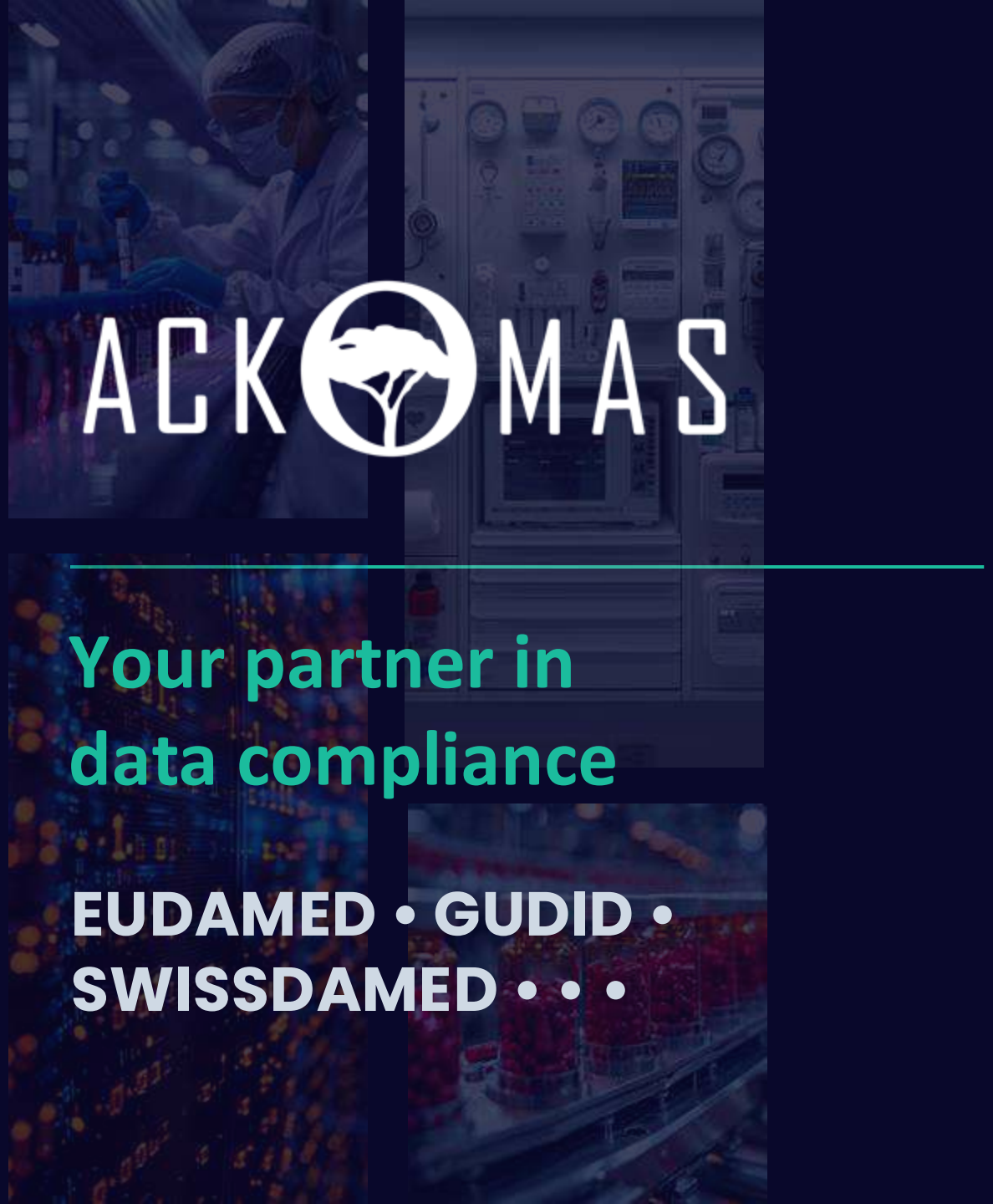
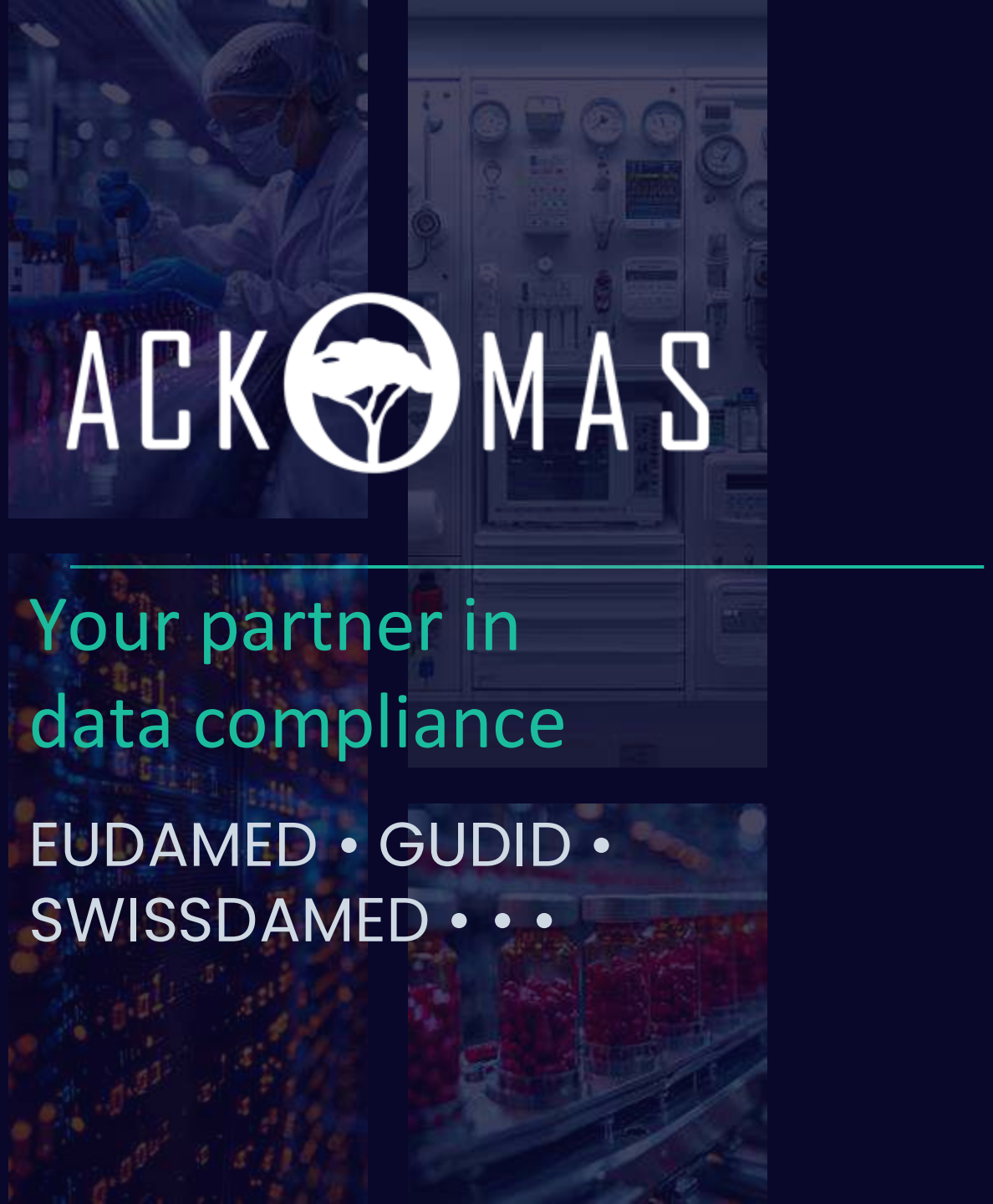
Registering medical devices on EUDAMED:

Operating mode & Feedback from a manufacturer



EUDAMED
Regulation & Timelines



Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

Regulation : EU 2017/745 (MDR) & 2017/746 (IVDR)

EUDAMED Purposes(1) :

