



# cem4

certifico machinery directive

# Manual User





# Manual User

# **CEM4**

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<b>First steps</b> .....	5
Step 1: New Company.....	6
Step 2: New Project.....	6
Step 3: New Machinery .....	7
Steps .....	9
Steps .....	9
Step 1.....	9
Step 2.....	10
Step 3.....	11
Steps 4.....	11
Step 5.....	12
Step 6.....	13
Step. 7.....	13
Step. 8.....	14
Step 9.....	14
Step 10. ....	15
Step 11. ....	16
Step 12. ....	16
Step 13.....	17
Step 14. ....	17
Step 15.....	18
Report .....	19
Index Technical File .....	<b>Errore. Il segnalibro non è definito.</b>
RA Complete summery .....	<b>Errore. Il segnalibro non è definito.</b>
Risk assessment .....	<b>Errore. Il segnalibro non è definito.</b>
EC Declaration of Conformity .....	<b>Errore. Il segnalibro non è definito.</b>
Customization .....	20
Customization .....	20
Company details - General.....	20
Company details - Access CEM4 .....	20
Administration.....	<b>Errore. Il segnalibro non è definito.</b>
1. Administration - Manage Rules.....	21
2. Administration - Manage Check list .....	22
3. Administration - Manage Hazards .....	23

4. Administration - Manage signs .....	23
5. Administration - Manage Section Technical File .....	24
6. Administration - Manage User .....	24
Advanced .....	<b>Errore. Il segnalibro non è definito.</b>
Advanced Features.....	25
Manage - Copy Manufacturer .....	25
Manage - Copy Project .....	25
Manage - Copy Machinery .....	26
Manage - Copy document (Risk Assessment).....	27
Manage - Copy EC Declaration of Conformity .....	27
Manage - Copy document CE marking.....	28
Manage rules .....	29
Manage rules.....	29
Inserting Technical Standards by the User .....	29
Rules propertys.....	29
Management standards.....	30
Requirements Standards insert.....	30
Support .....	32
1. Helpdesk .....	32
2. How to Backup / Restore .....	32
3. How to manage images.....	33
4. How to install CEM4 systems with OS Window XP 32-bit .....	34
5. How to install SAP Crystal Reports runtime for .NET Framework.....	34
Risk assessment .....	35
Risk assessment .....	36
Custom risk Assessment.....	39
Custom risk assessment.....	39
Custom risk assessment.....	39
Assessment check list.....	42
Check-list assessment.....	42
Import CEM file (type check list) .....	42
Assessemet check-list.....	42
Technical file .....	45
Technical file.....	45

New Section .....	45
New Document .....	46
Related Resources.....	46
CEM Standards Update file .....	47
General Standards Update file .....	47

# First steps

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This section describes the first steps to be carried out with CEM4 for the insertion of a machine.

## Important

First and foremost always you must check the applicability of the machine to other Directives of the "New Approach" which provide for CE marking:

- Dir 2006/95/EC "Low Voltage"
- Dir 2004/108/EC "Electromagnetic Compatibility"
- Other eg ATEX, PED, etc.

For each machine, you must specify the following information , in order:

- 1 . Company Data (Manufacturer Data);
- 2 . Project Data;
- 3 . Machine data.

Through the tree structure of the archive in the main window, the user can work on documents needed to administer the requirements of the Machinery Directive:

- Risk Analysis;
- Risk Assessment;
- Compliance to Technical Regulations/Standards;
- EC declaration of conformity;
- Project files.

Steps 1 and 2 describe the procedures to insert a New Company and a New Project.

Step 3 illustrates the procedure to insert a New Machine.

Each company can have multiple projects and each project can contain multiple machines in turn.

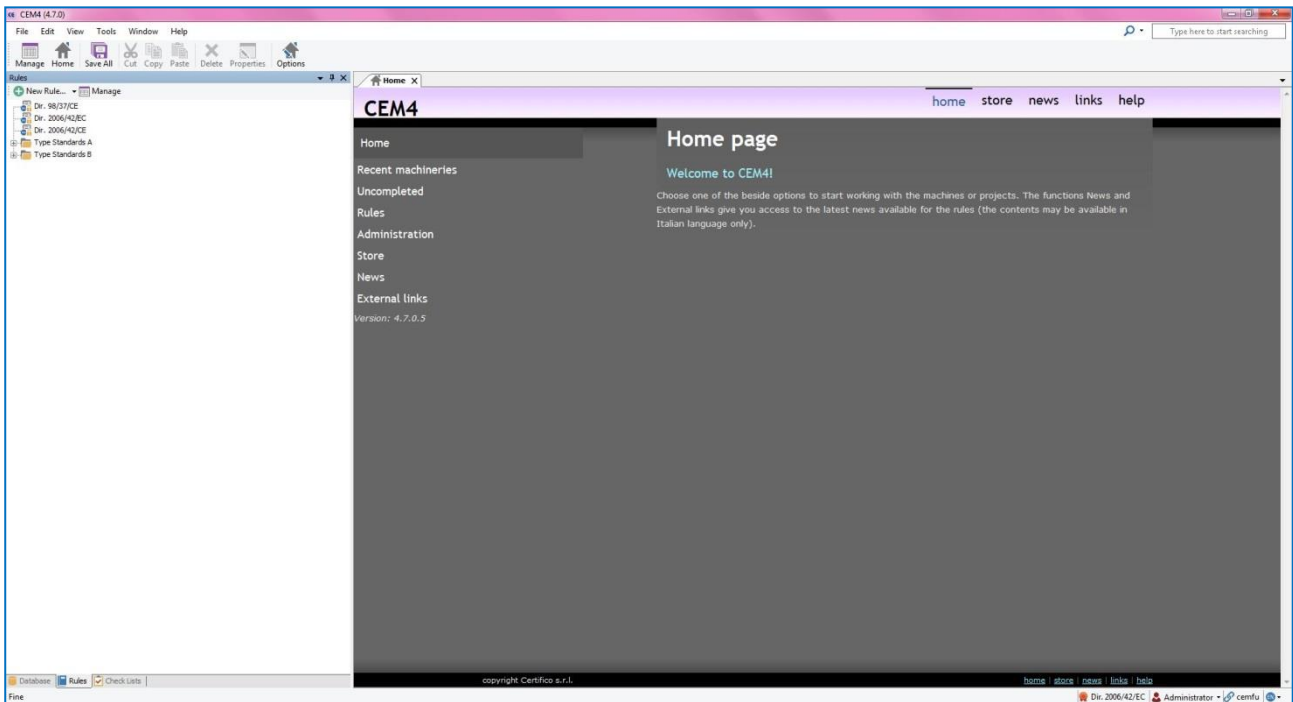
Each machine has its own **CEM4 Home** summary and a tree structure that represents the **Technical File**.

