COSMO UDI (UNIQUE DEVICE IDENTIFICATION)

based on Microsoft Dynamics 365 Business Central

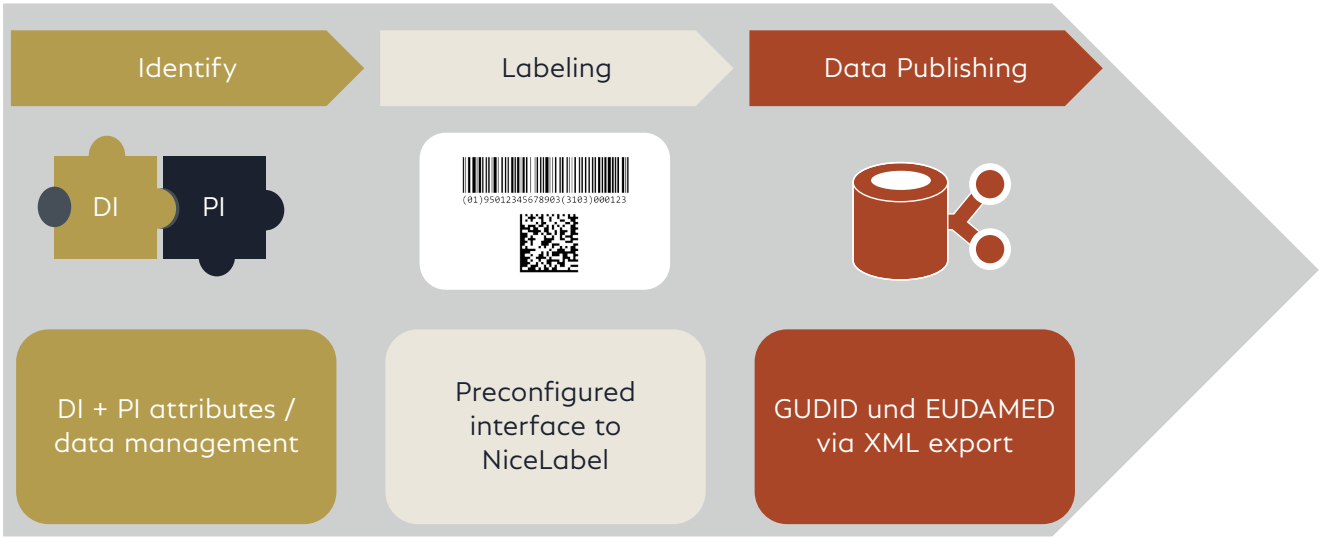
COSMOCONSULT

Highlights

- supporting the three pillars of medical device labeling (UDI product data, UDI data carrier, UDI database)
- integrated UDI product data management according to FDA and EU MDR.
- managing relevant master data and attributes for the classification and identification of medical devices (e.g. basic DI, DI, direct marking, alternative DI, other additional product attributes)
- PI – data directly from system
- supported label printing based on GS1 standards
- logging of every label printing process including label data, as well as an embedded interface for the integration of label printing software (NiceLabel)
- simple XML export as basis for data upload to the GUDID or EUDAMED database
- strong usability through dynamic data insertion and extensive plausibility checks
- full integration with Microsoft Dynamics 365 Business Central
- implementation of master data management at item level possible
- simple and fast implementation of the UDI solution using preconfigured data packages

Unique Device Identification

Unique Device Identification - or "UDI" in short - has been mandatory for medical device manufacturers since the European Medical Device Regulation (MDR) came into force. In some countries, for example in the USA, the UDI system has already been mandatory for several years. An important goal of UDI is the clear identifiability and traceability of medical devices along their entire product life cycle. The UDI requirements determine that medical devices worldwide must bear a unique product number (device identifier). This number can be printed on the product itself or on its outer packaging with a barcode or DataMatrix. In addition, dynamic product information (Product Identifier) such as the serial / lot number, the expiry date or the date of manufacture must also be applied. **COSMO UDI** supports you with a comprehensive range of user-friendly tools to meet the requirements of the new labeling regulations.