- Market transparency
- Unique Device Identification (UDI)
- Cooperation between well-informed competent authorities

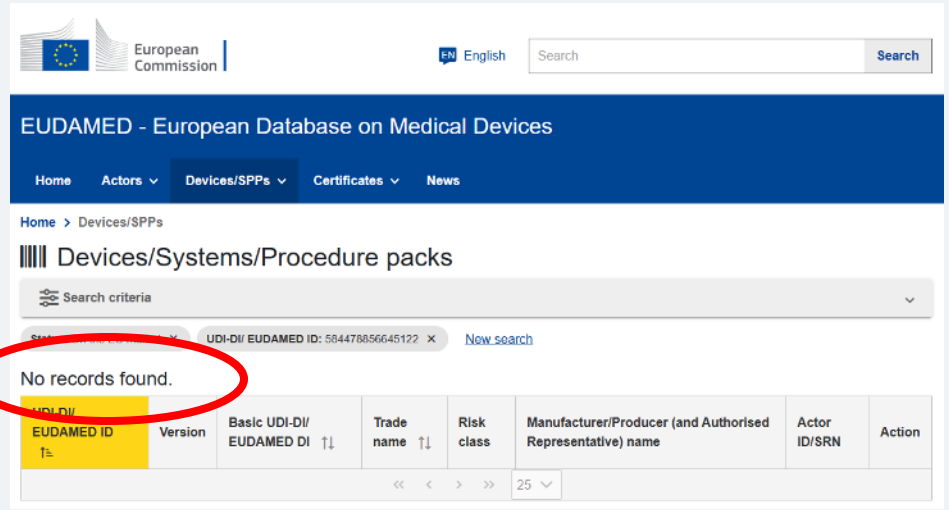
Consequence for legal manufacturers:

Medical device placed on European Market, but **not registered** on EUDAMED, is considered **not compliant.**

(1) Art 33.1 EU 2017/745

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

EUDAMED non-conformity: what consequences?



Non-registered device

Business

=

No access to European market (Articles 10.7 & 29)

Breach of contract with distributor

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

6 modules:

Modules used by manufacturer :

- ACTORS
- DEVICES
- VIGILANCE & PMS
- NB & CERTIFICATES
- MARKET SURV.
- CI/PS

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

DEVICE

The main module in terms of data volume

3 ways to input your data :

- **Manual input** directly on the plateform
- **UDI Bulk upload** via XML files
- **Automatic link M2M**(1) via dedicated software

how to select the right approach ?

Manual = low volume of data

M2M = high volume of data

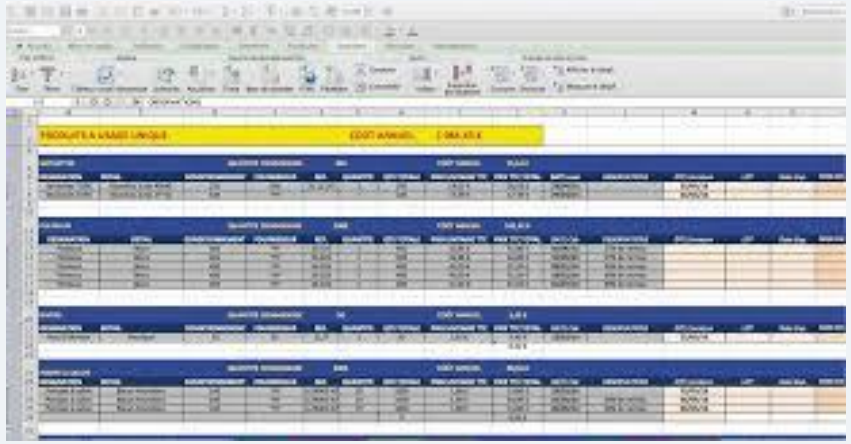
(1) « Machine to Machine » = qualified link to EUDAMED platform

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

DEVICE

Bulk upload via **XML files** on the website:

EUDAMED
European Database on Medical Devices

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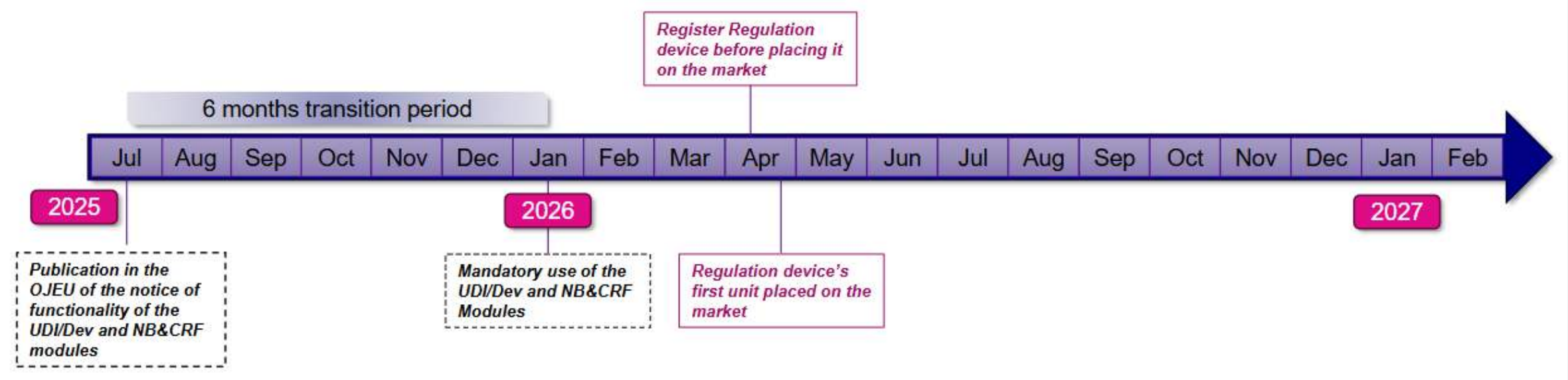
NB. the EUDAMED platform does **Not accept** spreadsheet files.

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

EU 2024/1860

Timeline for Regulation Devices placed on the market after JAN 2026:

