

# Collect product data once – use it everywhere



**Product master data as the basis for regulatory and global market access**

# Why this topic is relevant



- UDI is a regulatory requirement and a necessary condition for market access
- UDI is based on complete, consistent product master data
- The same data must be used for regulatory, logistics, and sales purposes
- A lack of coordination leads to delays and compliance risks
- Different global requirements increase the effort involved

# Welcome

## Today's topics

- **Welcome and introduction**
- **GS1 standards in healthcare**
- **Overview of UDI databases and publication requirements**
- **Global master data exchange with GDSN**
- **Publication for UDI databases with firstbase**



# GS1 – The Global Language of Business

**118**

local member organisations

**150**

countries covered

**GS1 develops and maintains global standards for efficient and secure business processes across all industries.**



Neutral & not-for-profit



By members, for members



Think globally, act locally



Open and collaborative

# GS1 – Global Standard Number One

10  
billion

Barcodes are scanned  
worldwide every day

**The chewing gum story**– the birth of GS1

1973- a supermarket in Ohio

The first-ever automatic scan of a Wrigley's Juicy Fruit chewing gum barcode

A revolution: no manual data entry, products captured instantly, inventory and sales recorded automatically, saving cost

Today on display at the Smithsonian Museum in Washington, D.C

# GS1 focus industries

## Key drivers of digital transformation in Switzerland



### Matching solutions for consumer goods/retail

Find the right solution with GS1 standards - whether as a supplier, manufacturer, retailer, or service provider.



### Standards for healthcare

Make healthcare more efficient and increase patient safety with GS1 standards.



### Technical industries rely on standards

Enable traceability of components and products throughout their lifecycle with GS1 standards.



### Solutions in transport logistics

Improve the transparency and sustainability of your supply chain processes with GS1 standards.

# GS1 network organisation - committee work

Mutual exchange is a key value for us <https://www.gs1.ch/en/network>



## Advisory board

The advisory board support GS1 Switzerland with strategic questions on GS1 topics.



## Expert groups

Experts meet in the specialist groups to jointly solve update-related tasks for specific subject areas and to exchange experiences.



## Working groups

Experts meet in the working groups to jointly implement a mission. The results are made available to all GS1 members after completion

# The GS1 system

## Three pillars of standardisation

### GS1 Standards for Identification



Identify

#### Company & Location

- Global Location Number (GLN)

#### Product

- Global Trade Item Number (GTIN)
- Serialised Global Trade Item Number (SGTIN)

#### Logistics & Shipping

- Serial Shipping Container Code (SSCC)
- Global Shipment Identification Number (GSIN)
- Global Identification Number for Consignment (GINC)

#### Assets

- Global Individual Asset Identifier (GIAI)
- Global Returnable Asset Identifier (GRAI)

#### Services & More

- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)

### GS1 Standards for Barcodes & EPC/RFID



Capture

#### GS1 Barcodes

EAN/UPC



GS1-128



ITF-14



GS1 DataBar



GS1 DataMatrix



GS1 QR Code



GS1 Composite Barcode



#### GS1 EPC/RFID

Electronic Product Code (EPC) RFID



EPC HF Gen 2

EPC UHF Gen 2



### GS1 Standards for Data Exchange



Share

#### Master Data

- Global Data Synchronisation Network (GDSN)

#### Transactional Data

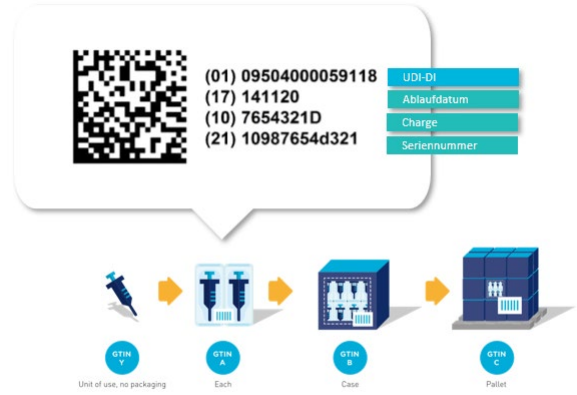
- Electronic Data Interchange (EDI): EANCOM, GS1 XML

#### Event Data

- EPC Information Services (EPCIS)

# UDI for medical devices

## GS1 as Issuing Agency



Requirements of the UDI legislation	Translation into GS1 standards
<b>Basic UDI-DI</b> « New » identification level into EU	<b>GMN</b> (Global Model Number) <i>No Application Identifier (AI) for the medical devices regulated</i>
<b>UDI-DI *</b> Device Identifier (DI)	<b>GTIN *</b> Global Trade Item Number
<b>PI *</b> Production Identifier (PI) <i>(if applicable)</i>	<b>AI * Application Identifier (AI)</b> - Expiration date AI(17) - e.g. 231131 - Batch - Lot AI(10) - e.g. 1234AB - Serial Number AI(21) - e.g. 12345XYZ - Manufacture date AI(11) - e.g. 190725 - Software version AI(8012) - e.g. 01.02
<b>UDI-DI + PI = UDI</b>	<b>GTIN of GTIN + AI(s) = UDI</b>

*The Production Identifier varies depending on the type of medical device and the manufacturer's current practice.*

