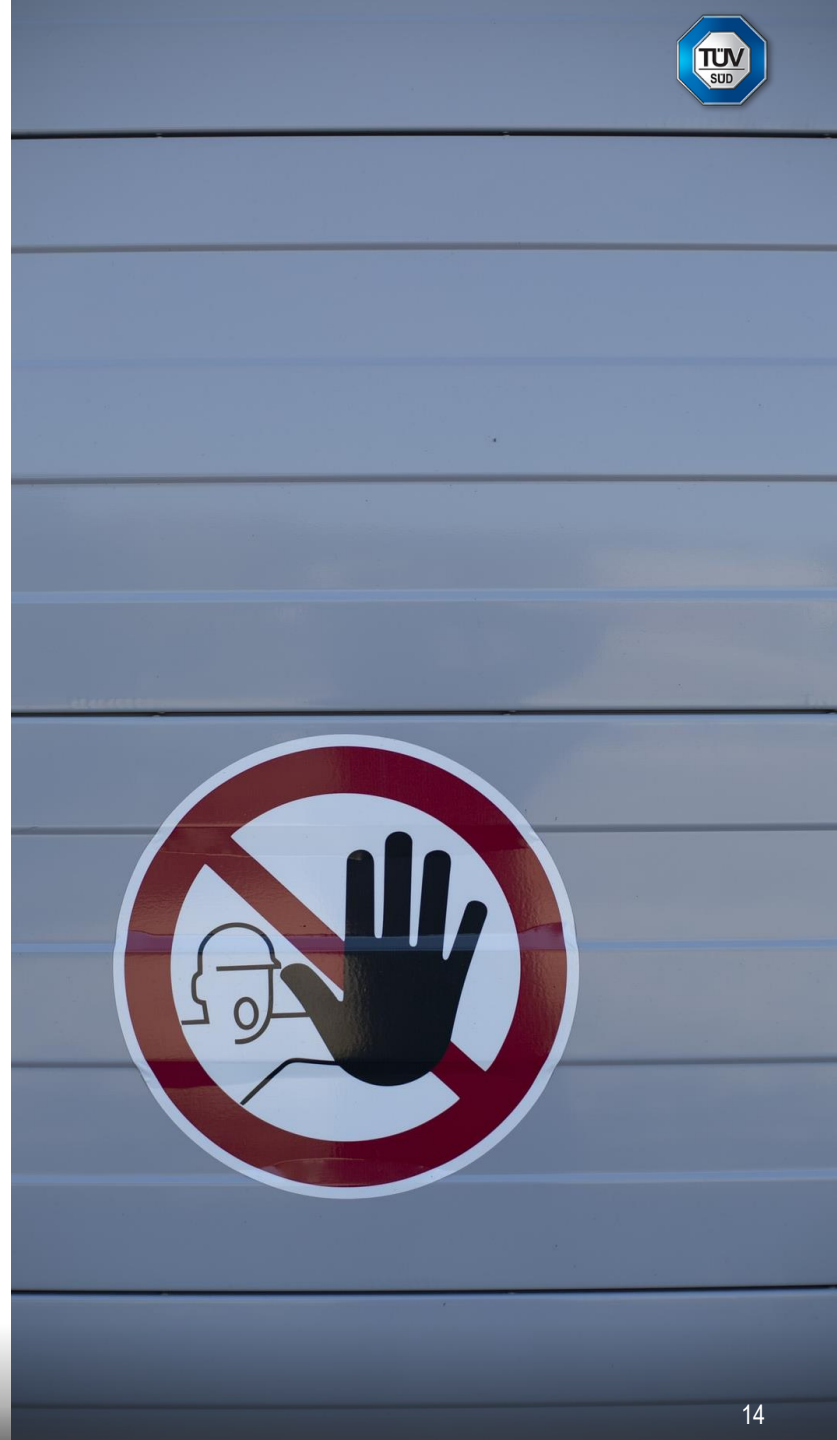
– Futuristic?