This section describe just how to insert New Machines.

For more information on other management functions ( move, copy , delete, etc. . ) Refer to the user manual of the product.

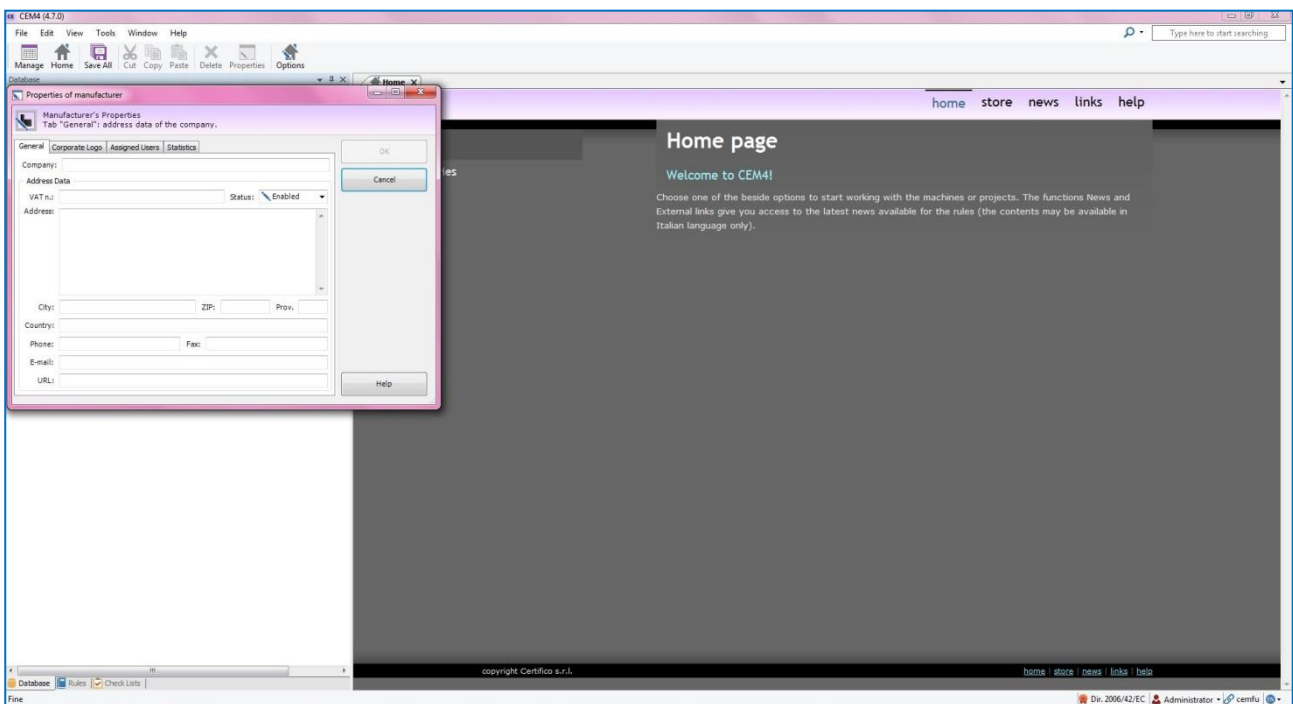
After starting the software, you can see the main screen (**CEM4 Home**), that is composed of the elements shown in the screenshot below:

- The left side of the screen show the archive of your projects and technical standards you use, with tree structures for navigation in the database.
- The right side of the screen show many tools: newer machines, legislation, administration, news, external links.