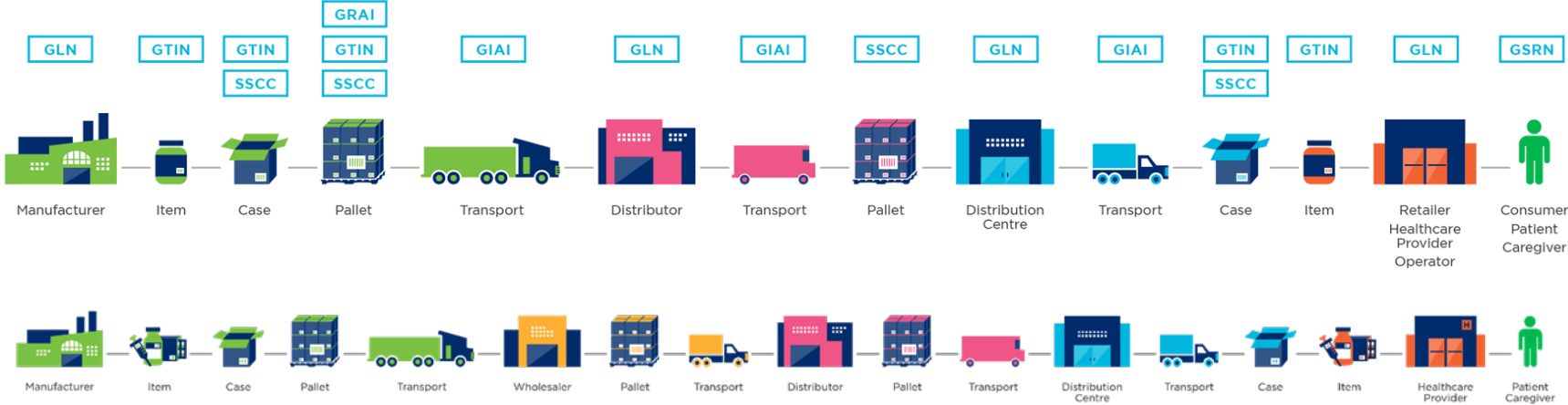
\* The written format follows the rules of the issuing body of UDI

Markenname	QTY: 1 EA	MD
<b>Beispielname</b>	<b>UDI</b>	
Produktbeschreibung		(01) 07612345654321
REF 7612345654321		(10) 11223344
LOT 11223344		(11) 240530
SN 999888777		(17) 261125
		(21) 999888777
2024 - 05 - 30	CE	STERILE
2026 - 11 - 25		CH REP
<b>Musterfirma AG</b> Beispielstrasse 0000 Musterdorf +41 00 00 00 00 www.musterfirma.ch		

# GS1 identification keys across the supply chain

## Identify: GS1 Standards for Identification

GLN Global Location Number    GTIN Global Trade Item Number    SSCC Serial Shipping Container Code    GRAI Global Returnable Asset Identifier    GIAI Global Individual Asset Identifier    GSRN Global Service Relation Number



# The Digital GS1 Hospital

<https://gs1hospital.gs1.org/>

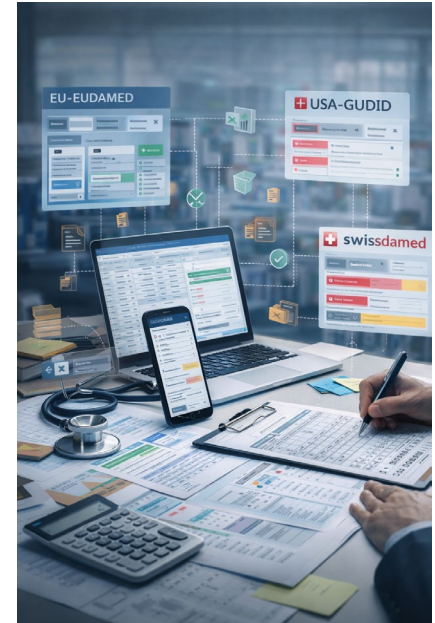




# UDI ist mandatory

Implementation is complex

- Multiple UDI databases
- Different mandatory fields and validations
- Medium discontinuity between ERP, Excel, and portals
- High manual effort
- Each new market increases risk and costs



# UDI regulations and databases worldwide

Each database has its own mandatory fields and business rules.

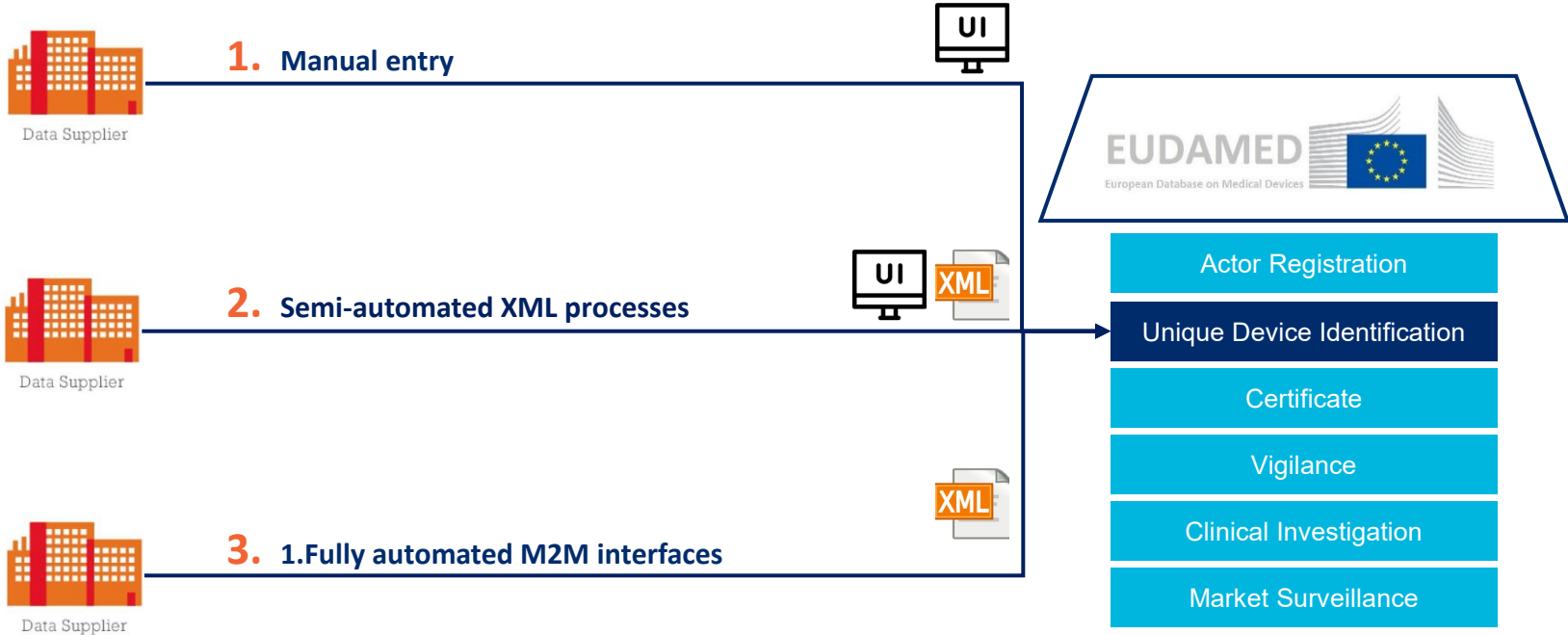
Land (UDI Database)	Number of data elements (estimation)
Ägypten (offen)	127
Australien TGA (AusUDID)	70
Brasilien (offen)	125
China NMPA (CUDID)	70
EU (EUDAMED)	141
Japan (MEDIS freiwillig)	49
Kolumbien (offen)	43
Malaysia (offen)	125
Saudi-Arabien SFDA (SAUDI-DI)	51
Schweiz (swissdamed)	130
Singapur HSA (SMDR)	38
Südkorea MFDS (IMDIS)	65
Taiwan TFDA (TUDID)	132
UK MHRA (GBDAMED)	125
USA FDA (GUDID)	70