Registration need to be done before placing on the market

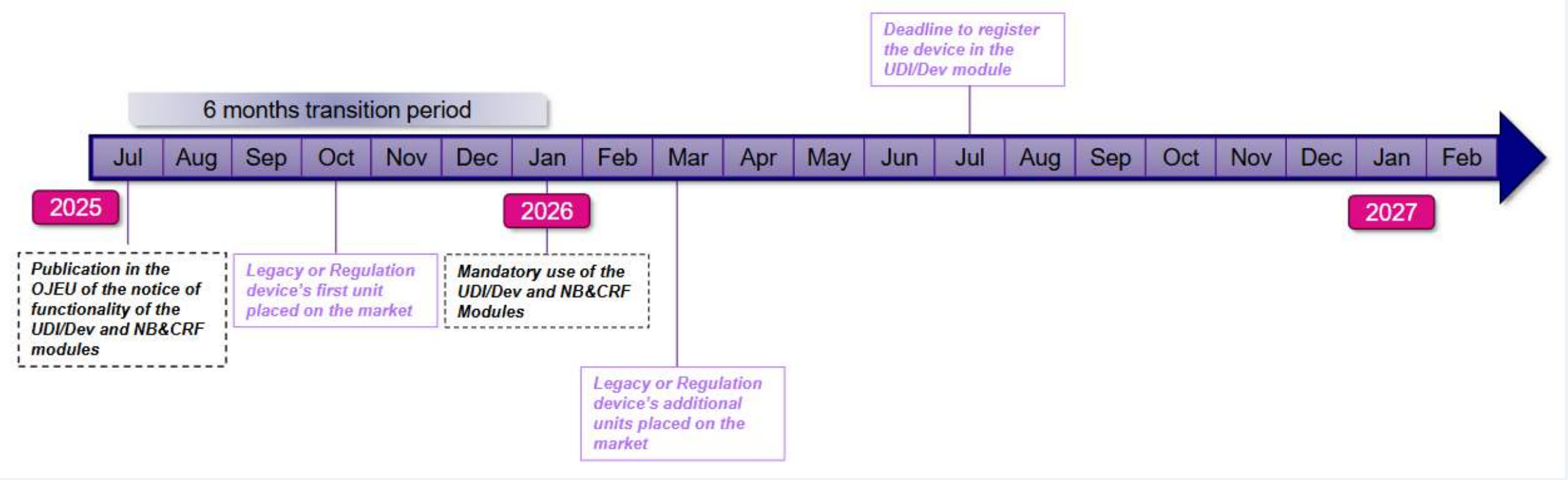


Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

EU 2024/1860

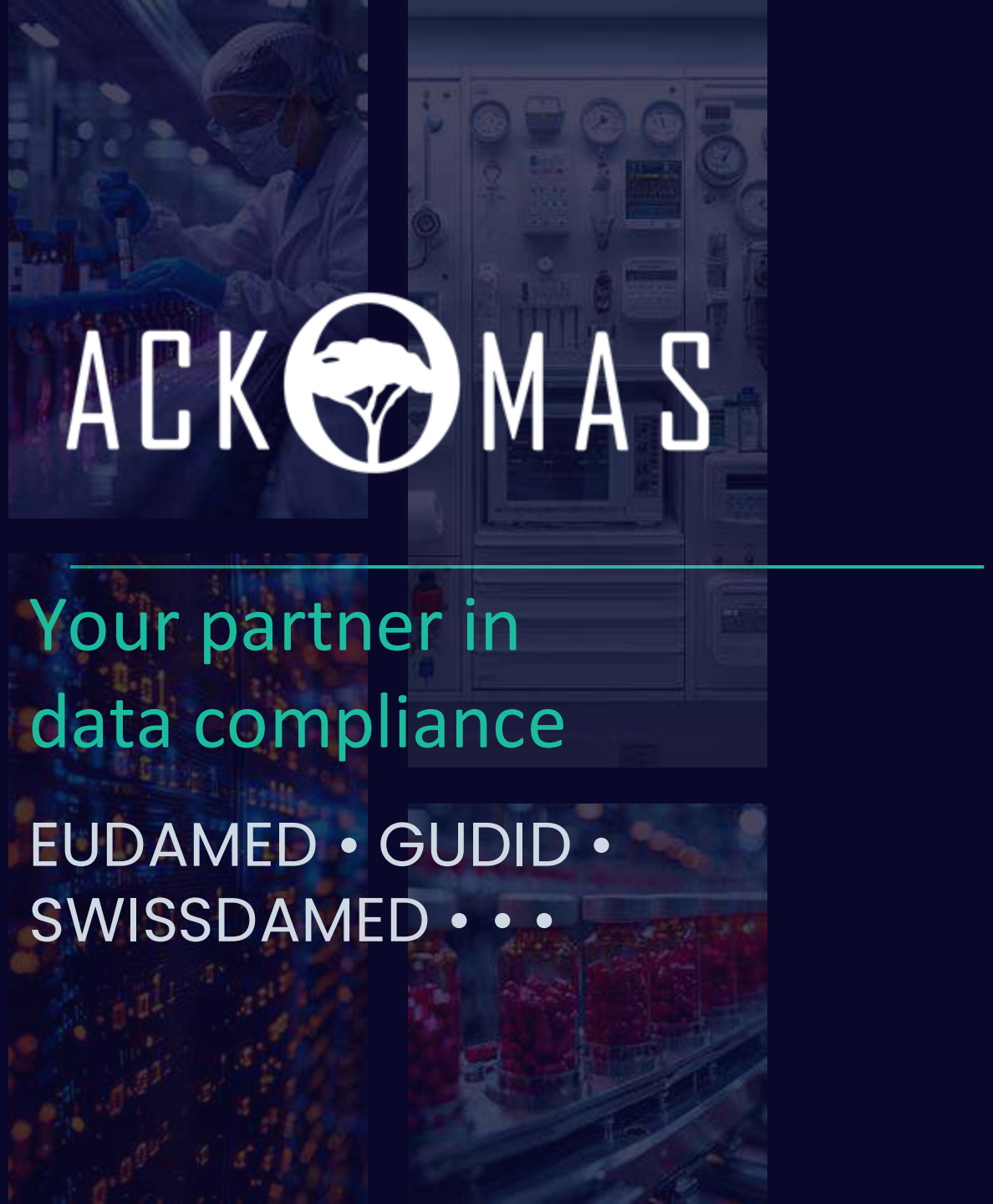
Timeline for Legacy and Regulation Devices placed on the market before JAN 2026 :

Deadline July 2026



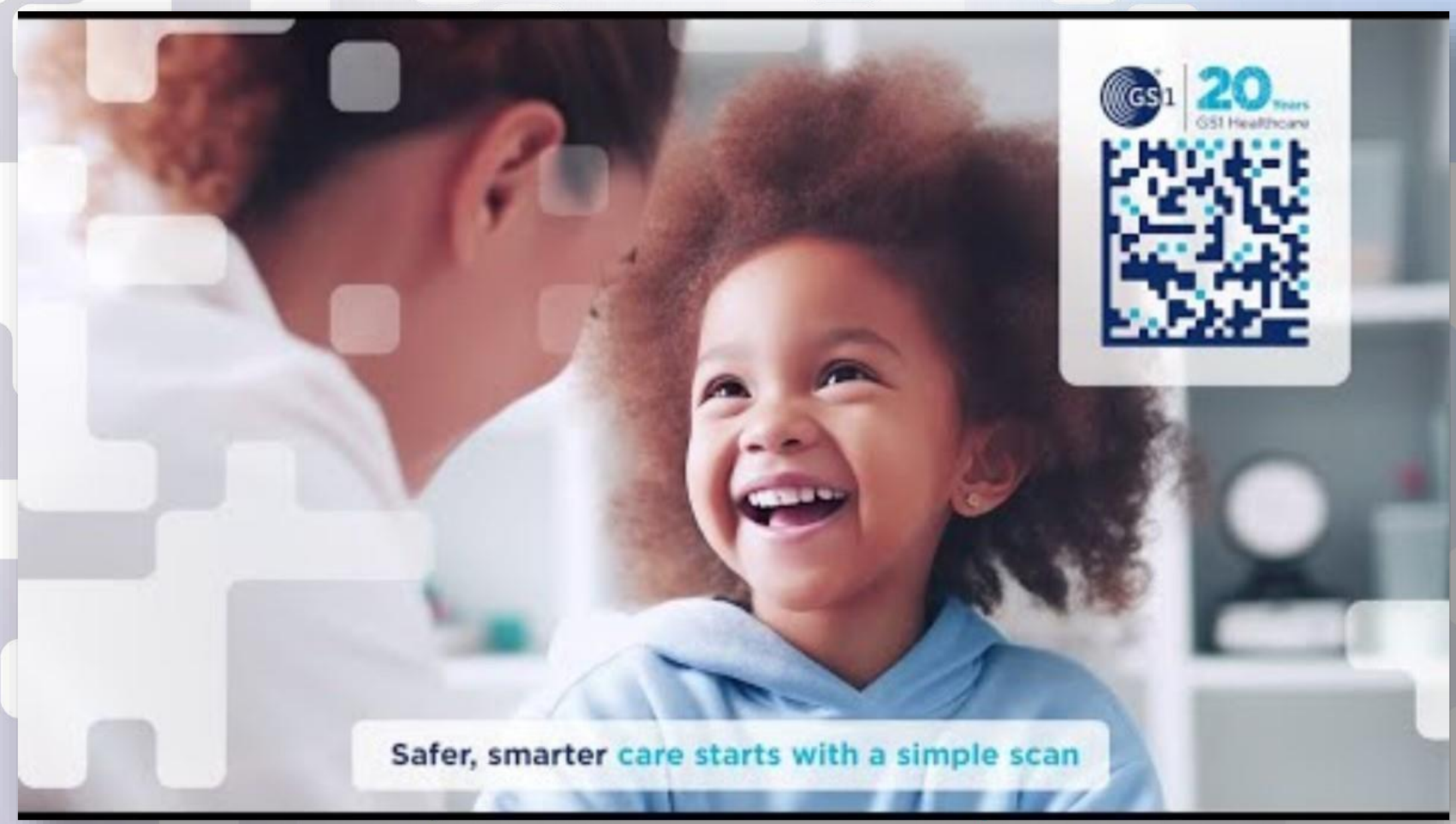
GS1 Austria

UDI requirements & obligations



Your partner in data compliance

EUDAMED • GUDID • SWISSDAMED • • •


GS1
20 Years
GS1 Healthcare
Safer, smarter care starts with a simple scan

GS1 Austria

The Global Language of Business

UDI Requirements & Obligations

Online webinar:
Registering medical devices on EUDAMED

Poppy ABETO KIESSE, MSc.
June 10th, 2025

Things to consider …

www.gs1.at/udi
www.gs1.org/udi
webgate.ec.europa.eu/udi-helpdesk/en/welcome-to-eu-udi-helpdesk.html
health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en

