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| Sample URS\_003 |
| Agile e6 PLM Labeling  User Requirements Specification |

| Role | Name and title | Signature and Date |
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| Author: | | |
| Author  (Author in Asset Management only uploaded the document) | Roland Bleisch  Systems & Strategy Senior Project Lead | N/A |

# Purpose

The Labeling User Requirement Specification (URS) captures the business needs of the labeling functionality of the Agile e6 PLM system. This document also states any constraints and defines regulatory and GxP requirements, if applicable. It describes the features or capabilities needed in order to meet the business goals and objectives of the project.

The intention of this URS is, to state the requirements for the system as defined by users involved in labeling activities, including but not limited to:

* To ensure that labeling data, content, layouts and formats can be managed with the PLM-System to comply with business needs and regulatory requirements.
* To ensure that label design, content and printing processes are validated and recorded.
* To ensure that, where appropriate, a history of actions concerning objects is recorded and available for review.

# Scope

This document is used to describe the intended use of Agile e6, as part of the Electronic Master Label (EML) system, and the operational and performance requirements for its accurate functioning. The requirements described will be used to develop the protocols necessary to validate Agile e6 as part of the Electronic Master Label system.

This User Requirement Specification applies to Agile e6 regarding to the Electronic Master Label system used at Synthes.

This document applies to label printing systems at Synthes US; SOUS; China, using SAP and Agile data to produce product identification labels.

# Definitions

See the SDLC Glossary for general definitions.

| Term/Acronym | Definition |
| --- | --- |
| CSLA | Country Specific Label with own separate Article |
| CSL | Country Specific Label without own separate Article |
| DataMatrix | Two Dimensional Code Type |
| DCO | Document Change Order |
| DCR | Document Change Request |
| EML | Electronic Master Label |
| GMP | Good Manufacturing Practice |
| GS1 | International standards organization (Global Standards 1) |
| GTIN | Global Trade Item Number |

# References

| Document ID | Title |
| --- | --- |
| GDL-1548 | SDLC Glossary |
| ISO 13485 | Quality management systems (QMS) for medical devices |
| 21 CFR Part 820 | Device Quality System Regulation |
| SDLC-57979 | User Requirements Specification - Agile e6 PLM Basis and administration |
| SDLC-100841 | User Requirements Specification - Agile e6.1 PLM Roles And Permissions |
| SE\_621892 | Generation of Label Data and Label Text |
| SE\_622253 | Revision of Label Data, Symbols and Label Text |
| W-G-S166 | Computer System Implementation |

# General Description

The Electronic Master Label (EML) system, as part of the Product Lifecycle Management, controls data which is printed on labels. All data records are product related and have an object relationship. The printed labels are used to ensure the correct identification, storage, dispatch and back tracking of manufactured products. The printed labels contain important information about the product.

## Assumptions, Dependencies and Risks

The labelling function is a module of the entire Agile e6 application, so has dependencies on other modules. As this is a system which has been in use for a considerable time, known risks have already been resolved or mitigated.

Note: This User Requirements Specification has been created by revising and updating one or more legacy Synthes documents. Due to this, some requirements are expressed in more technical terms than might be normally expected. However, it was decided to retain these as the system is mature so the Users are now familiar with most of the technical features.

# Requirements Information

## Requirement ID

A unique identifier is required for each requirement to allow traceability in later phases of the project. The naming convention for process requirements is defined as:

**U\_[???]\_[Group]\_nnnn**

Example: “U\_LBL\_SFT\_0020”

U Letter “U” Indicates User Requirement.

Code (???) Indicates a Performance requirement, in this case LBL. Substitute the three letter code for the “???” in the following table.

Group Triple of letters and digits. Identifies the business process, sub-process or requirement category.

nnnn Is a numeric sequence number. [0001, 9999] The requirement number

The table below contains a list of codes that correspond to the business process and sub-process suitable for the project (or across projects). The preferred format for a code is 3 characters. Additional codes may be used.