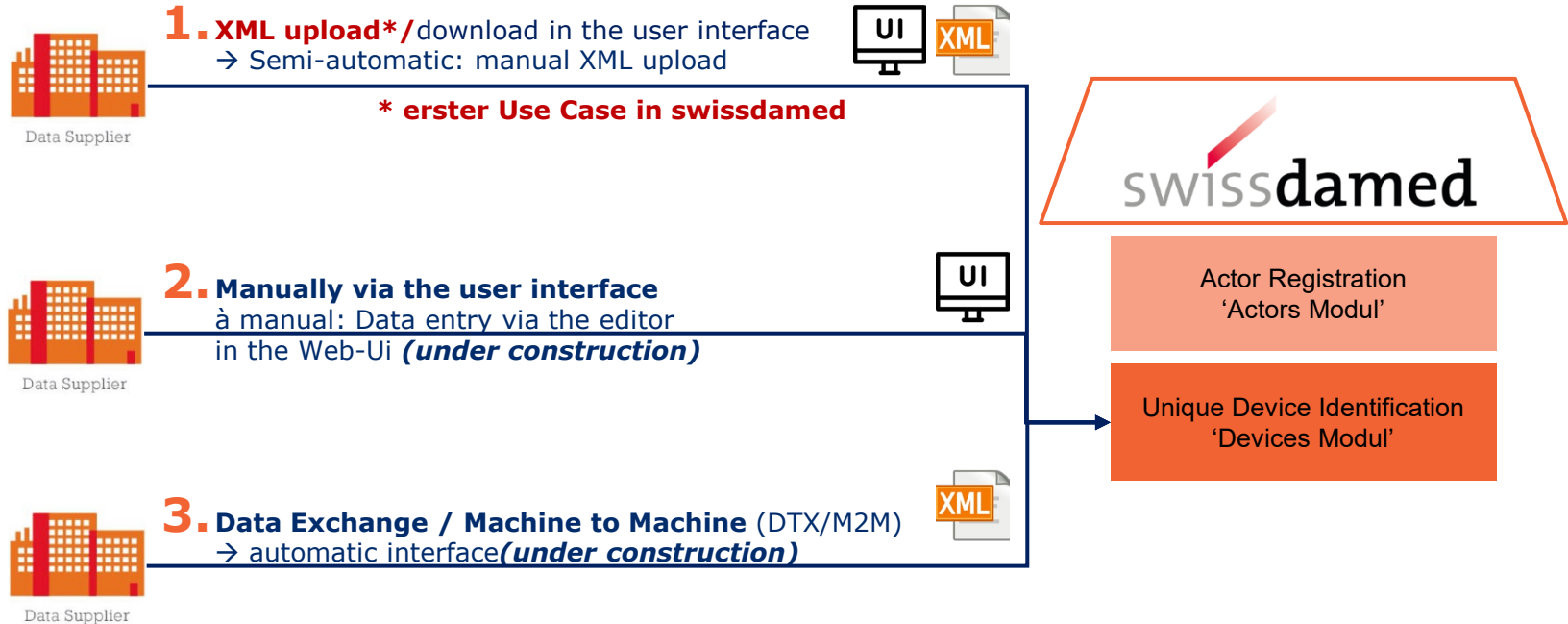
Countries where UDI requirements for the labeling of medical devices are currently being implemented or discussed.

**Please note that the map is constantly changing!**

# EUDAMED UDI transmission channels (current)



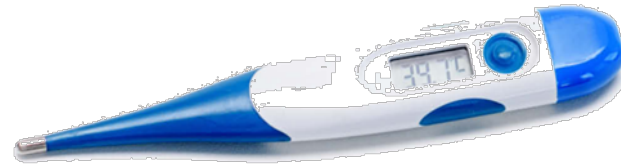
# swissdamed UDI transmission channels (plan)



# The challenge for manufacturers

The real problem is not UDI

- Missing central data source
- No consistent standards
- No scalable process
- Recurring maintenance efforts
- Manual entries = sources of error
- Different data models and business rules
- Lack of synchronization between ERP and portals



Gesunde Prozesse.