Requirements for
Manufacturers & SPP-Producers

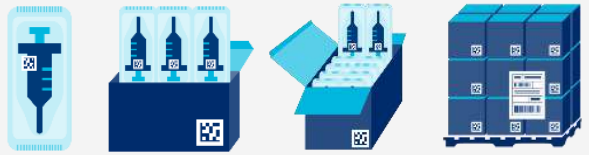
1

Contract with
issuing entity

2

Basis UDI-DI
assignment

3



UDI assignment:
UDI-DI + UDI PI

4

Labelling with
UDI-carrier

5

Registration of **Basis UDI-DI**(s)
& **UDI-DI**(s) in **EUDAMED**

Safer, smarter care starts with a simple scan

UDI & QMS (MDCG 2021-19)

Auditing the implementation of the UDI system

The Notified Body should ensure that its personnel involved in auditing the UDI requirements, as defined by the regulations, have the knowledge of these requirements. The documented assessment procedures should clearly outline the topics regarding the UDI system that needs to be covered by the auditors.

All applicable requirements of the UDI-system are part of the processes that are audited by the Notified Body. Those processes include but are not limited to the following aspects:

- selection of an issuing entity for the UDI codes;
- structure of the UDI-DI system (e.g. granularity of the Basic UDI-DI, grouping of UDI-DI);
- assignment of the UDI-DI codes;
- definition of UDI-PI and applicability to the product types;
- registration process into the UDI Database;
- record keeping procedures;
- issuing the EU Declaration of Conformity with the Basic UDI-DI;
- Change management of the UDI system, including update of the database
- labelling process, including barcode reference code and software validation
- maintenance of printing equipment,
- training of personnel on UDI system,
- processes used in post market surveillance and other monitoring activities.

In order to ensure that the UDI System meets the requirements, it is recommended that the Notified Body considers the elements listed above when assessing the quality system of the manufacturer .

1. **Registration Process**
2. **Change Management**
3. **Training of personnel on UDI system**

Training of personnel on UDI system

Connect with your issuing entity & stay up to date!

- Seminars, webinars, etc.

- Brochures, White Papers & Specifications:
  - Brochure on the fundamentals of UDI
  - GS1 General Specifications
  - GS1 Healthcare GTIN Allocation Rules
  - https://www.gs1.org/industries/healthcare/udi
  - https://www.gs1.org/standards/get-barcodes

- Barcode verification

Change Management & Triggers

Please analyze & document all factors that trigger a change to Basic UDI-DI, UDI-DI or UDI-PI!

Main Questions:

- What is a new device model? (→ New Basic UDI-DI, Notified Body?)
- What is a new device/SKU? (→ New UDI-DI)
- What is a minor change? (→ New UDI-PI)
- Regularly reevaluate your labelling strategy

Study all relevant & recent documents, guidances, etc.:

- MDR/IVDR
- MDCG Guidances
- EU UDI Helpdesk
- GS1 GTIN Management

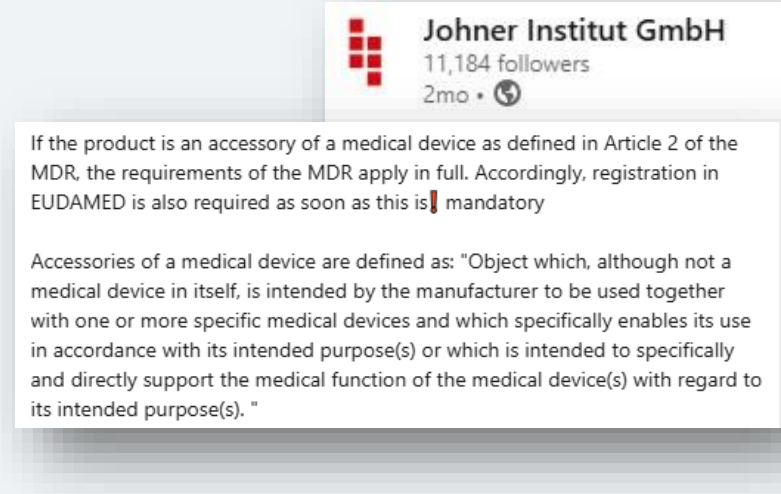
Contact your local GS1 MO here →

Avoid common mistakes

„verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices "

How/Where do you manage all Basis UDI-DIs?

- Regularly verify your UDI assignment strategy
- Do you use a validated ERP system or xls-files?
- „As part of the technical documentation …, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned"
- Don't forget: EVERY TYPE OF ACCESSORY requires a separate Basic UDI-DI and respective UDI-DIs



New obligations for manufacturers of contact lenses, spectacle frames, lenses and ready-made reading glasses

1

Vertrag mit GS1 Austria

+

UDI-Vereinbarung

2

Zuteilung der **Basis UDI-DI**

3

Zuteilung der **Master UDI-DI**

- **MUDI** + **GTIN** + **UDI-PI**
- **MTO-GTIN** +**UDI-PI**

4

Kennzeichnung mit einem **UDI-Träger**

5

Registrierung der **Basis UDI-DI**(s) und **Master UDI-DI**(s) in **EUDAMED**

Safer, smarter care starts with a simple scan

New requirements for manufacturers of contact lenses, spectacle frames, lenses and ready-made reading glasses

1

Contract with issuing entity

2

Basis UDI-DI assignment

3

Master UDI-DI assignment:
- **MUDI** + **GTIN** + **UDI-PI**
- **MTO-GTIN** +**UDI-PI**

