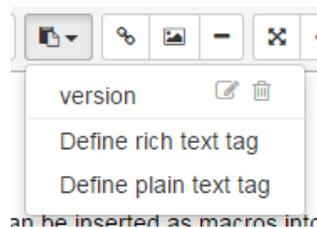# RELEASE NOTES

SOFTWARE IDENTIFICATION

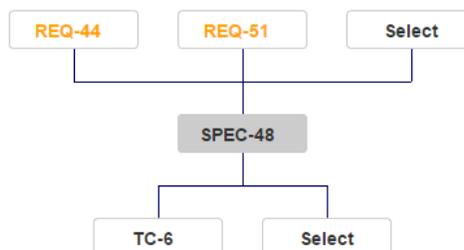Matrix Requirements Medical Release 1.6.1235.6238

NEW FUNCTIONALITY IN THIS RELEASE

New Features

- **MATRIX-708** Smart Text: reusable text blocks
  Smart text blocks are reusable (rich) text blocks which can be inserted as macros into rich text fields or used as *Word* templates, e.g. in the document header. Smart text can be defined and through the toolbar of rich text controls. **Rich text** tags can be used in rich text controls only while **plain text** tags can be used in rich text controls as well as Word Document templates by adding them as document properties and these into the template.

- **MATRIX-669** Allow to select existing items in Reference Dialog
  The Reference Dialog now allows to to choose existing items as up or down links

All dates and times are in the project's default time zone and formatting.

- **MATRIX-737** References into other projects
  It is now possible to create references which point into other projects. Ask us for details

CROSS PROJECT LINKS

Links DEMO:F-UC-1 , CAN_SPOT:F-DOC-3 , CAN_SPOT:DOC-4   Select Items

- **MATRIX-609** Allow drag and drop file attachments and in rich text control
  You can drag and drop any file into either the rich text editor or the file manager control. In both cases the files will be uploaded. If you drop the files into a rich text control they will either be shown as image or as a file name, allowing you to download the file from the server.

- **MATRIX-711** Allow rich text editing in test table
  When editing a cell in the test table you can now press Shift-Enter which will open a rich text editor, allowing you to define list or import images into the test table.

- **MATRIX-619** Configurable parameters of risks
  The risk definition can now be configure to have additional parameters (besides probability, severity and detectability) and also any value for a mitigation including negative mitigation.

- **MATRIX-734** Report showing DOC numbers
  A new report shows for all documents which document number they use.
- **MATRIX-921** Report for external reviews
  A new report which shows items to be reviewed with revision number next to columns for customer and provider to review

SPEC

Item Id	Version	Customer Status	Customer Comment	Supplier Status	Supplier Comment
SPEC-1	4	□ Passed □ Failed □ Other			
SPEC-2	2	□ Passed □ Failed □ Other			

- **MATRIX-78** Report with all the links between Matrix and Jira
  Note: This report is not instantiated by default. In needs to be created from its template anywhere in the REPORT category (using "*Create Report Template*" and selecting "*Jira Links Report*")
- **MATRIX-750** File name of reports and docs
  When downloading documents (as word, pdf or html), the document name is now the file name of the downloaded document. When Creating SIGNed documents from documents which have a document number, the document number is added as prefix to the signed document title.
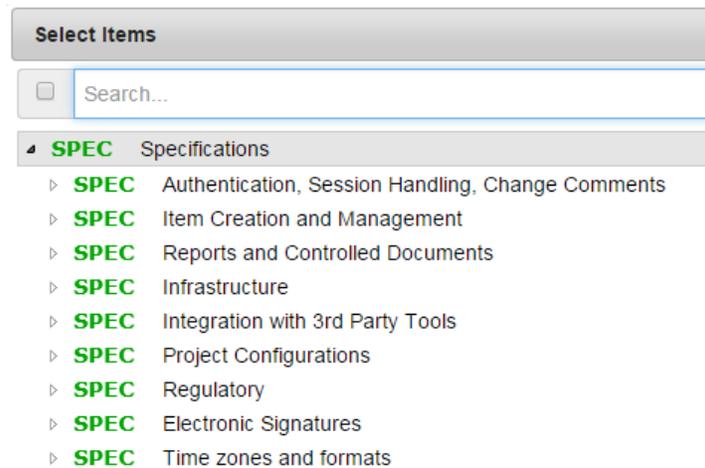
- **MATRIX-864** Traceability rules can now be configured as project setting
  Traceability rules can now be defined and updated as project setting. The new default reports will analyze the project using these settings just like the reference dialog and icon.

<u>Improvements</u>

- **MATRIX-647** Browser tab title shows item IDs
  If you have multiple open tabs in your browser you can see which tab is which item.

- **MATRIX-670** Select item dialog opens first level of categories
  For example when selecting referenced specifications the tree will already be opened to the first level.