# Shared responsibility

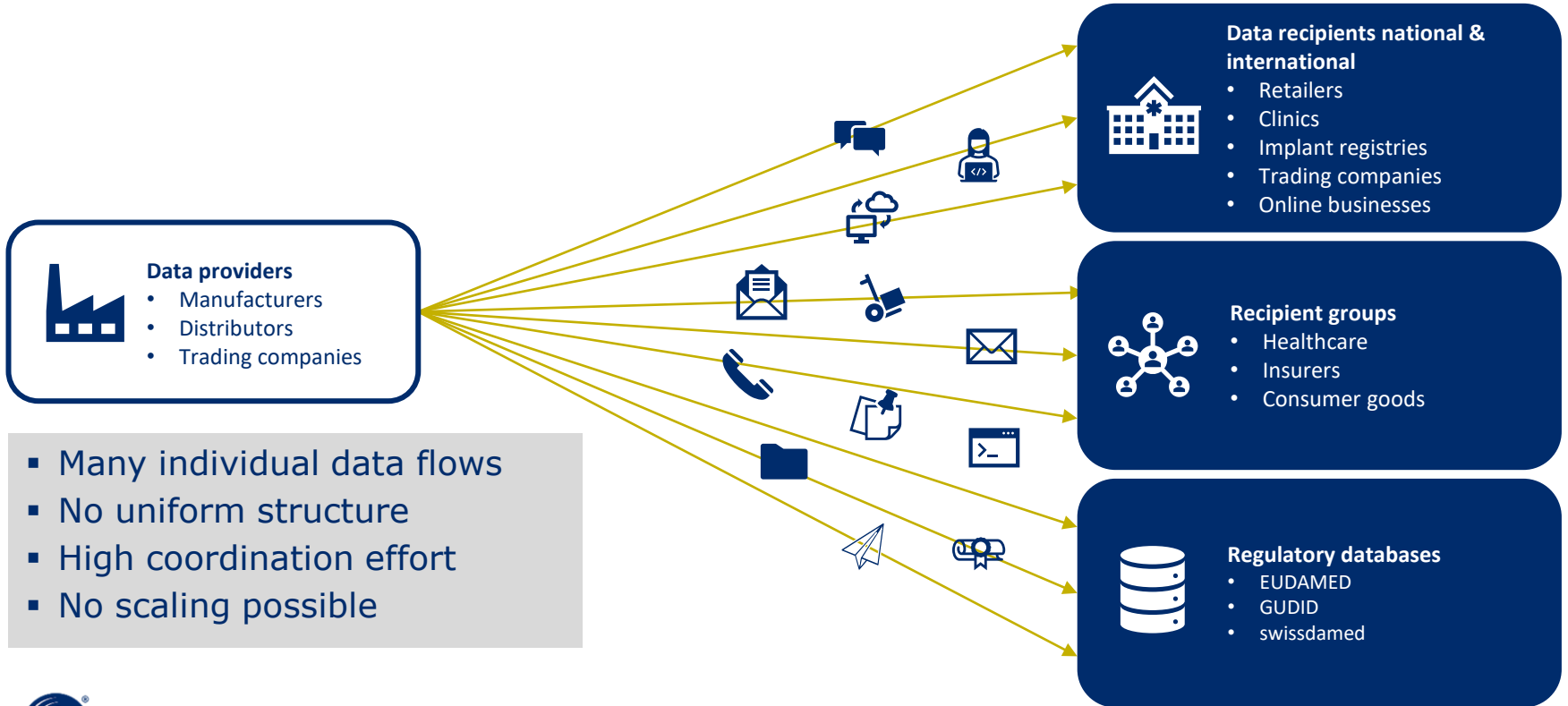
Master data is a strategic asset

**Supply security and compliance start with reliable data—and can only be achieved together**

- Manufacturers are the source of data
- Authorities define requirements
- Retailers and hospitals use data operationally
- Without clean master data, the system fails

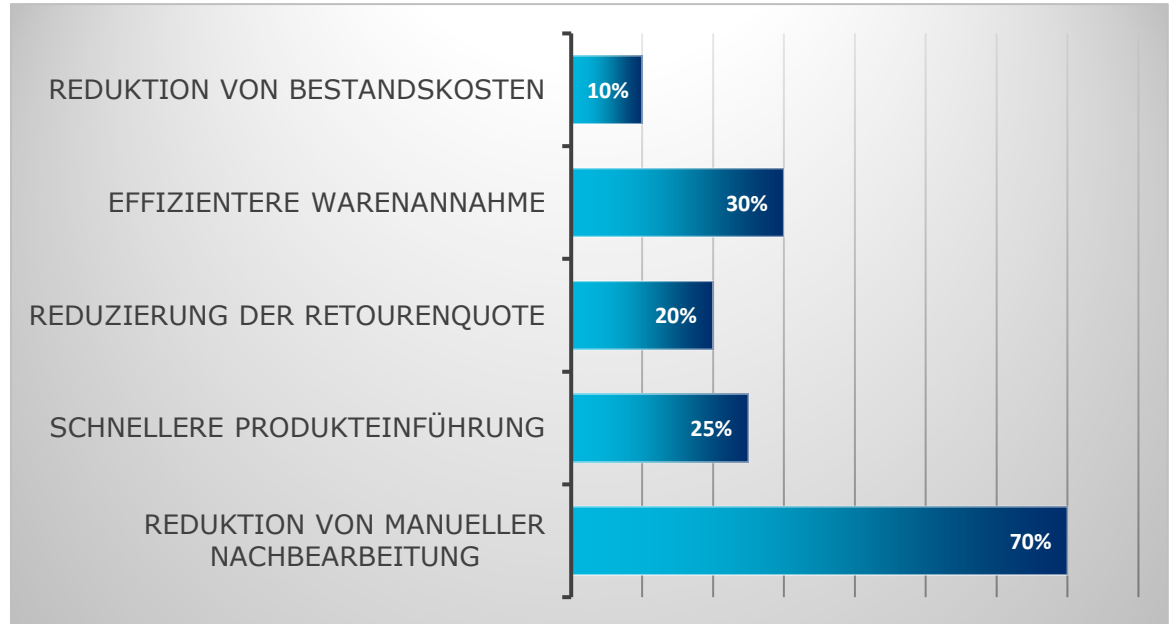


# Typical master data exchange



# Efficiency potential through high-quality product master data

Based on cross-industry studies and completed customer projects, there is clear potential for improvement through the implementation of digital master data exchange.