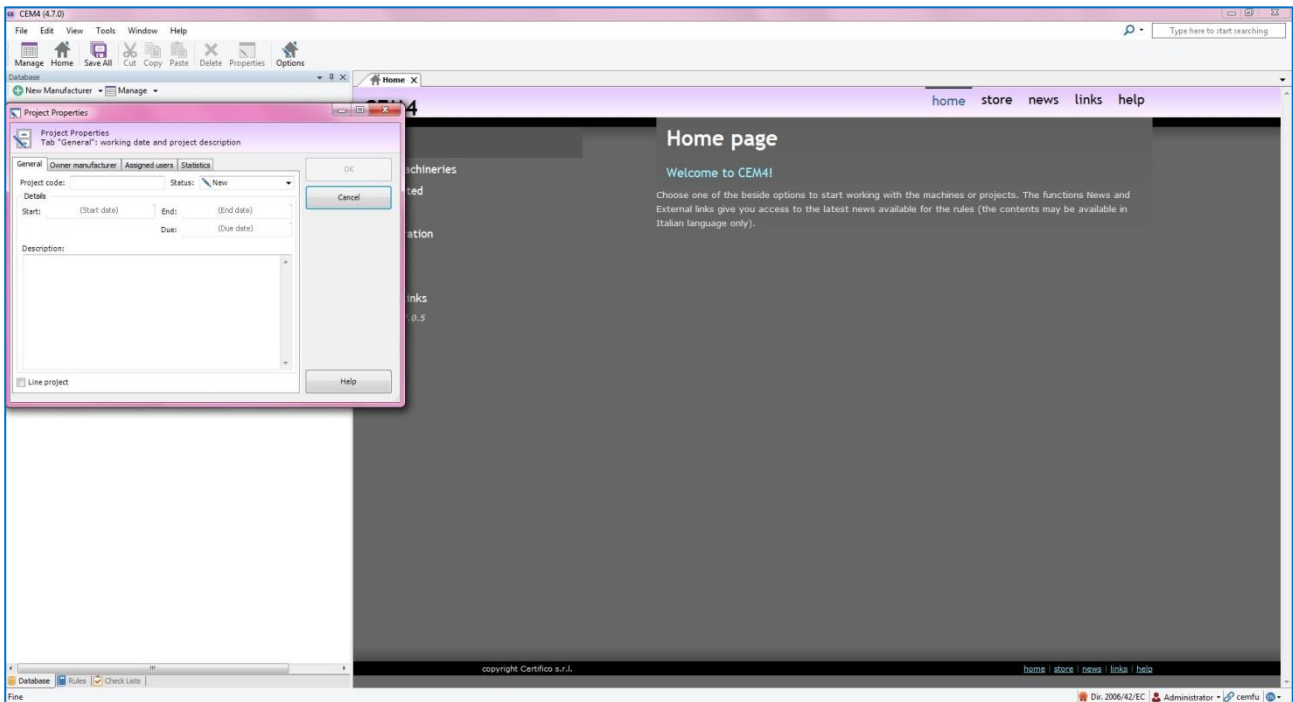
## Step 1: New Company

To insert a New Company, in the toolbar, click on **New Manufacturer** and fill in all the required data.



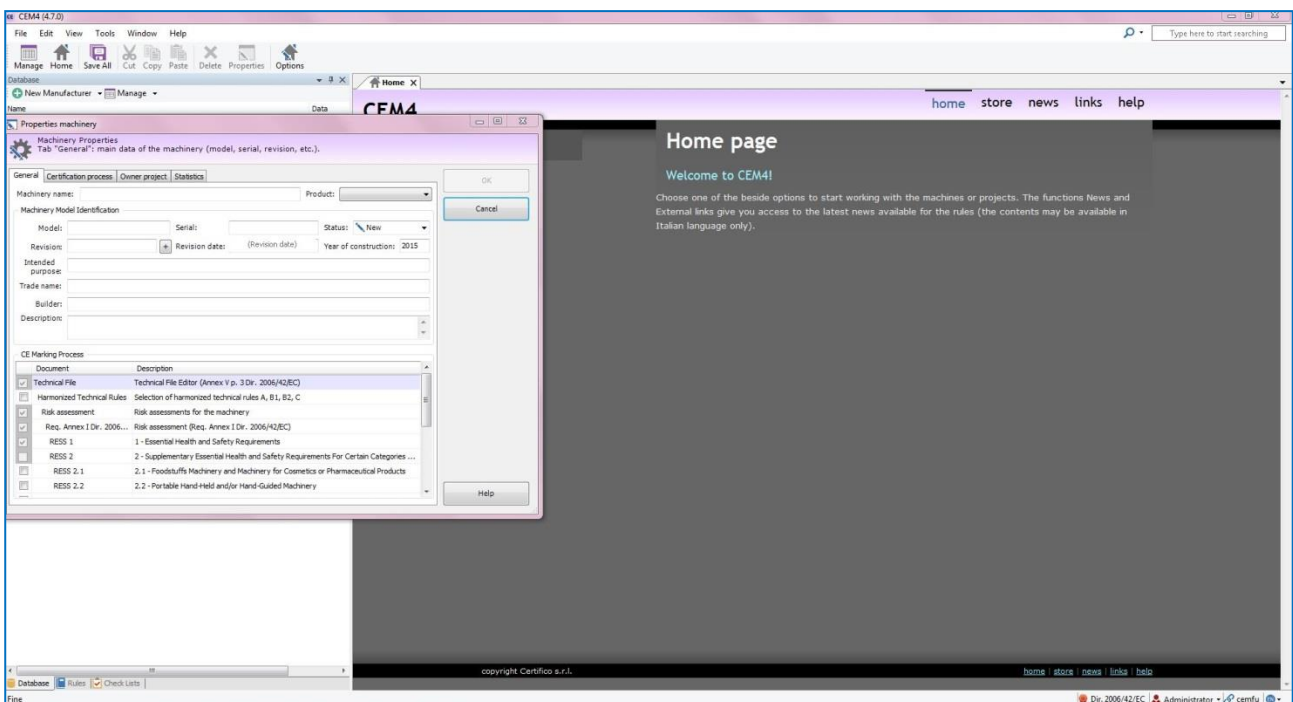
## Step 2: New Project

To insert a new project, in the toolbar, select the company in which you want to create the project and click on **New Project**, after you click fill in all the required data.



