



Digit -ization -alization

MedTec & Regulators

Martin Witte – OSMA Spring Meeting

April 2025

**Add value.
Inspire trust.**

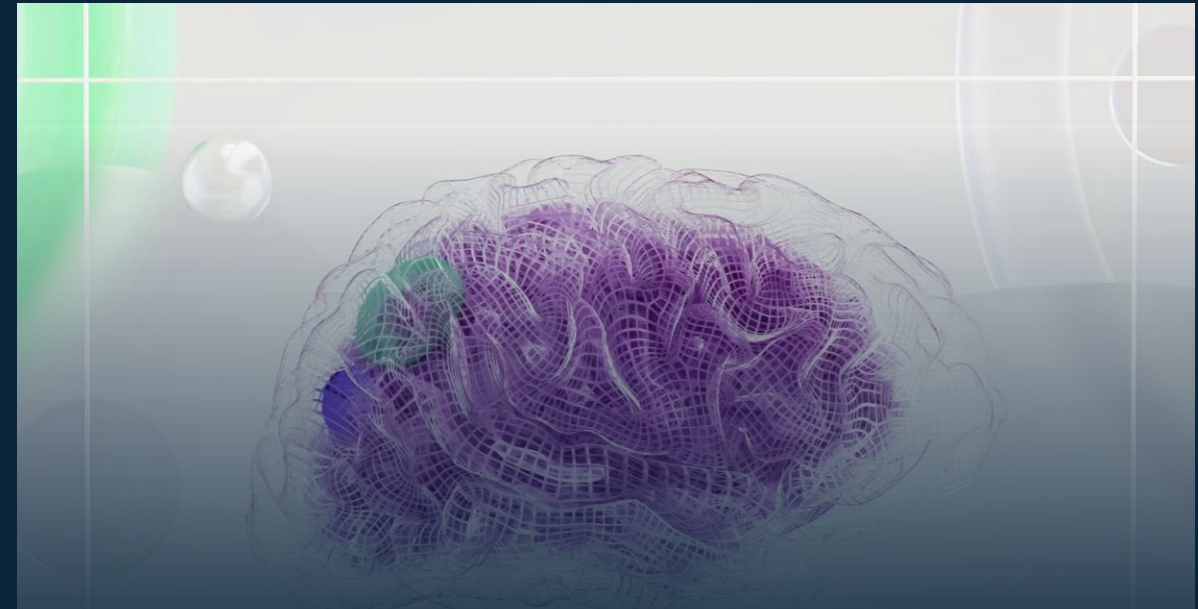
Digit...

...ization



- “...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

...alization



- “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.

MDR Annex II – 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

Annex II 1.1. – Device description and specification



General

- Product name
- Trade name
- General description
- Intended purpose
- Intended User

Basic UDI-DI

- As soon as it becomes available

Intended patient population

- Medical conditions
- Patient selection criteria
- Indications
- Contraindications
- Warnings

Principle of Operation

- Mode of action
- Scientifically justified if necessary

Rational

- for the qualification as device vs. not a device (product)

Risk Class

- Justification for the classification rule(s)
- Annex VIII

Novel Features

- Explanation

Accessories

- Devices / products used with the device
- Combination of devices

Variants/Configurations

- Complete list or description
- Intended to be made available

Key functional elements

- General description
- Parts, components, formulation,
- Quantitative & qualitative composition
- Drawings indicating parts

Raw materials

- Incorporated into key functional elements
- contact with the human body or indirect contact with body

Technical Specifications

- Features
- Dimensions
- Performance attributes
- Devices / Accessories typically appearing in brochures / catalogues