# Hirlanden Group testimonial



“

Wir benötigen für unsere operativen Prozesse valide Daten. Produkte ohne dazugehörige Daten sind in unserer digitalen Welt wertlos. Ohne qualitätsgesicherte Daten können wir Artikel weder bestellen, noch den Verbrauch dokumentieren, Warenbewegungen abbilden, oder Rechnungen bezahlen.

**Eugenio Di Biaso, Head of Supply Chain Management**  
Hirlanden-Gruppe

# firstbase – Data exchange made easy

## Requirements for modern master data systems



A central source



Immediate availability of  
changes



Validation thanks to global  
standards

**Complete, up-to-date, and accurate master data**

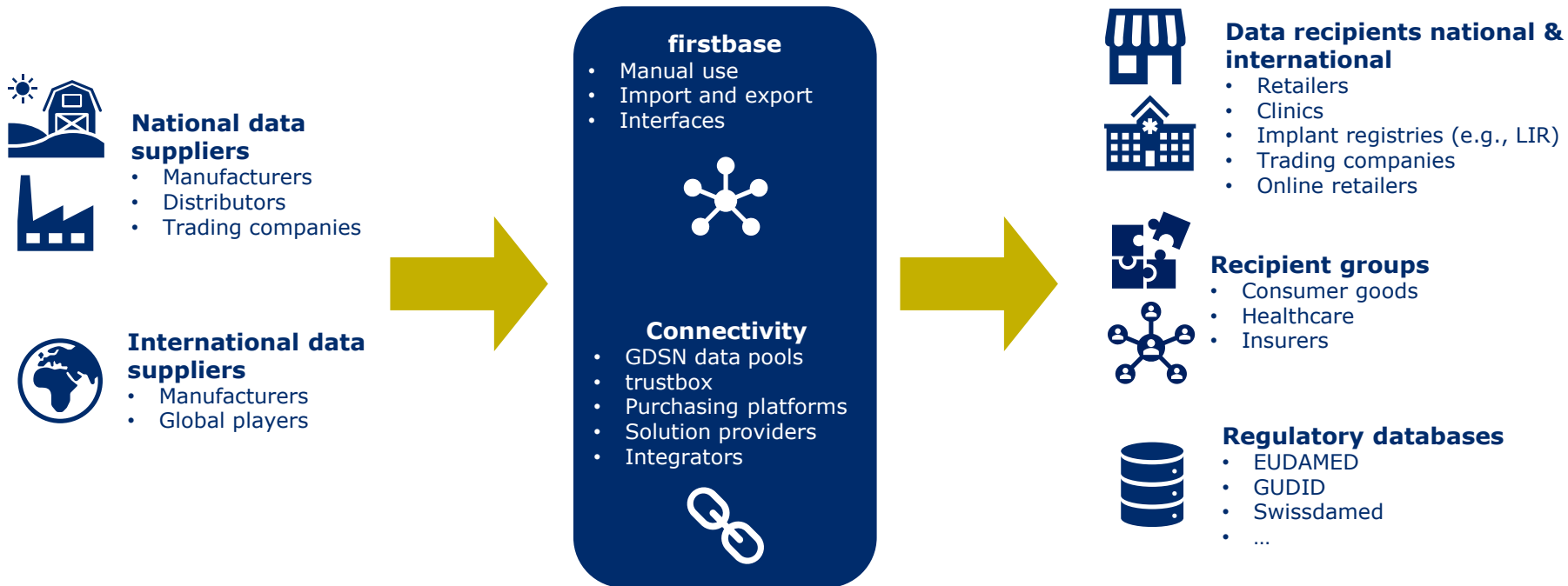
# What is firstbase?

- Certified GDSN data pool for structured master data exchange
- Central platform for the exchange of product master data between trading partners
- Interconnected with other solutions and data pools in Switzerland and internationally
- Flexible use. Web interface, import, export, or interface
- Scalable and future-proof for growing requirements



# firstbase connected

## More than a GDSN-Datapool



# Benefits for data suppliers

- Single point of entry for product master data
- No duplicate maintenance
- Reduced manual effort
- Systematic compliance with regulatory requirements
- Faster time to market
- Consistent data for trading partners

**Centralized data collection increases efficiency, data quality, and compliance**





**firstbase is the Swiss GDSN data pool; globally connected, locally established.**

# Master data with firstbase



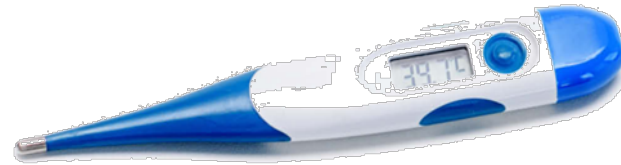
- Less administration
- More time for high-value work
- Data is a key to market access

**NO DATA – NO PRODUCT**

# The challenge for manufacturers

## Challenges become opportunities

- No central data source
- No consistent standards
- No scalable process
- Recurring maintenance costs
- Manual entries = sources of error
- Different data models and business rules
- Lack of synchronization between ERP and portals



Gesunde Prozesse.