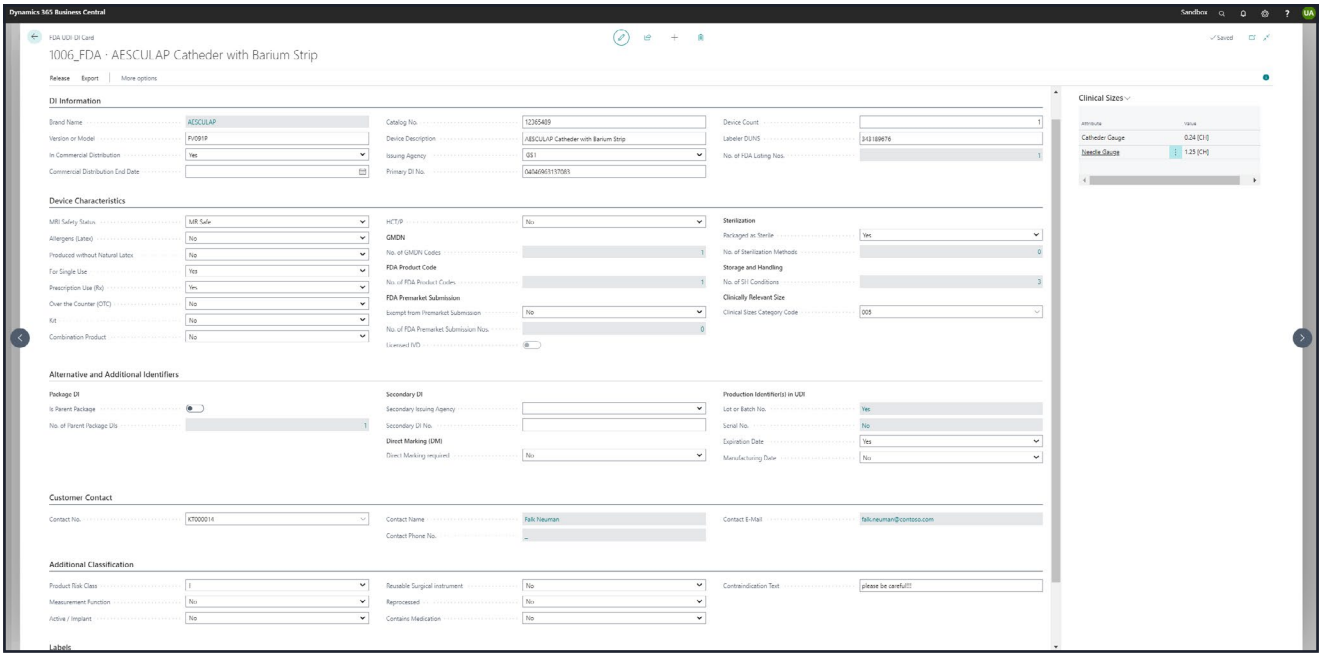
UDI-Componentc at a glance

Core features of COSMO UDI

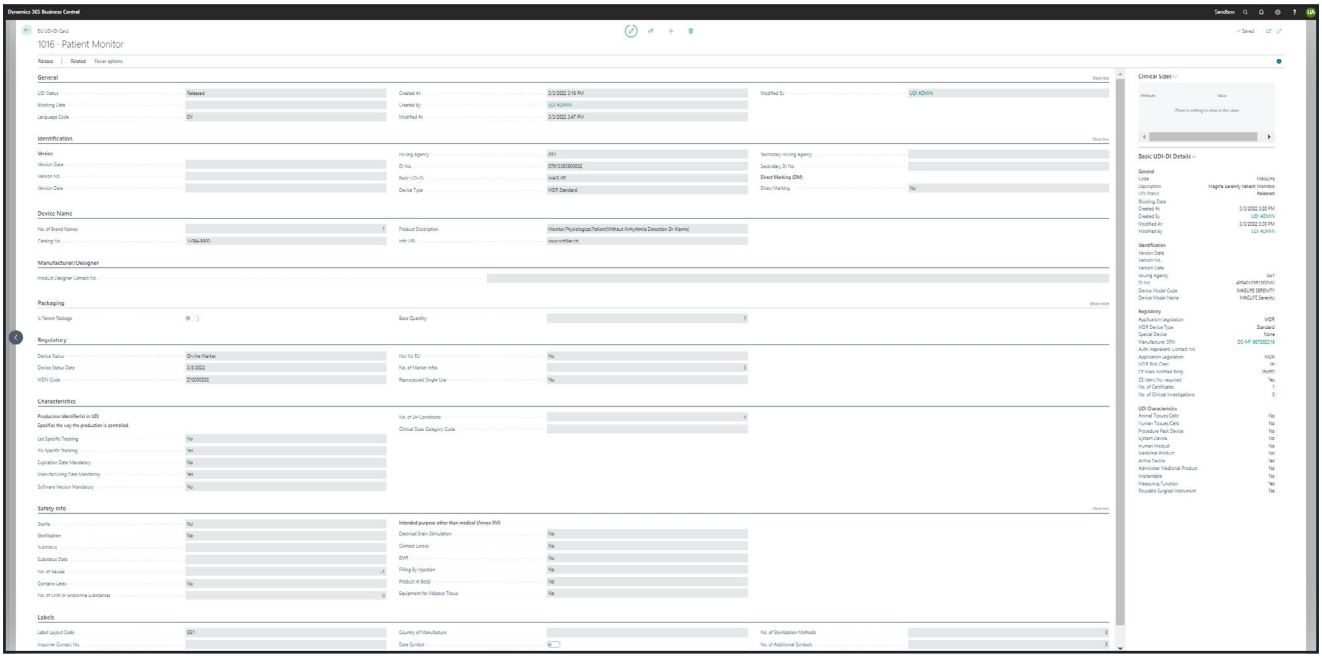
UDI master data management (Identifier, brandnames, attributes, additional information)

Since the US FDA requirements regarding UDI identifiers and attributes are not completely congruent with the European MDR requirements, **COSMO UDI** provides separate data acquisition pages. Seamless integration with Microsoft Dynamics 365 Business Central makes it easy to maintain data at item model and item variant level. Dependent information such as storage conditions, brand names, packaging structures, sterilization methods, clinical sizes, etc. are available in form of input tables or code lists. The assignment of the Basic UDI-DI is mandatory and enables the user to record a model-related identification number (GMN) as well as the associated attributes. The entirety of these data are the basis for export to the central databases (GUDID or EUDAMED).