4

Labelling with **UDI-carrier**

5

Registration of **Basis UDI-DI**(s) & **Master UDI-DI**(s) in **EUDAMED**

Safer, smarter care starts with a simple scan

UDI for contact lenses

Made-To-Stock

MUDI + GTIN + UDI-PI

MUDI (8014) 901234567MUDIStock16U
(01) 09120095090319
(17) 291101
(10) Charge1

MUDI
GTIN
Expiry date
Lot

© https://leanbase.de/lexicon/make-to-order-mto

Made-To-Order

MTO-GTIN + UDI-PI

(03) 09120095090319
(17) 291101
(10) Charge1

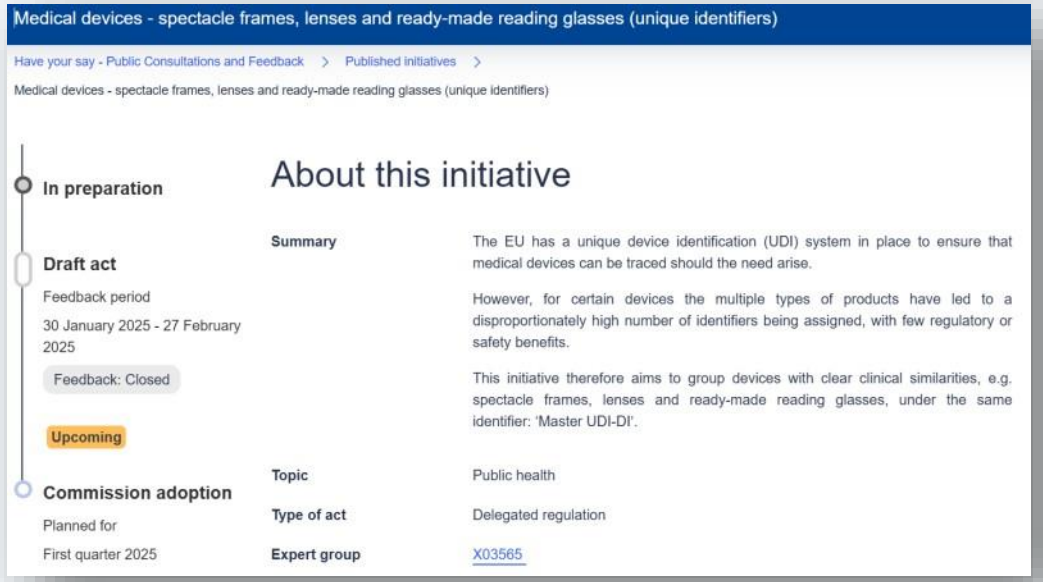
MTO-GTIN
Expiry date
Lot

© https://leanbase.de/lexicon/make-to-order-mto

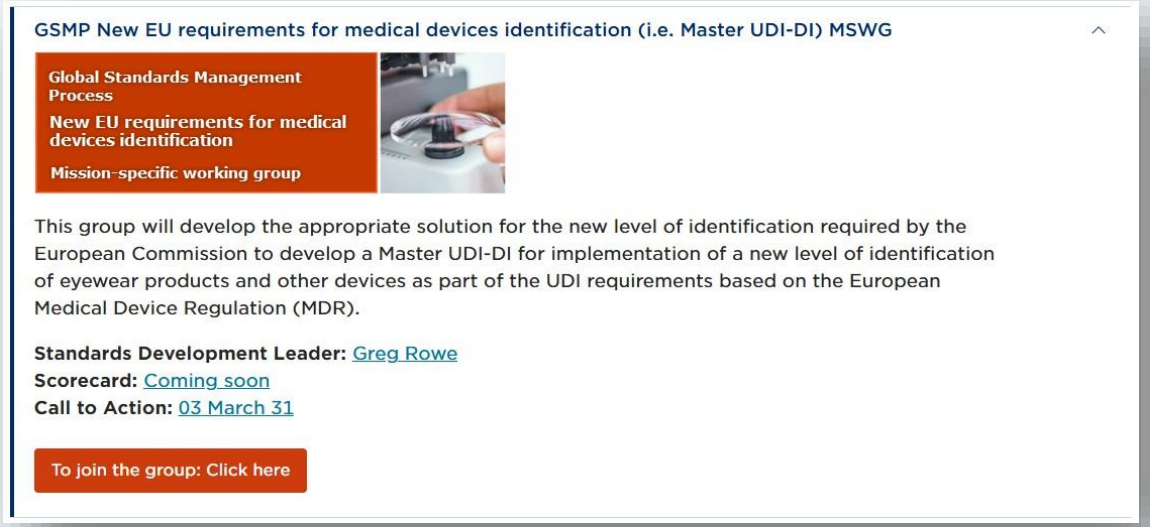
2
2

Master UDI-DI
for spectacle frames, lenses and ready-made reading glasses

Delegierte Verordnung



GS1 Arbeitsgruppe

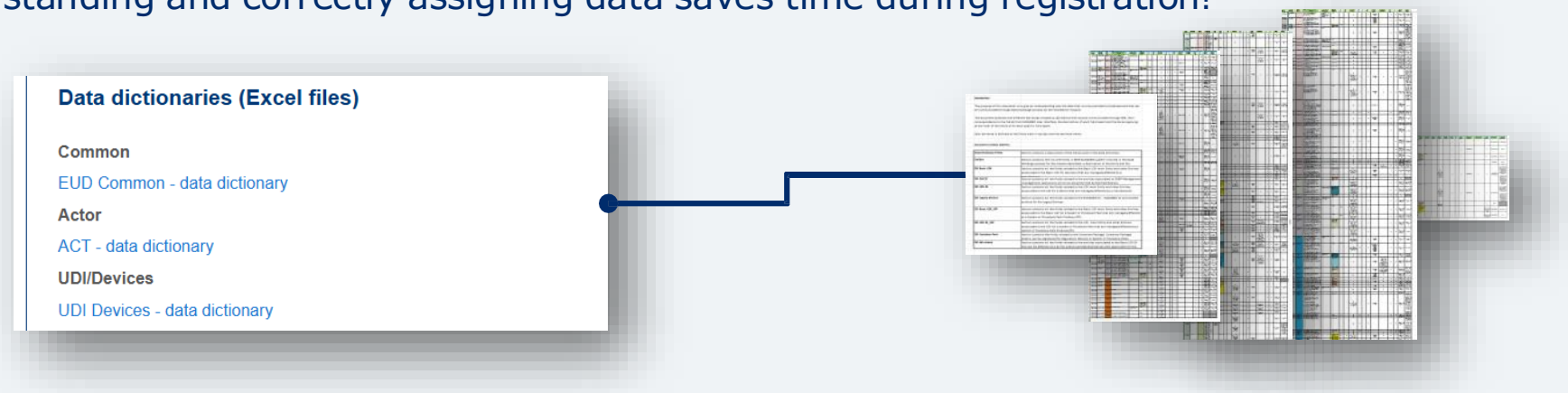


- ✓ Kick-Off on May 15th, 2025
- ✓ Interested organizations can join the initiative at any time!

Registration Process

« ensuring consistency and validity of information provided in accordance with Article 29 "

- **UDI Devices - data dictionary**
- - Understanding and correctly assigning data saves time during registration!



An error during registration can lead to a complete (physical) change of all UDIs (Basic UDIs and already registered UDI-DIs)!!

Join the ECHO Initiative for B2B-MD-Data!

The ECHO initiative focuses on harmonising market strategies and data requirements of the Global Data Synchronisation Network (GDSN) across borders and translates this into a common data model used by the different countries involved: Belgium, Denmark, Finland, France, Germany, Ireland, Netherlands, Spain, Switzerland, Sweden, Austria and other countries who may join over time.

Download here the CORE ECHO data model.

About ECHO

ECHO is a collaboration of GS1 Member Organisations together with healthcare stakeholders.

Read more

How to get involved?

The ECHO initiative is made by and for the healthcare industry. We encourage stakeholders to embrace ECHO as part of their local and global strategies regarding data discussions and GDSN implementations.

Read more

Testimonials from the industry

See what the experts have to say. Expert explanations on why the value of a harmonised approach is beneficial for the different organisations and departments involved in the supply chain.