### Step 3: New Machinery

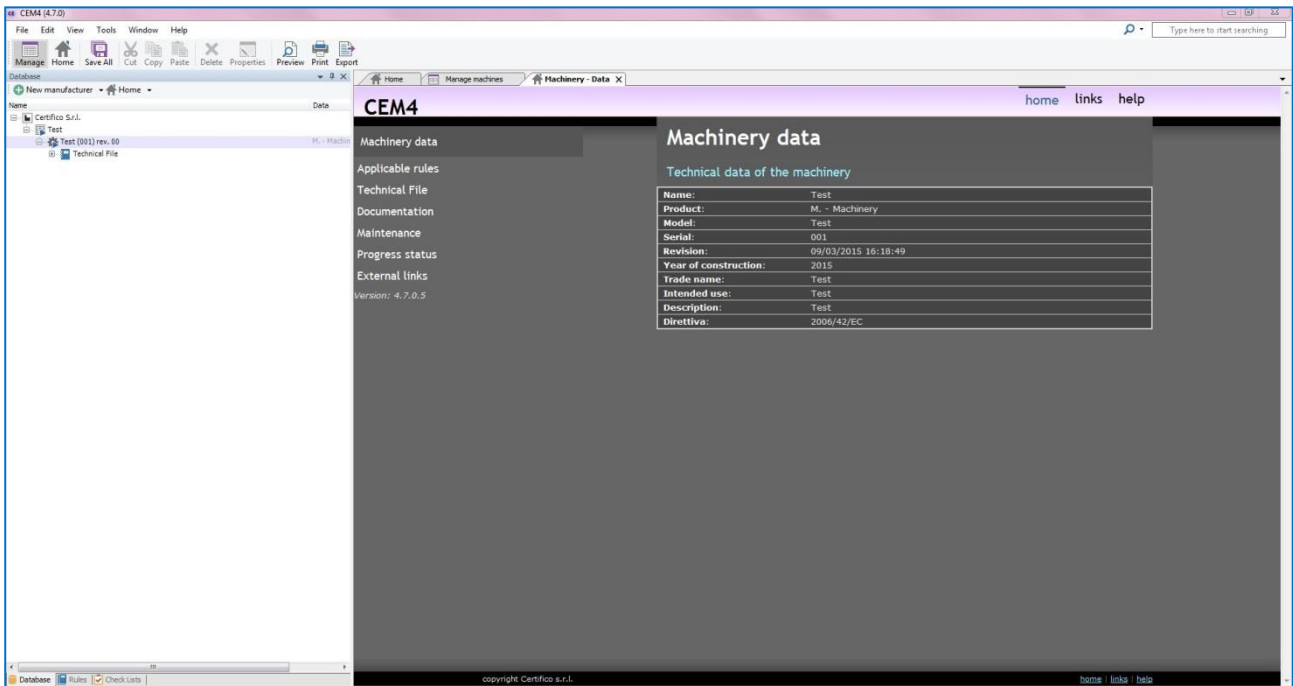
To insert a new machinery, in the toolbar, select the project in which you want to create the machinery and click on **New machinery**, after you click fill in all the required data.



Clicking on a machinery in the tree of the archive, the software displays the properties of the machinery.

The Home Page of the machine collects a summary of properties of the machinery, in the archive tree instead there are the documents of the Technical File required to comply with the obligations laid down by the Machinery Directive ( Risk Assessment , EC Declaration of Conformity, etc. ). To start working on the documents, click on the nodes on the tree.





Machineries and projects on which you have worked on recently are displayed in CEM4 Home.

In this way, the user can immediately go to the preferred machine by double-clicking on the name of the machine.

# Work Steps

## Steps

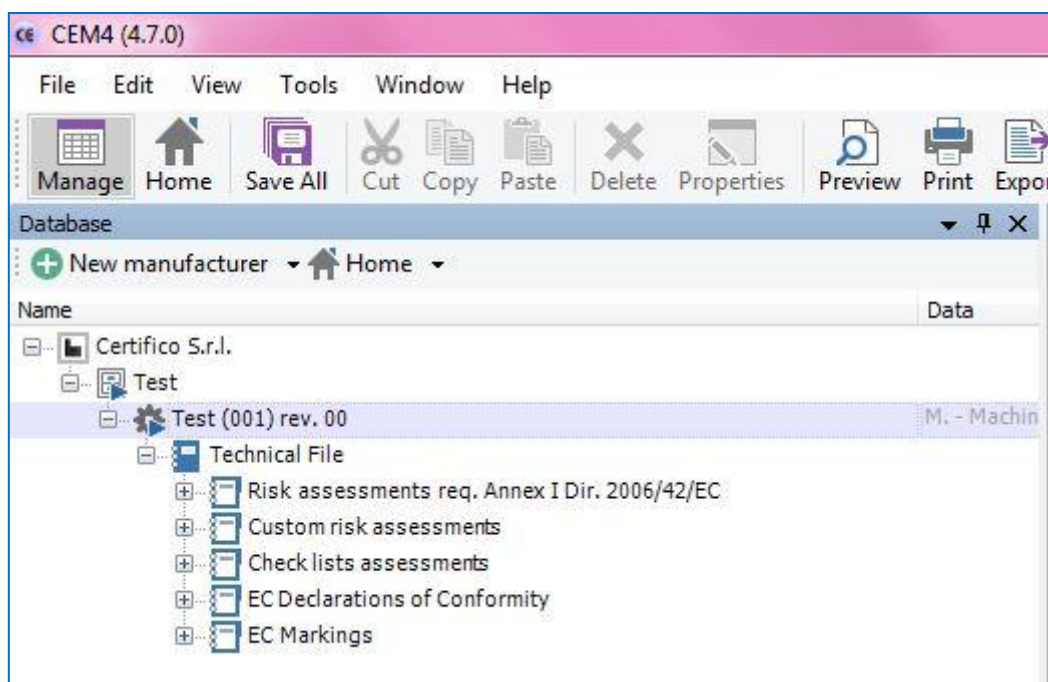
This section shows the route to be followed with CEM4 to manage the main requirements of the Machinery Directive:

- **Technical File;**
- **Risk Assessment;**
- **EC Declaration of Conformity;**
- **CE marking.**

Once inserted the machinery, as described in the First Steps, you can begin to organize Technical File and its related documents.

To do so, you must use the software as described below.