The recording of all data subject to UDI is supported by the system through mandatory field and plausibility checks as well as context-related checks. This makes for an appealing user experience.



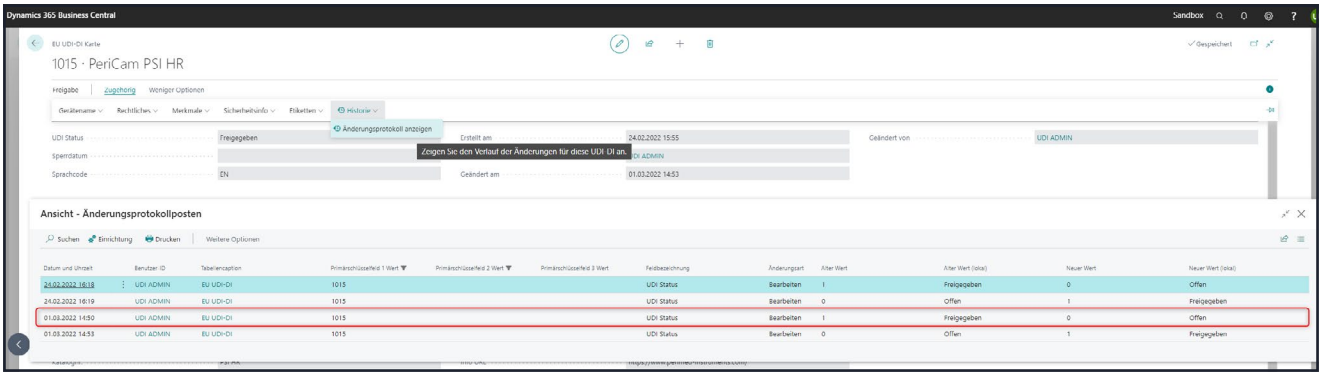
FDA UDI-DI record



EU UDI-DI incl. basic UDI-DI data as infobox

Data release und Auditrail

To meet compliance requirements regarding the logic and correctness of the data, comprehensive plausibility checks already take effect during data acquisition. Furthermore, a configurable authorization management is available, via which the release processes of the UDI data records can be controlled. The change log functionality included in Microsoft Dynamics 365 Business Central consistently tracks data changes – with the changelog history always being only one click away.