- **MATRIX-722** Configurable font for rich text fragments in word / pdf documents
  It is now possible to add CSS information which is used as default when formatting rich text components. If you want to change output format for rich text, ask us. For example the configuration below will change the default font to Calibri and add a border around tables.

```
{
  "richtextCSS":"font-family:Calibri,Arial;font-size:11pt;table, th, td { border: 1px solid black;}",
  "richtextStyle":"table, tr, th, td  { border: 1px solid #ddd; border-collapse:collapse }"
}
```

- **MATRIX-662** Label status change of item updates it's visibility in tree
  If you set or unset a label of an item, the tree will reflect this if you filter the tree by the same label.

- **MATRIX-714** Folders can be displayed in item lists

F-REQ-1 Requirements

F-REQ-12 Regulatory Requirements

REQ-44 EN 62304 Medical Device Software Life-Cycle Processes	*Author:*	Da
	matrixadmin	20
		10

Example of folders in list of items

- **MATRIX-719** Controlled documents have options to include table of content of items with folders (section of type item references)

REQUIREMENTS OVERVIEW
F-REQ-1 Requirements
- F-REQ-12 Regulatory Requirements
  - REQ-44 EN 62304 Medical Device Softwa
  - REQ-50 IEC 62366 Application of usabilit
  - REQ-51 ISO 14971 Risk Management for
  - REQ-47 FDA CFR Part 11 Electronic Reco
- F-REQ-14 User Requirements
  - F-REQ-2 Items

Example of list of item references (like a table of content)

- **MATRIX-715** Smart links are rendered in reports and documents

Description

The user wants to

- have references pointing from from one item to another
- see the references back (items pointing to an item)

See also REQ-11 Reference Selection

Example of a smart link

- **MATRIX-690** Improvements for print (ctrl-p)
  Minor formatting changes.

- **MATRIX-645** Progress dialog is shown when uploading big file attachments or pictures in rich text

- **MATRIX-750** File name for document downloads
  When downloading documents (REPORT, DOC, SIGN) the name of the file name of the downloaded document is created based on the title of document. All special characters are replaced by '_'.

- **MATRIX-710** Do not ask for specific signature password in user settings unless option is enabled

- **MATRIX-667** Improved usability of user settings dialog

- **MATRIX-668** Logout redirect to specific login page

- **MATRIX-709** When signing documents a confirmation box is shown if there is no signature image uploaded

- **MATRIX-699** Using time icon instead of calendar for history icon

- **MATRIX-772** Improved user interface for adding sections to controlled documents

- **MATRIX-797** EN/ISO 14791 changes
  The default project configurations now check boxes for each risk, indicating whether it fits the ALAP criteria and whether the benefits outweigh the remaining risk. These flags are analysed in the Risk Analysis Report. Existing projects can be upgraded to have the same fields, ask us!

☑ **Cannot be reduced any further**

☐ **Benefits outweigh remaining risk**

New check boxes in the default risk items

Remaining Risk After Mitigation

Risks which can be reduced further

The following risks can be reduced further:
- RISK-3 Tipping
- RISK-4 Bad Brake Pads Assembly

Risks which do not outweigh benefits

The following risks do not outweih the benefits:
- RISK-2 Brake Failure
- RISK-4 Bad Brake Pads Assembly

Summary of ALAP principle of risks

RISK-2 Brake Failure	AUTHOR:	DATE:	REVISION:
	matrixadmin	2015/05/30 09:35:27	3

CAUSE Overheating due to use (e.g. downhill)	PROBABILITY	2 - Remote
EFFECT Fire	SEVERITY	3 - Serious
Risk Before Mitigation (Cause + Effect)		**2 + 3 = 5**
MITIGATION SPEC-3 Use Brake Unburnable Brake Pads		reduces probability by 2
Risk After Mitigation (Cause + Effect)		**0 + 3 = 3**

✓ **Cannot be reduced any further**

✖ **Benefits outweigh remaining risk**

Rendering of individual risk in report

- **MATRIX-806** Indicate out of date references in reference lists
  In the image below the TC-1 needs to be reviewed because the item referring to it changed after the test case.

- **MATRIX-870** Show items reference in reference list in grey if they are not in filter
  In the image below the reference to TC-1 is grey because the link exists but the TC-1 is not in the set of the item for the current filter.

- **MATRIX-821** Speed up saving of items
  Saving items is about 2 times faster, this can be noticed if there is a latency between the server and the client.

- **MATRIX-911** Jira Plug-In allows search for Matrix Requirement IDs

Bug Fixes

- **MATRIX-702** Scroll bar missing in reference dialog
- **MATRIX-480** SIGN OUT and SIGN IN directly after does not work (Safari)

KNOWN ISSUES

- **MATRIX-822** "Remove Fonts" button in rich text editor (IE, Firefox)
  In case the user copies and pastes some formatted code into the rich text editor the "Remove Fonts" button will clean this up to a certain degree. Chrome does a much better job than IE or FireFox

SIGNATURES

Signature Meaning	Name	Title	Date	Signature
Approved By	Wolfgang Huber	CEO	2015/07/27	sign-p14-i21687-b20150727135408633
Approved By	Yves Berquin	CEO	2015/07/27	sign-p14-i21687-b20150727140149947