Read more

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Business Development Manager Healthcare

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1040 Wien

T +43 (1) 505 86 01 - 101

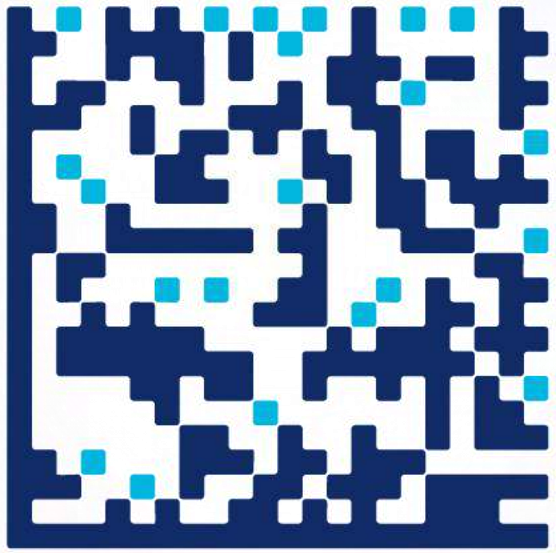
M +43 676 655 00 83

E abeto@gs1.at

www.gs1.at/healthcare

healthcare@gs1.at

GS1 | 20 Years GS1 Healthcare

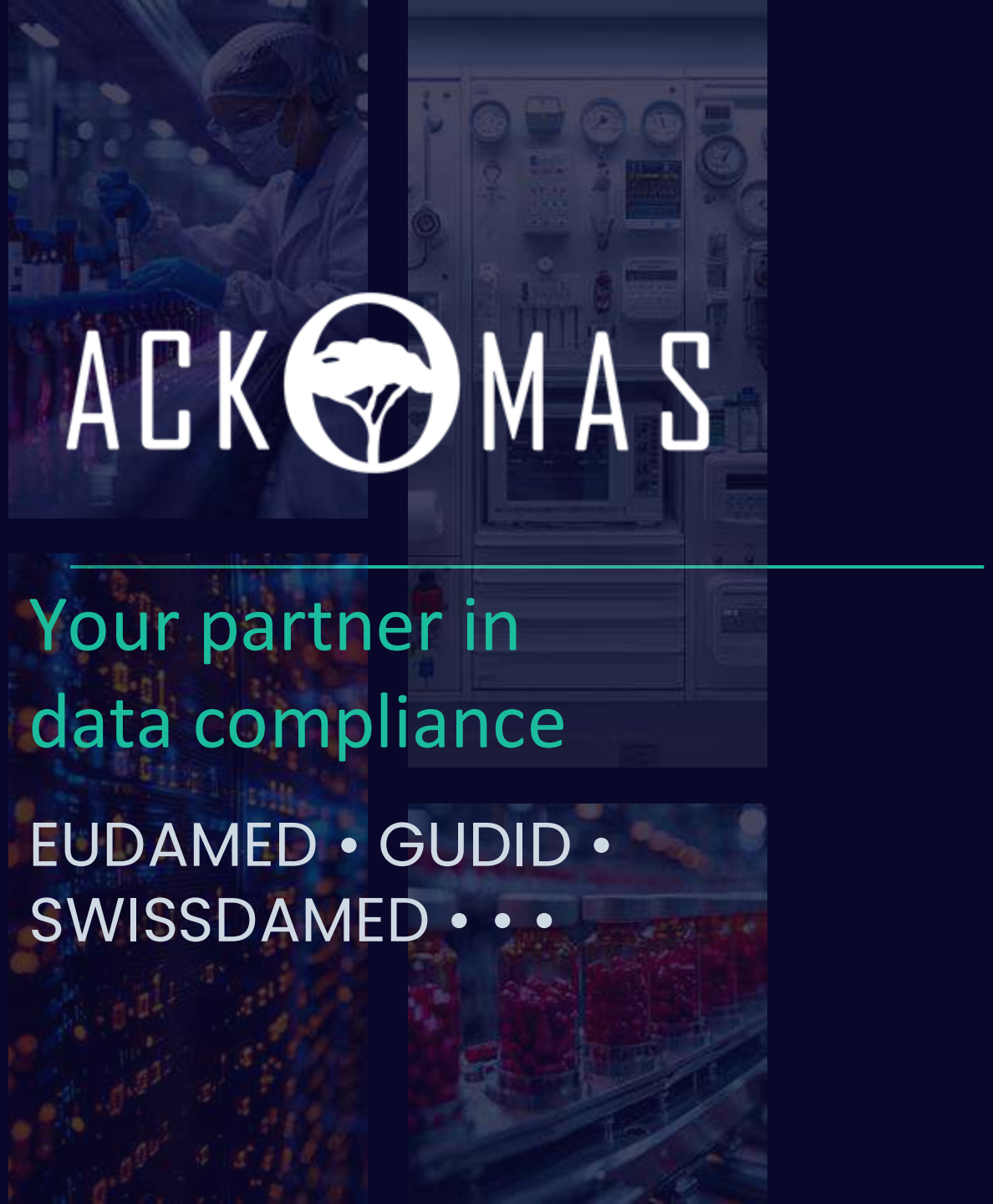


Safer, smarter care starts with a simple scan

The Global Language of Business

Feedback from a manufacturer

NOVASPINE



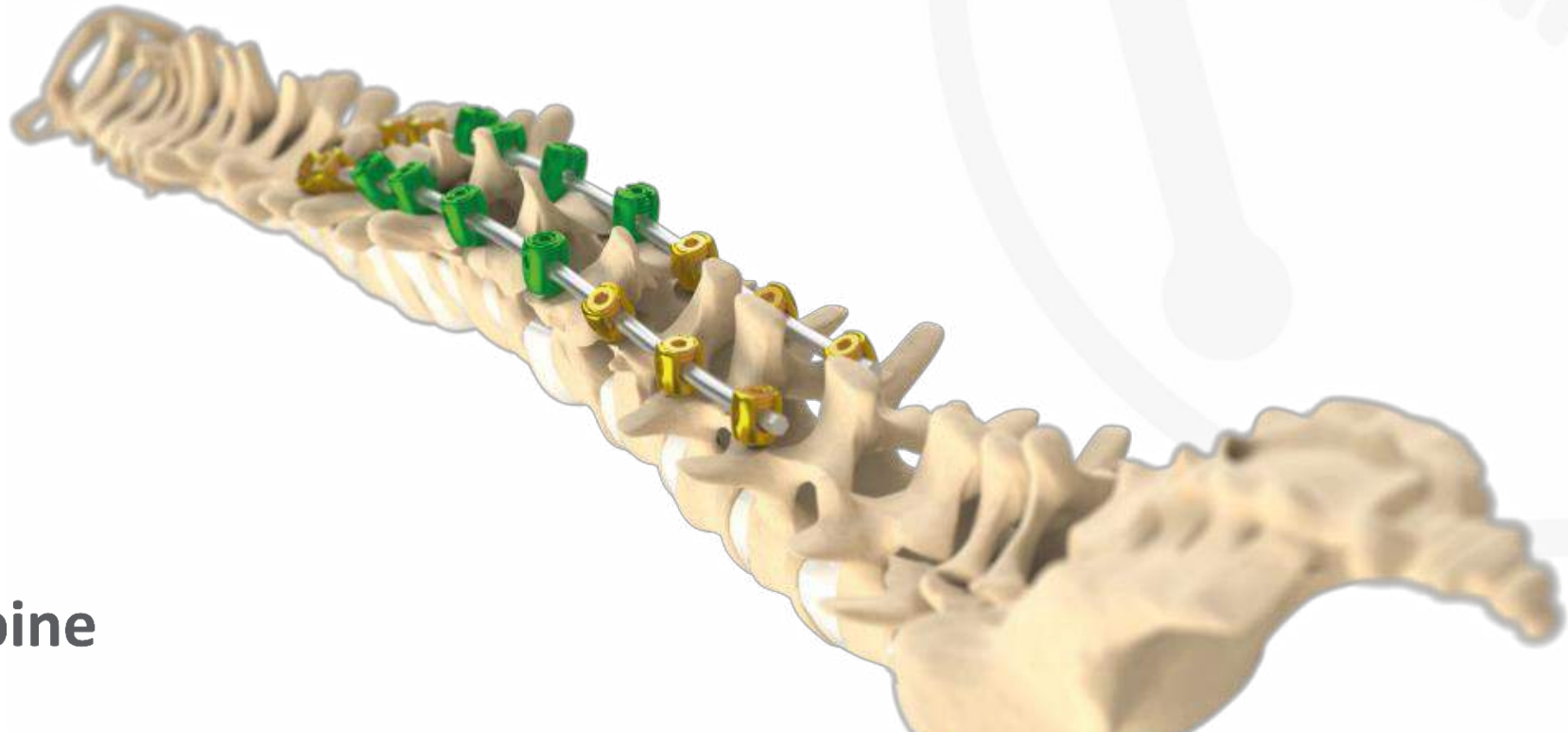
NovaSpine

FEEDBACK ON ACKOMAS SOLUTION

2025-06-10

ABOUT NOVASPINE

NovaSpine is a **French** company, based in Amiens and specialized in **the design and production** of advanced implants and instruments for spinal surgery.
We are committed to excellence and the betterment of patient care.