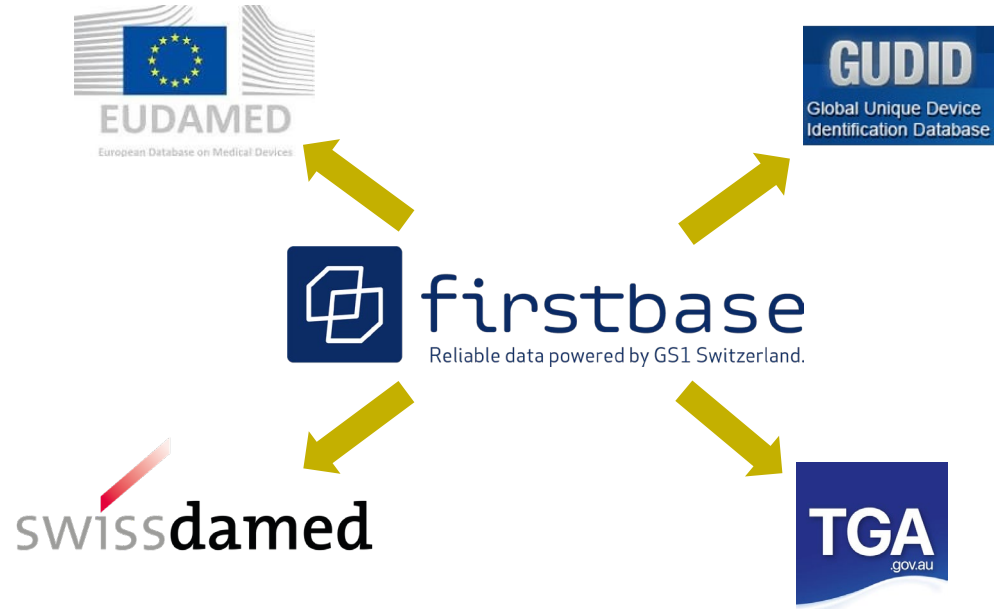
With firstbase, fragmented, manual processes are transformed into standardized, networked data flows - the basis for healthy processes in healthcare.



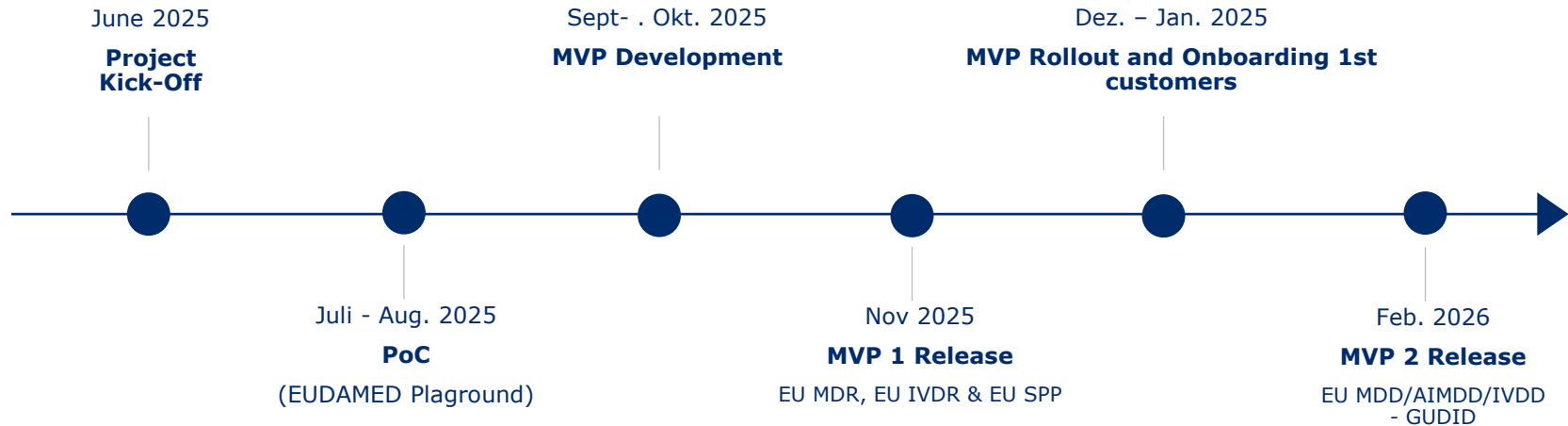
# UDI Publication with firstbase

More than GDSN

- **A single database**
- **Multiple UDI target systems**
- **Uniform logic regardless of different rules**
- **No duplicate maintenance**



# GS1 UDI Connector Roadmap



# Detailed specification

MDR, SPP, IVDR, MDD/AIMDD, IVDD

Mapping and detailed documentation of the six different EUDAMED data sets relating to the various legal provisions

Scope	Scope Remark	Field ID	Field Label	Entity Name	MDR Status	SPP Status	IVDR Status	MDD/AIMDD Status	IVDD Status	Attribute Name	Attribute Help text (UDI Profile Overview)	Example Value
Yes		FLD-UDID-14	Basic UDI- DI code	BasicUDIDate	M	M	M	-	-	Global Model Number (GMN)	Indicate the GS1 Global Model Number (GMN), which is the GS1 identification key used to identify a product model or product family based on attributes common to the model or family, as defined by industry or regulation. Once assigned to a specific product model or product family, this GS1 identification key SHALL NOT be reassigned to another. The GMN SHALL NOT be used to identify a trade item.	7612345GOLDenTest193G
Yes		FLD-UDID-11	Applicable Legislation / Regulatory	BasicUDIDate	M	M	M	M	M	Regulatory act	The name given to the requirement assigned by the regulatory agency. This attribute is used in combination with 'Regulatory agency' (TC ID 2603).	MDR
Yes		FLD-UDID-11	Applicable Legislation / Regulatory	BasicUDIDate	M	M	M	M	M	Regulatory agency	<b>EUDAMED, swissdamed:</b> The required information is the name of the specific entity in charge of issuing the permit to a company. This attribute is used in combination with 'Regulatory act' (TC ID 2604).	EU
Yes		FLD-UDID-16	Risk Class	BasicUDIDate	M	M	M	M	M	Additional trade item classification code value	Indicate the category code of the trade item based on the alternate classification scheme used in the UDI Database. This attribute is used in combination with 'Additional Trade item classification system code' (TC ID 3131).	EU_CLASS_IIB
Yes		FLD-UDID-16	Risk Class	BasicUDIDate	M	M	M	M	M	Additional trade item classification system code	<b>EUDAMED, swissdamed:</b> Indicate the classification system used in the UDI Database. This attribute is used in combination with 'Additional Trade item classification code value' (TC ID 3132).	76
Yes		FLD-UDID-10	Legal Manufacturer SRN	BasicUDIDate	M	-	M	M	M	Additional party identification type / value	Indicate the unique registration number of the actor registered in the UDI database. Select the relevant type code. This attribute is used in combination with 'Contact type code' (TC ID 3182).	CH-MF-000023141
Yes		FLD-UDID-10	Legal Manufacturer SRN	BasicUDIDate	M	-	M	M	M	Contact type code	<b>EUDAMED, swissdamed:</b> Indicate the code specifying the type of contact for a product. This attribute is used in combination either with 'Additional party	EMA