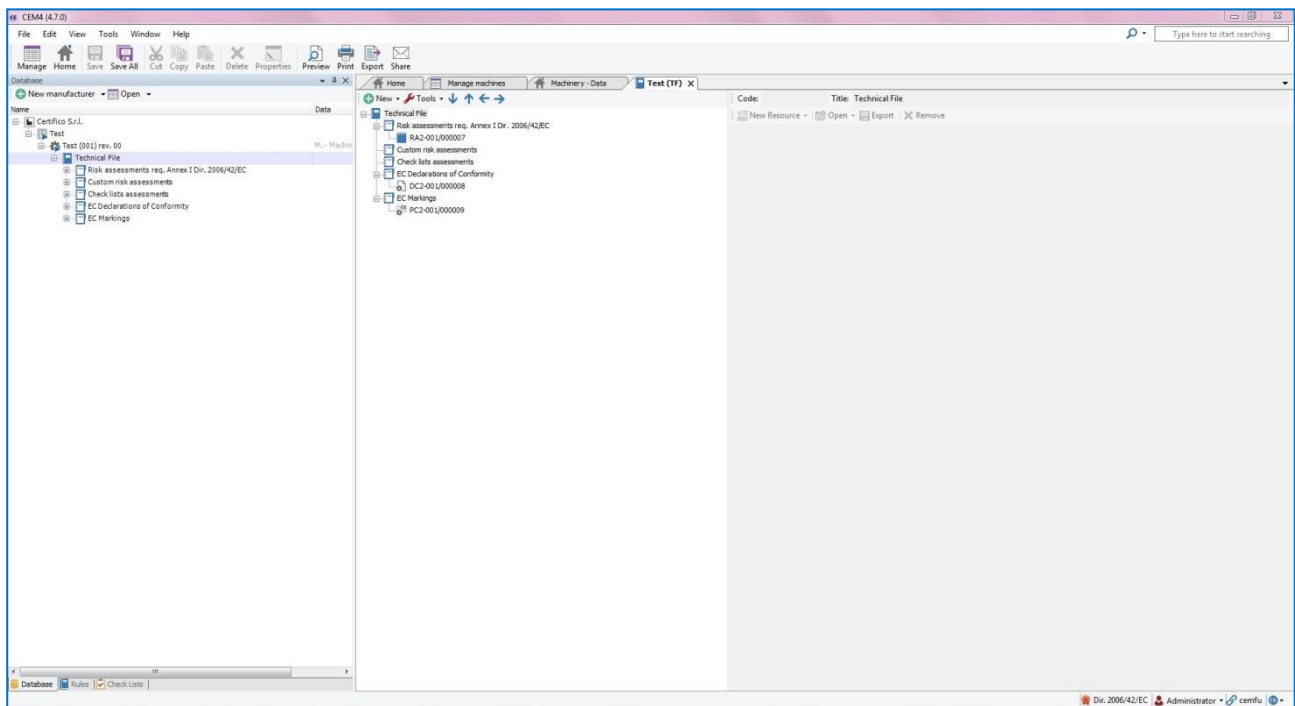
Opening CEM4, the tree on the right consists of the following sections:



## Step 1

To create the Technical File, click on the Technical File on the relative section of the tree to the right; the structure of the Technical File will be present in a central column and New Sections can be added by clicking on the **New** icon that appears in this column. You can create a **"New Folder"** or a **"New Document"** and you can embed an external resource to the database.

The external resources can be opened read/write directly with CEM4 with the launch of the third-party applications for the type of resource.

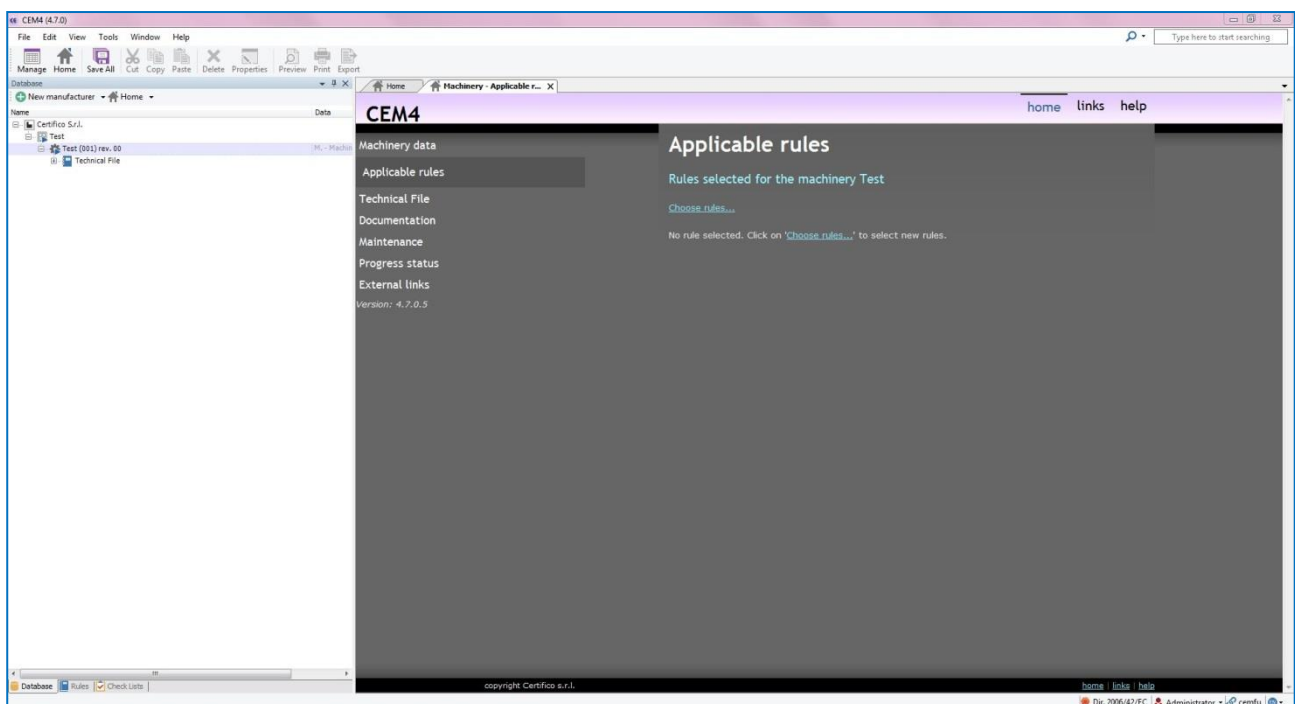


## Step 2

Selection of the Technical Standards.