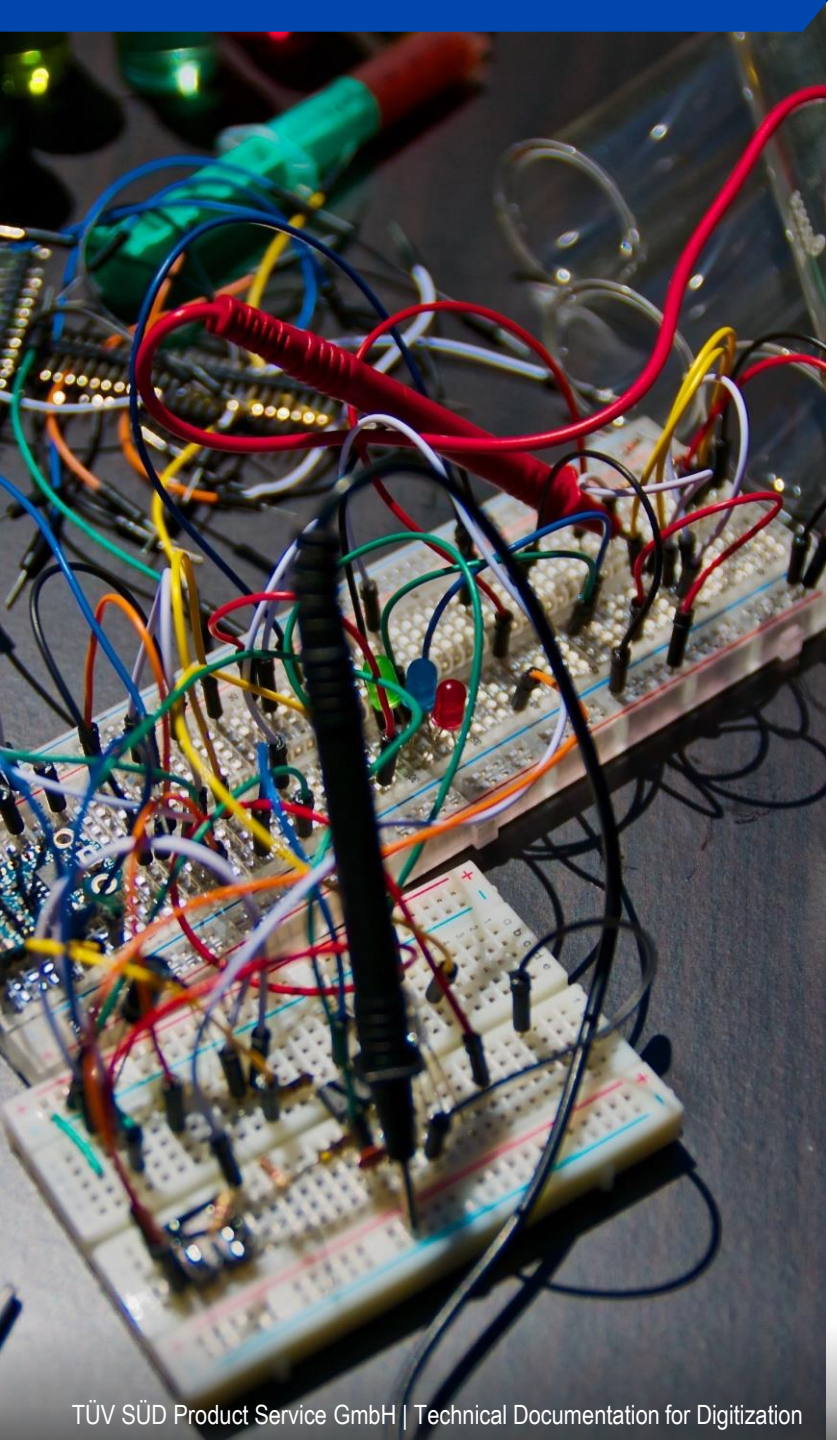
5. Risk Analysis and Risk Management

- The documentation shall contain information on:

a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.