EU MDD/ AIMDD (ca. 79)

EU IVDD (ca. 63)

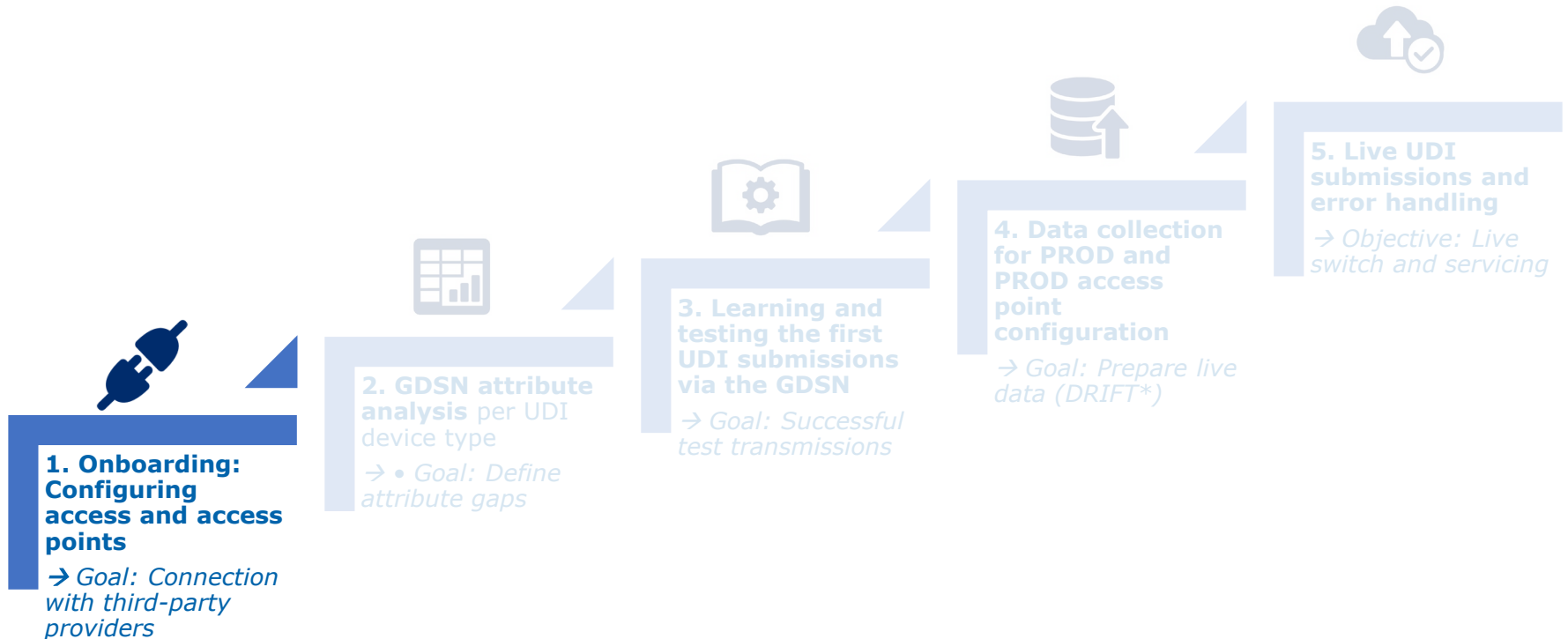
EU MDR (ca. 100)

EU IVDR (76)

EU SPP (33)

# General UDI onboarding process

How UDI submissions are implemented step by step



# A first look at the firstbase web interface data collection

The screenshot displays the Firstbase web interface for data collection. The top navigation bar includes the logo, user information (34505450545202 Schweiz Public), environment (Testumgebung UAT CH 3.1.30), and search options (Attribut hinzufügen, Suche nach Attributen). The main content area is titled 'Artikeltexte und -beschreibungen' and shows a form for entering article descriptions. The form is organized into sections: '3336 Markenname' (Swiss Test), '3297 Artikelkurzbezeichnung / Sprache' (English: Surgical glove L, 1 PR gold; German: OP-Handschuh L, 1 PR gold), '3318 Artikelbezeichnung / Sprache' (English: Swiss surgical glove L, 1 pair gold; German: empty field), and '3293 Zusätzliche Artikelbeschreibung / Sprache' (English: Swiss test item for demo; German: Schweizer Testartikel zur Demo). A sidebar on the left contains navigation options like 'Status', 'Basisdaten', 'Zielmärkte und Partner', 'Asset', and 'Artikeltexte und -beschreibungen'. A right sidebar shows a 'Checkliste' with error messages (Fehler) and warnings (Warnungen) related to missing safety data sheets for specific assets.