To do this, click on the machinery in the archive, then click on "Applicable rules" and after click on "Choose rules".

(You can add only technical standards that you have added to the database).



## Step 3

Fill out the Risk Assessment Document EHSR Annex I (the risk analysis will be done in accordance to EN ISO 12100:2010 and to ISO/TR 14121-2:2012 p. 6.5).

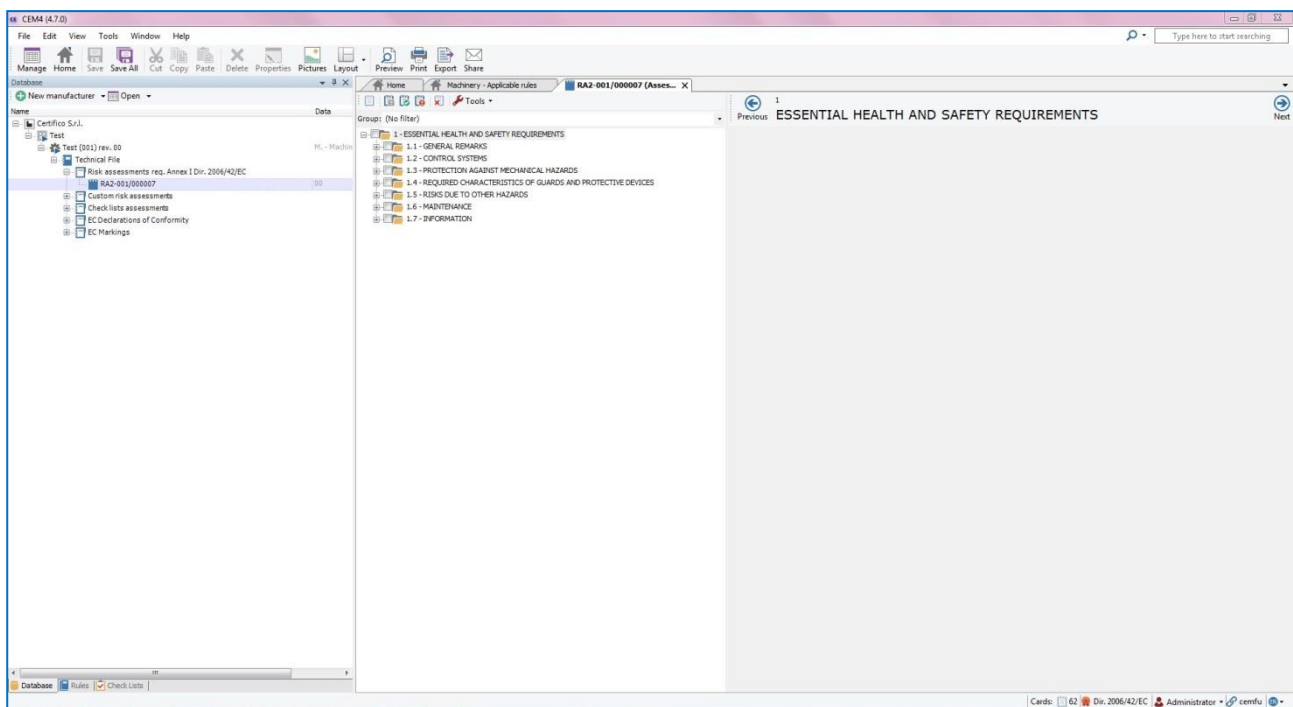
To do this, click on click on the default document RAX-001/XXXXX.

Select one of the EHSR and establish the applicability or otherwise of the requirement.

You can select:

- Requirement not examined
- Requirement Applicable
- Requirement not applicable

This operation will open a section of the software where to make the risk assessment in accordance to EN ISO 12100:2010 and to ISO/TR 14121-2:2012 p. 6.5.