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Application forms by NB

Certificate

CIP

Risk management

Classification decision

CER

Instruction for use

Numerous other places

SSCP

Patient information

PSUR

V&V data

EUDAMED

MISTAKE

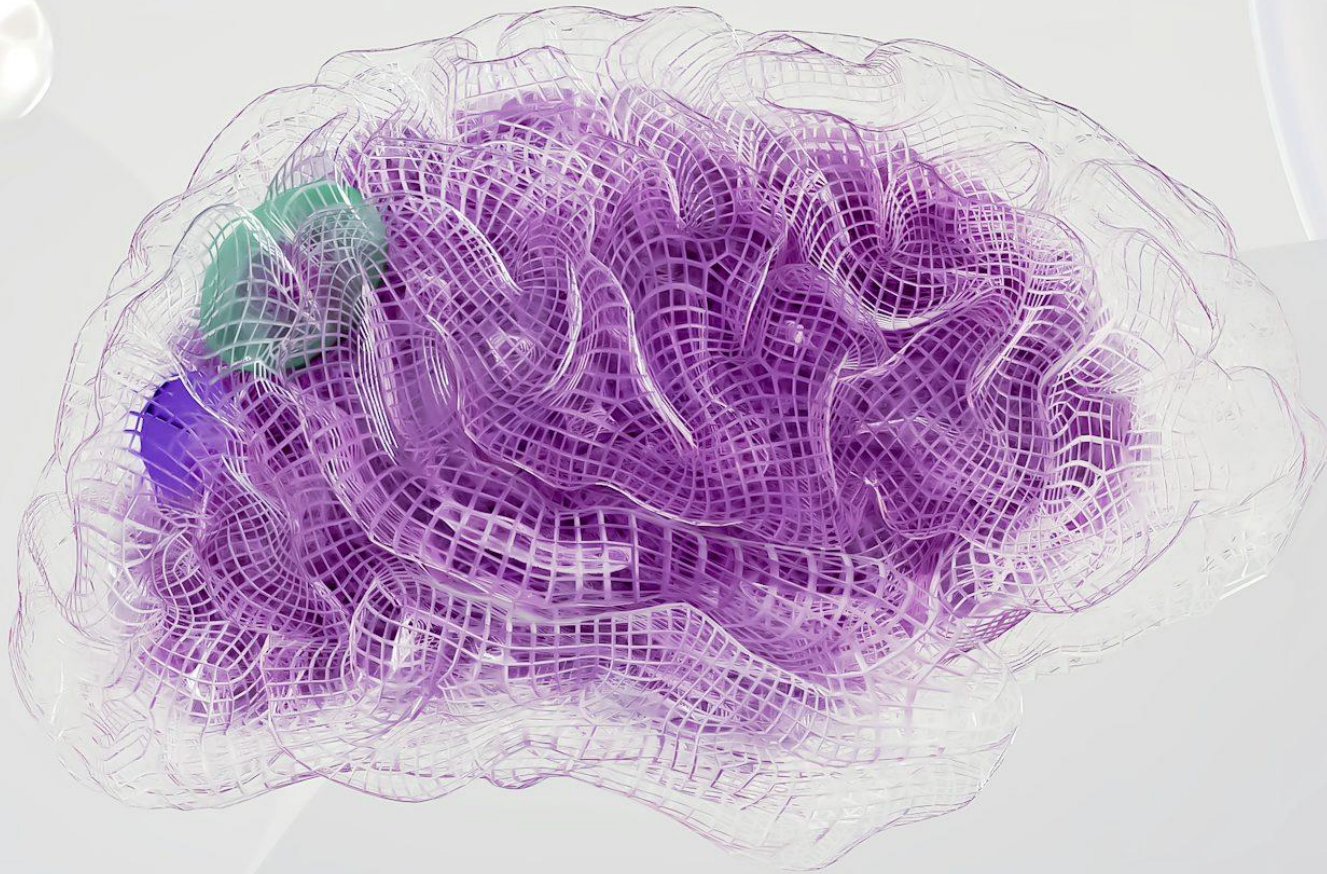
AND LABRADOR



Business Banking



Where is your data




Databases
Excel Files
SharePoint(s)
SAP
Oracle
Access
Supplier Management
Design Files
QMS
Doc Control System
Risk Management Tool




Martin Witte

TÜV SÜD Product Service GmbH

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 **Book a virtual coffee with me**



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