NovaSpine

NOVASPINE PRODUCTS

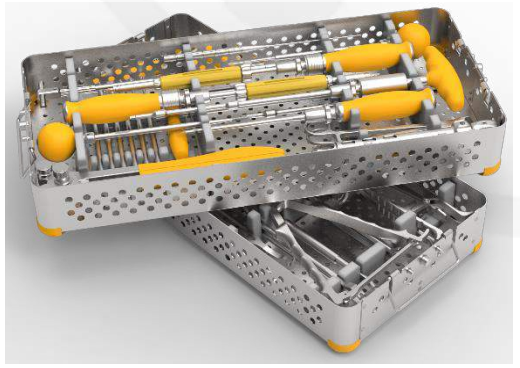
SOCORE :
Screws and rods
Class IIb

DIVA :
PEEK and 3D printed Cages
Class III

MATRIS :
Cervical plates
Class IIb

RODD :
Interspinous devices
Class III

INSTRUMENTS :
Class Ir



NovaSpine

MAJOR MILESTONES

Creation

Dec. 2005

Feb. 2006

First CE and ISO 13485 Certificates
SNCH
Non-sterile devices

Mar. 2007

2017

CE and ISO 13485 certificates
BSI UK
Non-sterile devices

Dec. 2020

Apr. 2020

CE and ISO 13485 certificates
BSI NL
Non-sterile devices

CE Certificates
KIWA
Sterile devices

ISO 13485 Certificate
BSI UK *(Recertification)*

Feb. 2024

Nov. 2024

MDR CE Certificates for 99% of the range
KIWA IT
Sterile and non-sterile devices

Office Relocation

July 2025

TODAY

MDR CE application
(Hooks, CoCr Rods and interspinous)

Dec. 2025

20 years of Novaspine

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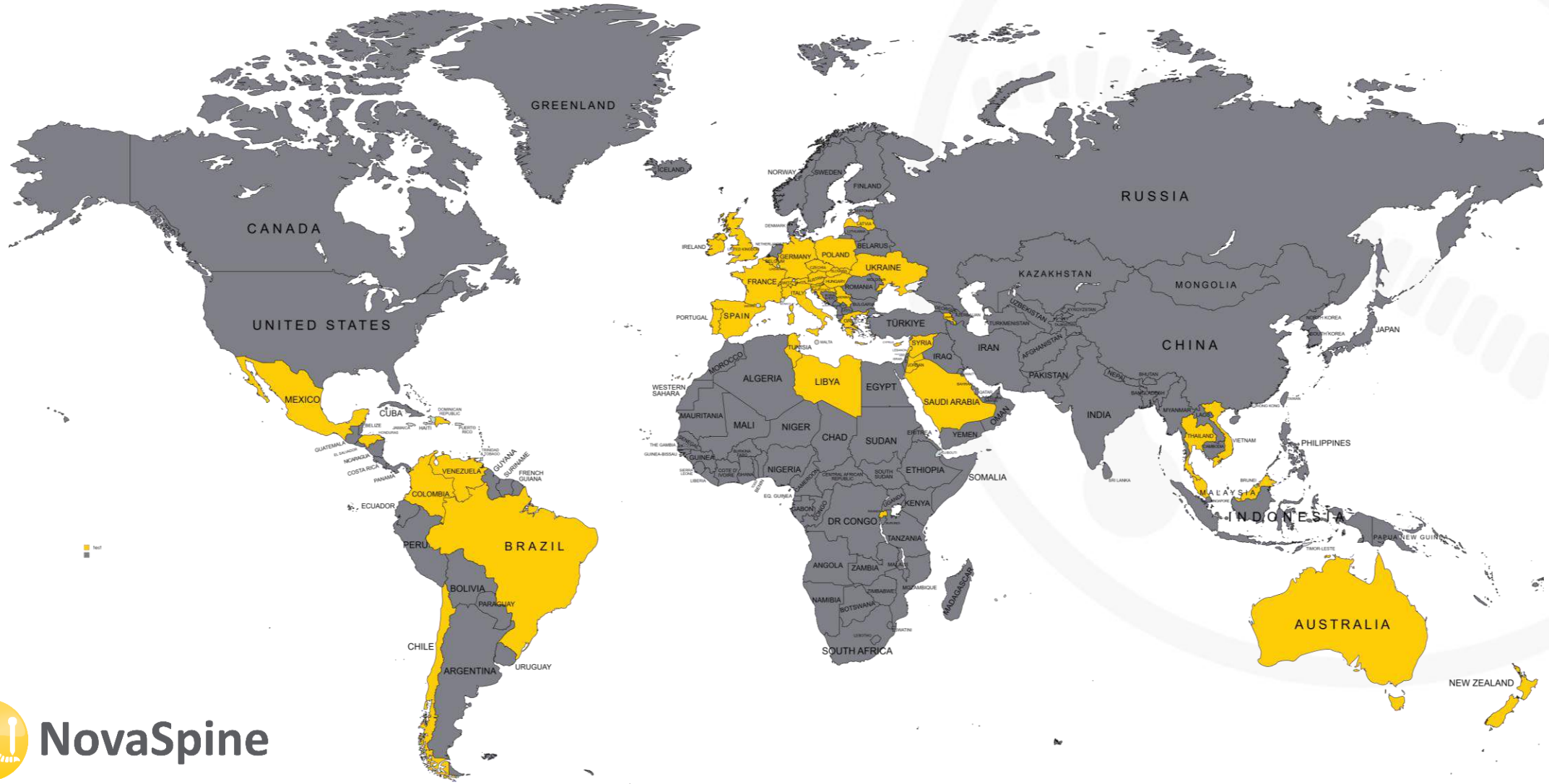
NOVASPINE IN THE WORLD



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KEY NUMBERS

First Surgery in 2006

First Robot assisted surgery in 2016

More than 120 000 implants sold in 2024

75 surgeries per day in 2024

10,3 M€ Turnover in 2024

15 employees

REF > 9000

NovaSpine

ACKOMAS SOLUTION

Why did Novaspine choose ACKOMAS solution?

<u>Objective :</u> Register all our medical devices on Eudamed

- *The number of Novaspine product references (> 9000) is "high"*
- *Novaspine is a family business without IT team*

1. Register products on EUDAMED → Too long

- *20 min per REF → 20*9000 = 180 000 min → 3000h → 21 months of work !!!*

2. Hire an intern to register the products

- Too complicated to verify data registered
- Need solid knowledges on Codification of Products and Traceability

3. Looking for help with an external company --> Mass upload

NovaSpine

ACKOMAS SOLUTION

Why did Novaspine choose ACKOMAS solution?