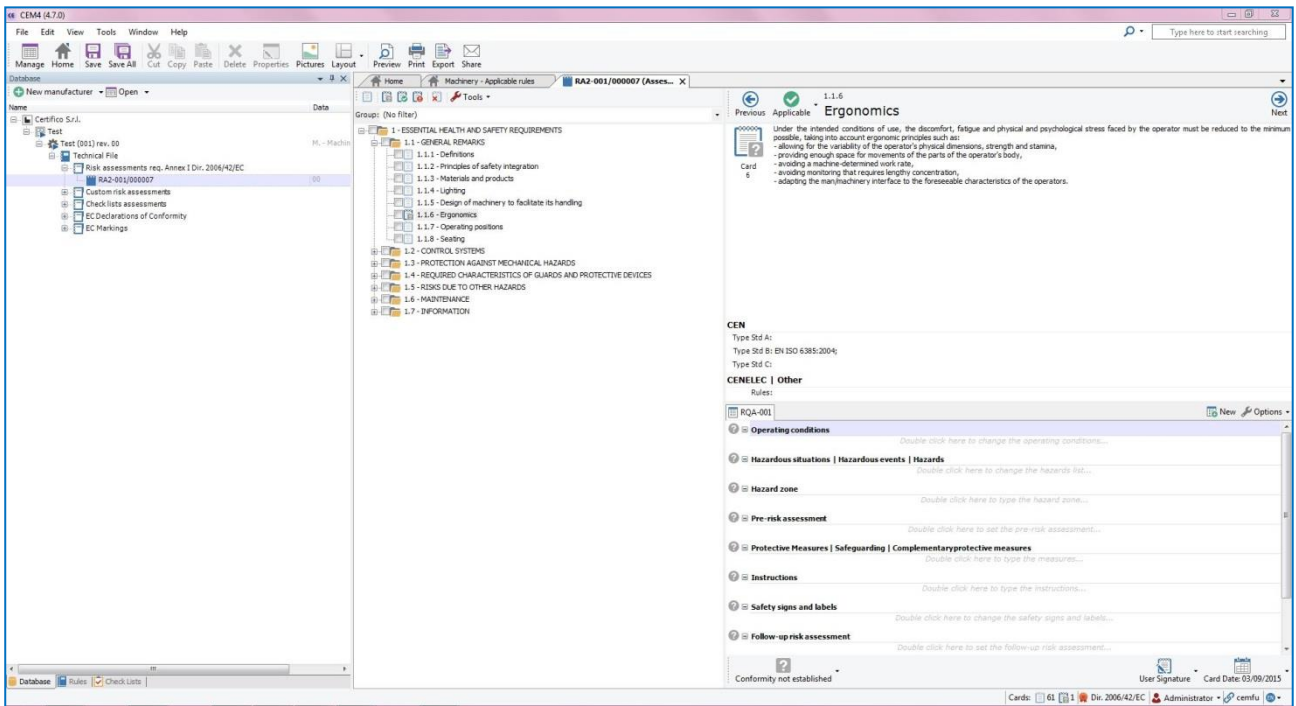
## Steps 4

Fill out the risk assessment schedule in compliance to the requirement selected.

In every requirement schedule, CEM4 suggest to you which harmonized technical standards you can use to establish the compliance to the requirement.

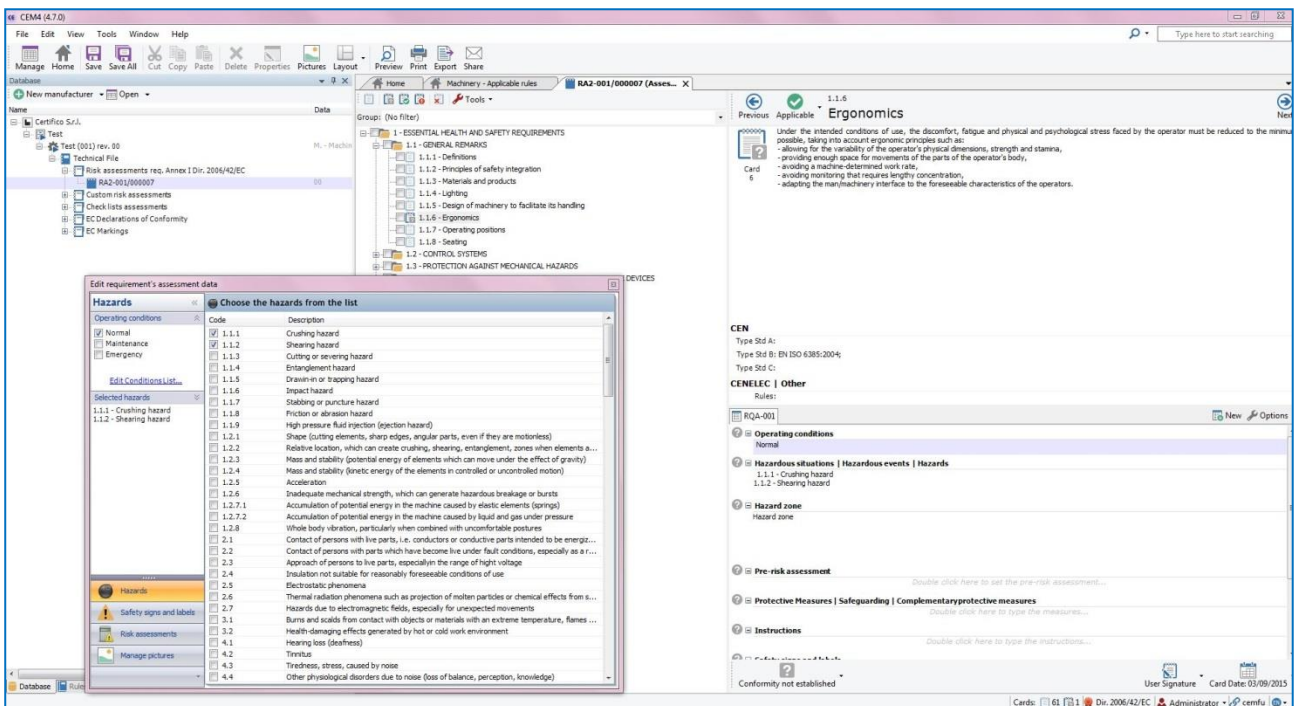
Each harmonized technical standards can be modified in accord to your project.

Remember, the harmonized technical standards assign to your project the "Presumption of Conformity" to respect the EHSR.