34505450545202 Schweiz Public

Testumgebung UAT CH 3.1.30

Attribut hinzufügen Suche nach Attributen

Basis oder kleinste Einheit Swiss Test OP-Handschuh L, 1 PR gold SID\_CH-9996

Aktuell Entwurf Live

Sektor: Healthcare Ansicht als: Module

Status Basisdaten Zielmärkte und Partner Asset

Artikeltexte und -beschreibungen

Bestell- / Lieferinformation / Verfügbarkeit

Gefahrgutangaben

GHS / Sicherheitsdatenblatt (SDS)

Handhabung

Healthcare Artikel

Laufzeit

Masse Gewichte Füllmenge

3336 Markenname Swiss Test

3297 Artikelkurzbezeichnung / Sprache

English (en) Surgical glove L, 1 PR gold

Deutsch (de) OP-Handschuh L, 1 PR gold

3318 Artikelbezeichnung / Sprache

English (en) Swiss surgical glove L, 1 pair gold

Deutsch (de)

3293 Zusätzliche Artikelbeschreibung / Sprache

English (en) Swiss test item for demo

Deutsch (de) Schweizer Testartikel zur Demo

Checkliste

Fehler Probleme, die vor der Publikation gelöst werden müssen. Mehr lesen

756.064 Healthcare / Medizinprodukte: Die Artikelbezeichnung (tradeltemDescription) muss angegeben werden.

Artikelbezeichnung / Sprache

Warnungen Optionale Vorschläge zur Korrektur von Artikeldaten. Mehr lesen

756.002 Healthcare / Medizinprodukte: Bei Gefahrgut wird das Sicherheitsdatenblatt erwartet. Bitte fügen Sie das Sicherheitsdatenblatt mit Datei: Code (referencedFileTypeCode) 'SAFETY\_DATA\_SHEET' an.

Asset hinzufügen

Asset Warning Ein Asset hat ein oder mehrere Attribute, die Aufmerksamkeit erfordern. Asset bearbeiten, um Details

# Project with MEDELA

## EUDAMED with firstbase



- **The first steps were taken together in May 2015.**
  - Excel template from GS1
  - Regular joint project work starting in June
  - Playground users in Eudamed
  - First data uploads starting in July
  - Intensive testing currently ongoing to optimize data quality
- **Once testing has been successfully completed, Medela will be able to start publishing to the EUDAMED production system in January 2026.**

# The challenge of master data

- Our biggest challenge was the lack of a central platform for our product data. The information was stored in different systems, on shared drives, in PDF and Excel files.
- When a hospital or retailer requested data, we had to manually fill out an Excel spreadsheet with over 30 attributes. This was repetitive and time-consuming.
- It took us 30 to 60 minutes per request.
- We often received follow-up questions because information was missing or incomplete.

# UDI with firstbase

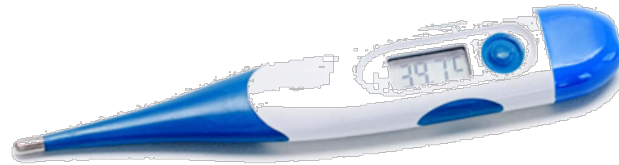


- Submitting several hundred articles is too slow
- We therefore were looking for a more efficient solution
- Successful in the EUDAMED playground
- Being ready when EUDAMED becomes mandatory

# The challenge for manufacturers

## Global accessibility through standardized master data and UDI connectors

- No central data source
- No consistent standards
- No scalable process
- Recurring maintenance costs
- Manual entries = sources of error
- Different data models and business rules
- Lack of synchronization between ERP and portals



Gesunde Prozesse.

With firstbase, fragmented, manual processes are transformed into standardized, networked data flows - the basis for healthy processes in healthcare.

Combined with UDI connectors for easy management/transmission of regulatory information, your workload is reduced several times over.

# For whom firstbase with UDI connectors is highly relevant



- Companies facing high regulatory pressure
- Manufacturers with multiple UDI target markets
- Companies with limited regulatory resources
- Organizations with mature IT landscapes
- Manufacturers focused on scaling and market access

# Stay informed

- Further information; [firstbase website on UDI](#)
- Don't miss any news about firstbase with the firstbase newsletter; [sign up](#)
- Receive targeted information about the UDI connector; sign up or scan the QR code



# Next steps for you

May we help you?

- The added value of firstbase becomes clear in specific application scenarios. We would be happy to assist you with a brief assessment of your current situation.
- Arrange a non-binding consultation with us
  - Online appointment: [Book your appointment](#)
  - In-person appointment at your premises: [Book your appointment](#)
- Request your personalized quote
  - Email [distribution@gs1.ch](mailto:distribution@gs1.ch)



# We look forward to answer your questions

Current status Interface FirstBase with EUDAMED & SWISSDAMED and deployment plan.

Können die Daten in firstbase eingegeben und dann in Swissdamed übertragen werden?

Which regulations can be fulfilled by firstbase? Swiss only or also EU, FDA etc.?

Quels sont les moyens à mettre en œuvre pour optimiser la saisie des données sur swissdamed et Eudamed?

# Thank you very much for your attention.



Armand Linge

Leiter Regulation & Innovation  
Mitglied der Geschäftsleitung

Swiss Medtech

T +41 31 330 97 74

E: [daniel.delfosse@swiss-medtech.ch](mailto:daniel.delfosse@swiss-medtech.ch)



Andrea Schütz Frikart

Senior Industry Engagement  
Manager Healthcare

GS1 Switzerland

T: +41 58 800 72 35

E: [andrea.schuetz@gs1.ch](mailto:andrea.schuetz@gs1.ch)



Domenic Schneider

Head of Distribution  
Value Added Services

GS1 Switzerland

T: +41 58 800 72 37

E: [domenic.schneider@gs1.ch](mailto:domenic.schneider@gs1.ch)