We chose ACKOMAS for:

- Its Position in the medical device market (MEDTECH, GS1, EUDAMED, etc…)
- Solution validated by the European Commission
- French Company, Reliable, Robust, Secure data protection
- Excel File to fill to upload data on KOA → Eudamed
- Its Availability and Adaptation to the customer

NovaSpine

ACKOMAS SOLUTION

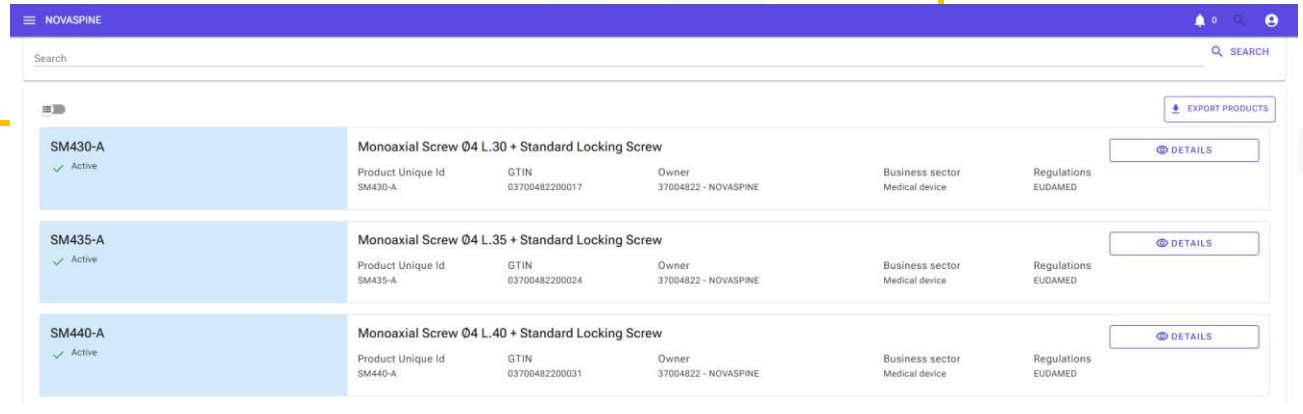
Novaspine team in charge of compliance with the EUDAMED platform

- Leatitia Ali Chikh – Quality Engineer
- Léa Berreby – Quality Engineer
- Chloé Khalifé Togna – Quality Engineer – Deputy PRRC

KEY STEPS:

1. Qualification of KOA software in our Quality System ✓
2. Configuring the Ackomas access point on Eudamed (Machine-to-machine – M2M):
    1. *Playground environment*
    2. *Production environment* ✓
3. Filling the Ackomas Excel file ✓

09/2025 :
Final Click to import data from KOA to Eudamed



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ACKOMAS SOLUTION

Ackomas' strengths

- Availibility of teams
- Adaptation to Customer system
- High level of knowledge - Expert in the medical field / EUDAMED
- Reliability
- Data Security
- Regulatory Watch (EUDAMED update)

Ackomas solutions make regulatory compliance and data security remarkably easy and accessible

NovaSpine

NovaSpine

CONTACT

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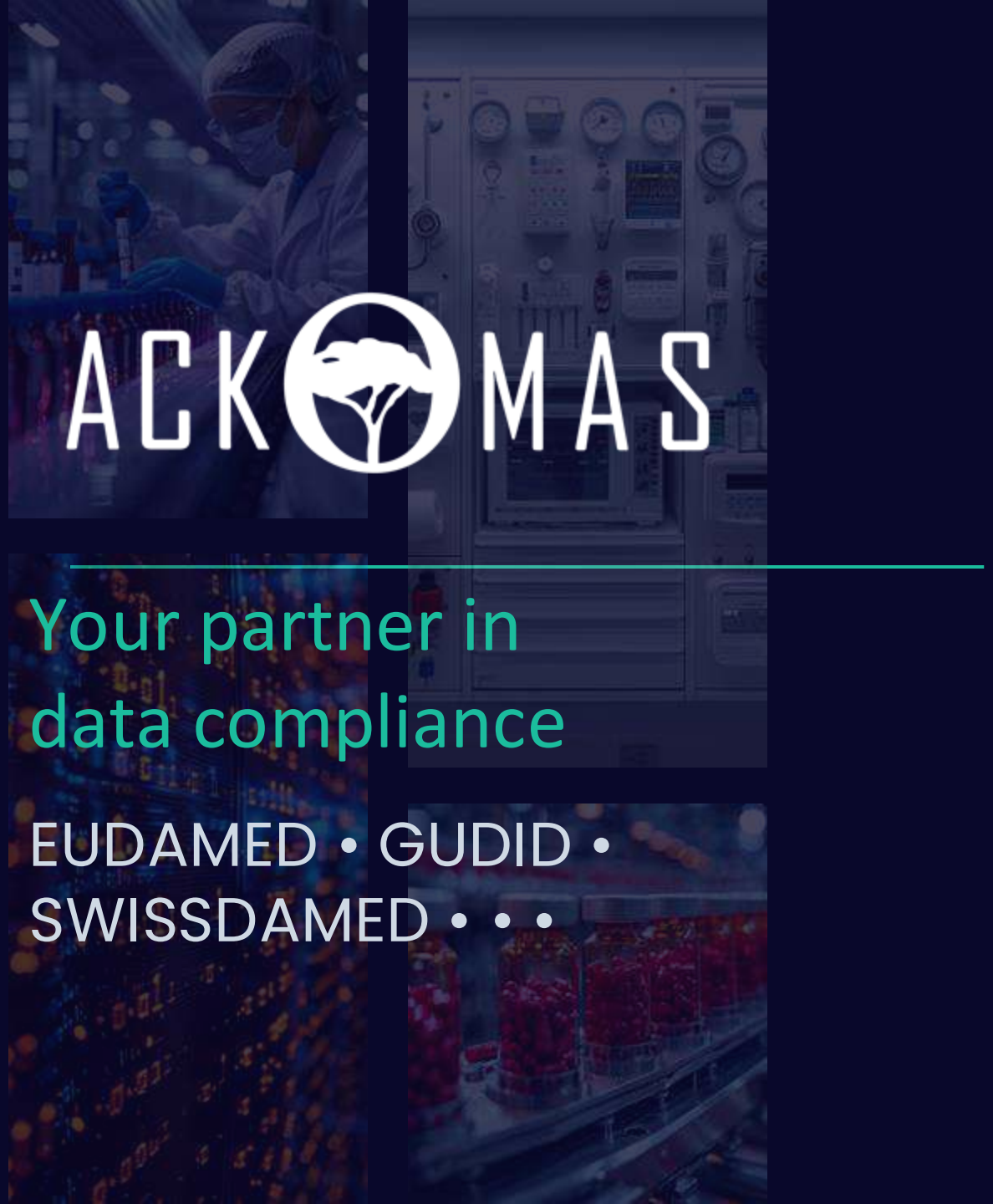
Our
Compliant solution



Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

ACKOMAS is a software publisher

- Dedicated to the Medical Device industry
- More than 20 years expertise in Regulatory Compliance
- M2M solution for EUDAMED and for other existing (GUDID) and upcoming regulatory databases (Swissdamed, MHRA, SFDA ..)

> **Our MISSION** is to simplify compliance processes, improve product data traceability, and ensure data security.

ACKOMAS is a partner of

- MEDTECH Europe
- GS1 Healthcare + GS1 (France, Italy, Germany..)
- ISPE *(international Society for Pharmaceutical Engineering)*

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

Our Platform :

- **Operational since 2021** for the UDI module, with **daily testing** on the EUDAMED playground, ensuring the robustness of the solution.
- **Fully automated integration with EUDAMED** — bulk imports, no manual uploads, no latency, and full control over submission timelines.
- Manages **MDR/IVDR** and **Legacy Devices** and **SPP** within a single, scalable environment.
- **User-friendly interface,** accessible even to non-experts, for managing both legacy devices and MDR devices, including their Basic UDI-DIs.
- **Industry-leading service in the medical device sector**, demonstrated by widespread adoption of our regulatory submission solutions.

Registering medical devices on EUDAMED: operating mode & feedback from a manufacturer

Operating mode with Ackomas software

EUDAMED updates = new software releases automatically

- Import via excel template file
- Manual input & data duplication
- Connector with internal software

Eudamed business rules check → Registration

Confirmation of registration

EUDAMED
European Database on Medical Devices

Manufacturer tasks | Software tasks

What will you gain by choosing our solution?

EUDAMED
European Database on Medical Devices

- ✓ **Faster registration** through pre-configured workflows, eliminating functional and technical complexity for the user.
- ✓ **Fewer errors** thanks to real-time validation and continuous alignment with EUDAMED rules.
- ✓ **Future-ready**: fully supports the upcoming transitions of legacy devices to MDR.
- ✓ **Automated integration of regulatory updates**, minimizing errors and the risk of non-compliance
- ✓ **Reassurance:** traceability, update history, and data continuity — all in one secure, user-friendly platform designed to save you time.

Long-term solution.

You're not alone in facing this complexity.

Let us simplify this process for you.

Thank You

Questions & Answers