| Code | Process / Sub-process | Description |
| --- | --- | --- |
| U\_???\_xxx\_nnnn | Process Title | Process description and reference to the process flow if applicable. |
| U\_???\_11R\_nnnn | Part 11 for Electronic Records | Regulatory requirements covering Part 11 for Electronic Records. |
| U\_???\_11S\_nnnn | Part 11 for Electronic Signature | Regulatory requirements covering Part 11 for Electronic Signature. |
| U\_???\_SXR\_nnnn | Sarbanes-Oxley / Revenue Cycle | Internal control requirements for Revenue Cycle. |
| U\_???\_SXP\_nnnn | Sarbanes-Oxley / Payment Cycle | Internal control requirements for Payment Cycle. |
| U\_???\_SXI\_nnnn | Sarbanes-Oxley / Inventory Cycle | Internal control requirements for Inventory Cycle. |
| U\_???\_SOx\_nnnn | Sarbanes-Oxley / Other | Internal control requirements for cycles other then above. |
| U\_???\_AUT\_nnnn | Authorization Requirements | Authorization Requirements identify the approval, permission, or empowerment for someone or something to do something within the system. |
| U\_???\_CON\_nnnn | Conversion Requirements | Requirements covering data conversion and/or data migration. |
| U\_???\_DAT\_nnnn | Data Requirements | Data handling requirements relevant to the user. |
| U\_???\_INT\_nnnn | Interface Requirements | External system requirements to which the system is required to interface. |
| U\_???\_PRV\_nnnn | Privacy Requirements | Privacy requirements for collection, transfer, storage, and access of personal data. |
| U\_???\_RIM\_nnnn | Records Management Requirements | Records Management requirements relevant to the system. |
| U\_???\_RPT\_nnnn | Reporting Requirements | Reporting requirements relevant to the user and/or compliance (e.g. SOx). |
| U\_???\_SEC\_nnnn | Security Requirements | Security requirements specify or regulate how a system or organization provides security services to protect sensitive and critical system resources. |
| U\_???\_SFT\_nnnn | Safety Requirements | Safety requirements for the software product. |
| U\_???\_SLV\_nnnn | System Administration Procedures and Service Level Agreements | System Administration requirements are functions that enable how a system is maintained, installed and supported. |
| U\_???\_USE\_nnnn | Usability Requirements | Usability constraints, for example, support for different types of user interactions including special requirements for visually challenges users. |
| U\_???\_WIC\_nnnn | Worldwide Internet Compliance | Requirements for Intranet, Extranet, or Internet applications, Web pages, or websites. |

## Priority

Below are the definitions for the business priorities with emphasis on identifying the mandatory requirements.

| Priority | Meaning |
| --- | --- |
| H | Mandatory (critical business process requirement, i.e. impact on the end product, legal requirement) |
| M | Beneficial (business process requirement – concerns quality not directly related to the end product) |
| L | Nice to have (improves the system) |

# Core Business Requirements

## Business Requirements

### General Requirements

| Requirement ID | Requirement Description | Priority | Compliance  Business / GxP | Notes |
| --- | --- | --- | --- | --- |
| U\_LBL\_0010 | **Administration**  The following objects must be managed in Agile:   Label Data   Layout   Pictogram   Label Texts | H | B/G | N/A |
| U\_LBL\_0020 | **Standard functions**  It must be possible to manage all objects of U\_LBL\_0010, with the standard functions of Agile.  (creation, versioning, status, history) | H | B/G | N/A |

## Migration/ Conversion Requirements

None applicable. Data will be replicated from the existing system in the same format.

## Data Requirements

| Requirement ID | Requirement Description | Priority | **Compliance**  Business / GxP | Notes |
| --- | --- | --- | --- | --- |
| U\_LBL\_DAT\_0010 | **Import function**  It must be possible to import data into Agile which has been prepared in MDS.   New data: A new data record is created automatically | H | B/G | N/A |
| U\_LBL\_DAT\_0020 | **Versioning**  Versioning is regulated via DCR/DCO and PLF. A new version is created manually, when the files are read in, the data must be imported into the correct version. | H | B/G | N/A |
| U\_LBL\_DAT\_0030 | The article, layouts (incl. country-specific layouts) and the pictogram must be linked automatically to the label data. | H | B/G | N/A |
| U\_LBL\_DAT\_0040 | The import procedure attaches the LMD as MS Word template to the label record. | H | B/G | N/A |
| U\_LBL\_DAT\_0050 | **Full download for MDS**  Once a day, all label data (full download) must be exported from labeldata as a text file. | H | B/G | N/A |
| U\_LBL\_DAT\_0051 | **Full download for RSC**  Once a day, the export file created in U\_LBL\_DAT\_0050 must also be provided to a folder location where the RSC process can pick it up. | H | B/G | N/A |
| U\_LBL\_DAT\_0052 | The full download for MDS file must include the variant value | H | B/G | N/A |
| U\_LBL\_DAT\_0055 | **Full download for MDS (Errors)**  If an error occurs while exporting, an error log must be created. | H | B/G | N/A |

## Usability Requirements

None applicable

## Authorization Requirements

Note: Full authorization testing is covered in greater detail in Roles and Permissions SDLC-100841

| Requirement ID | Requirement Description | Priority | **Compliance**  Business / GxP | Notes |
| --- | --- | --- | --- | --- |
| U\_LBL\_AUT\_0010 | Only trained and authorized users must be able to print labels. | H | B/G | N/A |

## Safety Requirements

None applicable.

## Reporting Requirements

None applicable.

# Compliance Requirements

## Security Requirements

The system is hosted on a legacy Synthes network and is externally accessible. It contains some restricted data.

All security requirements are considered in the separate URS for Basis functionality, SDLC-57979.

## GxP Regulatory Requirement

The system is of high GxP relevance, and uses electronic records and signatures. All ERES/Part 11 requirements are covered in the separate URS for Basis functionality, SDLC-57979.

## Internet Compliance Requirements

There are no WICO requirements for this system.

## Privacy Compliance Requirements

The system contains personal data. All Privacy requirements are covered in the separate URS for Basis functionality, SDLC-57979.

## SOx Compliance Requirements

There are no Sarbanes Oxley requirements for this system.

## Records Management Requirements

Not stated in this specification document; all standard functionality is covered in the separate URS for Basis functionality, SDLC-57979.