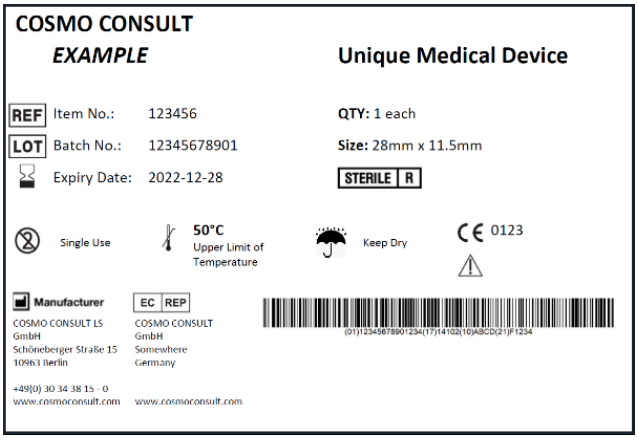
Audit trail change logging incl. releases directly in access

UDI label printing based on standards

Another pillar in the UDI system is formed by the labeling obligations on the product itself in the form of direct marking or via the printing of a UDI label. The UDI consists of the DI (device identifier) and PI (production identifier). Both types of information must be stated via a unique numeric or alphanumeric code, which is applied in both machine-readable form (AICD) and human-readable form (clear text). While the DI is a fixed code embedded in the master data, the PI identifies the specific version or specific model of the medical device. The PI thus contains the item tracking information (serial number, lot number) and its expiration or manufacturing date.

In addition to comprehensive data management, **COSMO UDI** supports the printing of a standard UDI label. In addition to the DI + PI elements, further information is displayed on the label (e.g., product attributes, manufacturer information, brand names, nomenclatures, etc.).

The assignment of the DI number and the associated labeling standard is carried out by the designated issuing bodies. **COSMO UDI** initially supports the GS1 standard.



UDI label

For easy integration of an external label printing solution, **COSMO UDI** provides an interface in which the print data is already collected and prepared for transfer. These data can be exported to any third-party system (NiceLabel is already preconfigured). The interface also enables logging of each UDI label print including the associated label data. Thus, reprints or renewed data exports are possible at any time.

XML data export as basis for data publishing (FDA GUDID; EU EUDAMED

The 3rd pillar of the UDI system is the requirement for data upload to the central GUDID and EUDAMED databases.

To support these requirements, **COSMO UDI** provides an XML data export, which follows the specifications of the implementation guidelines.

Your benefits

- managing UDI data and additional Attributes of your products directly in the ERP system and thus supporting the process for conformity assessment
- stay compliant with FDA and EU core UDI requirements
- comprehensive plausibility / approval checks ensure data quality and guide you through the data entry process safely
- consistent change logs help you to improve your ability to provide audittrail information
- direct label printing from the system as well as the possibility to integrate external label management systems support your labeling obligations.
- the prepared XML data export makes it easy to upload data into central databases
- time / cost savings through full integration with Business Central

Target markets / industry focus

- Medical Technology

Additional and complementary solutions for medical technology manufacturers

As an industry expert for the regulated industry, COSMO CONSULT provides further complementary solutions and modules from the areas of ERP, Quality Management and CRM, which could also be of interest to you.

- **COSMO Advanced Manufacturing Suite**
- **COSMO Quality Assurance**
- **COSMO Ragulatory Affairs**
- **COSMO Quality Management** - Incident Management
- **COSMO Quality Management** – Document Control
- **COSMO Life Science Services** – Computer System Validation, Quality Management Consulting

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