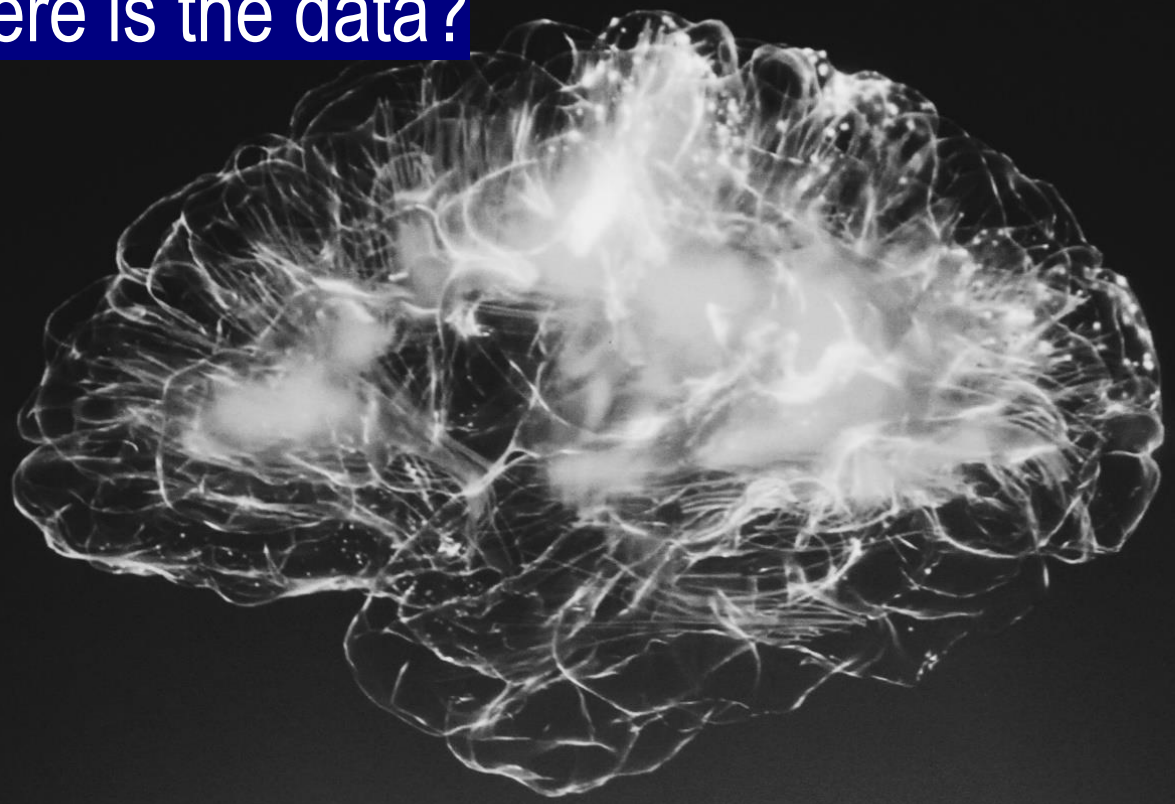
6. Verification and Validation

- The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

- 6.1 Pre-clinical and clinical data
  - (…) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
    - the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
    - physical, chemical and microbiological characterisation;
    - electrical safety and electromagnetic compatibility;

- 6.2 Additional information required in specific cases

Where is the data?



seeing the **beautiful brain** today

Santiago Ramón y Cajal employed the art of drawing to depict his observations and to convey scientific arguments. He understood the [illegible] other neuroscientists of his theories. The aesthetic appeal and subtle emotional qualities in Cajal's images underscore their scientific content. Today neuroscientists have access to vastly more complex

- Databases
- Excel Files
- SharePoint(s)
- SAP
- Oracle
- Access
- Supplier Management System
- Design Files
- QMS
- Doc Control System
- Risk Management Tools
- etc.

What is needed for the Notified Body

- The **full** Technical Documentation
  - Including all elements set out in Annex II & III

- In which format?
  - Today: PDF, XLS, DOC, … graphics and other file formats (QM records)
  - Tomorrow:
    i. Independently running databases with links between all relevant information
    ii. Wiki based format allowing cross reference to and from relevant information packages
    iii. Always up to date information at the spot

- How to share it with the Notified Body and what they will do with it
  - Database interfaces with dumps that can be saved for archiving purposes
  - AI could check for inconsistencies and human being can focus on the relevant elements

Danke!