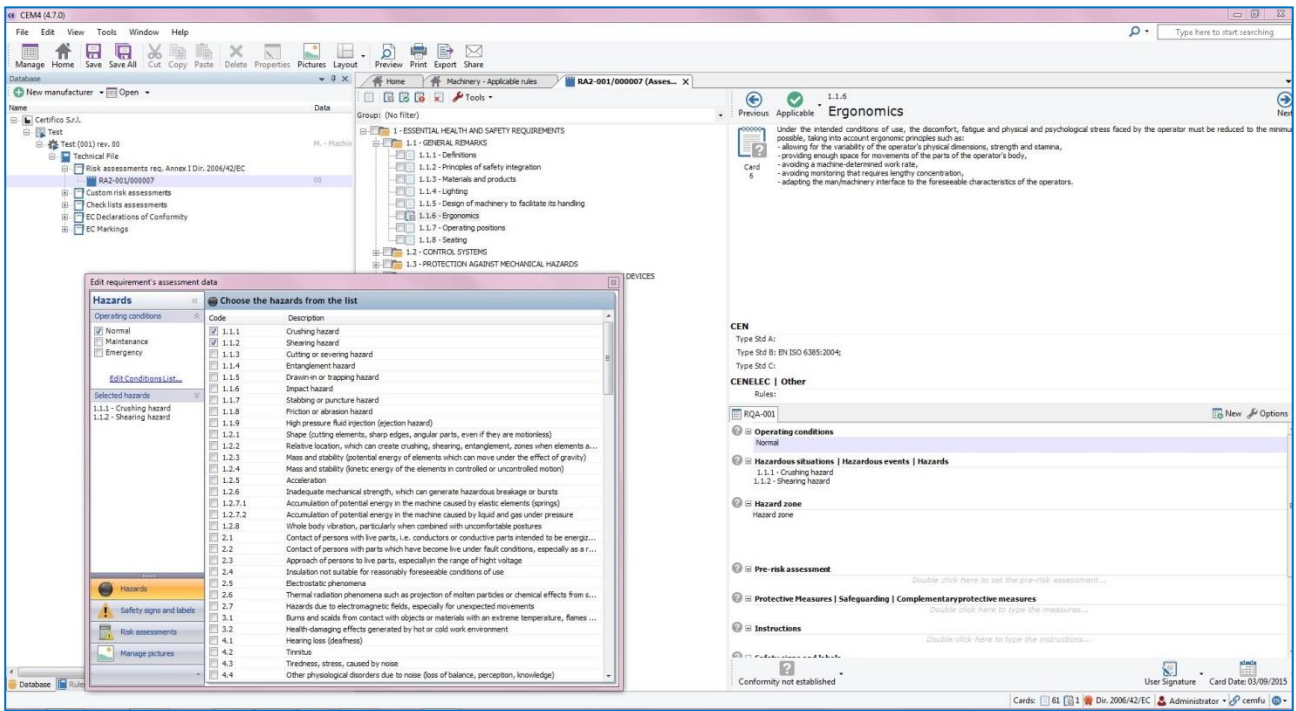
## Step 5

Analyze the operating conditions in which is possible to have hazards in refer to the EHSR that you have selected.



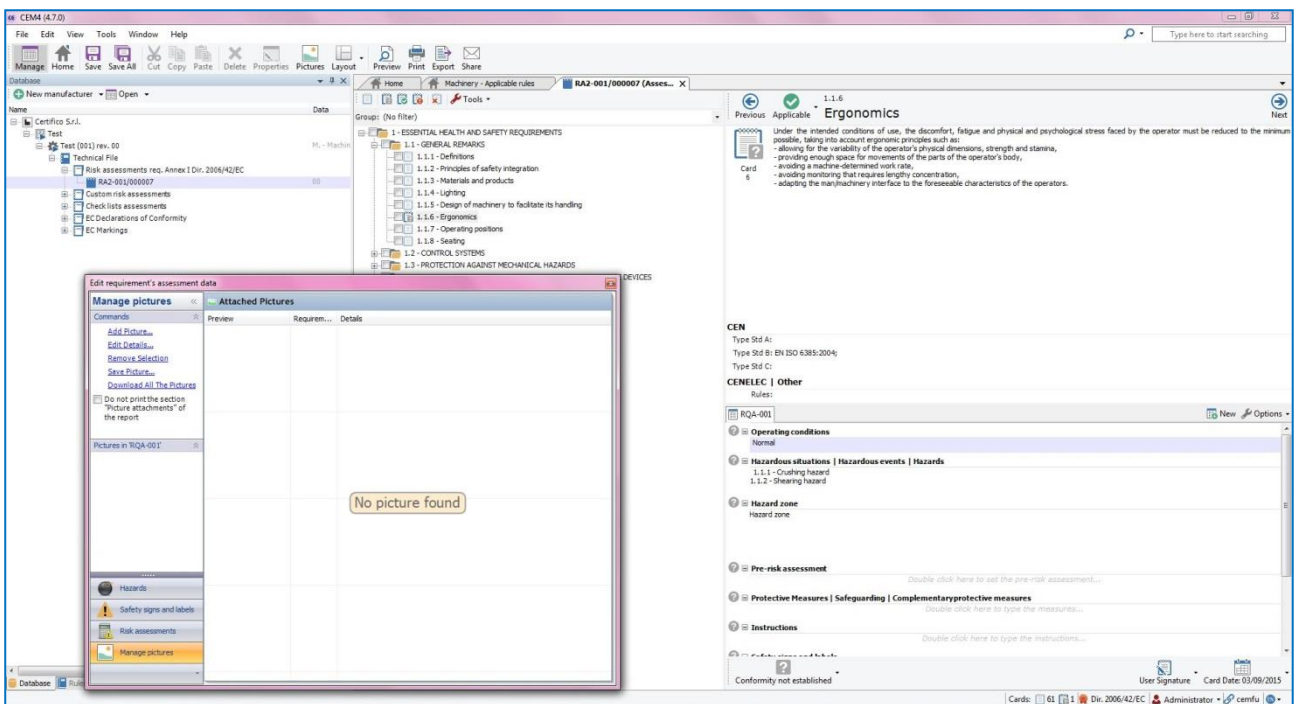
## Step 6

Select the hazards that can occur during the operating condition selected and in refer to the requirement selected.



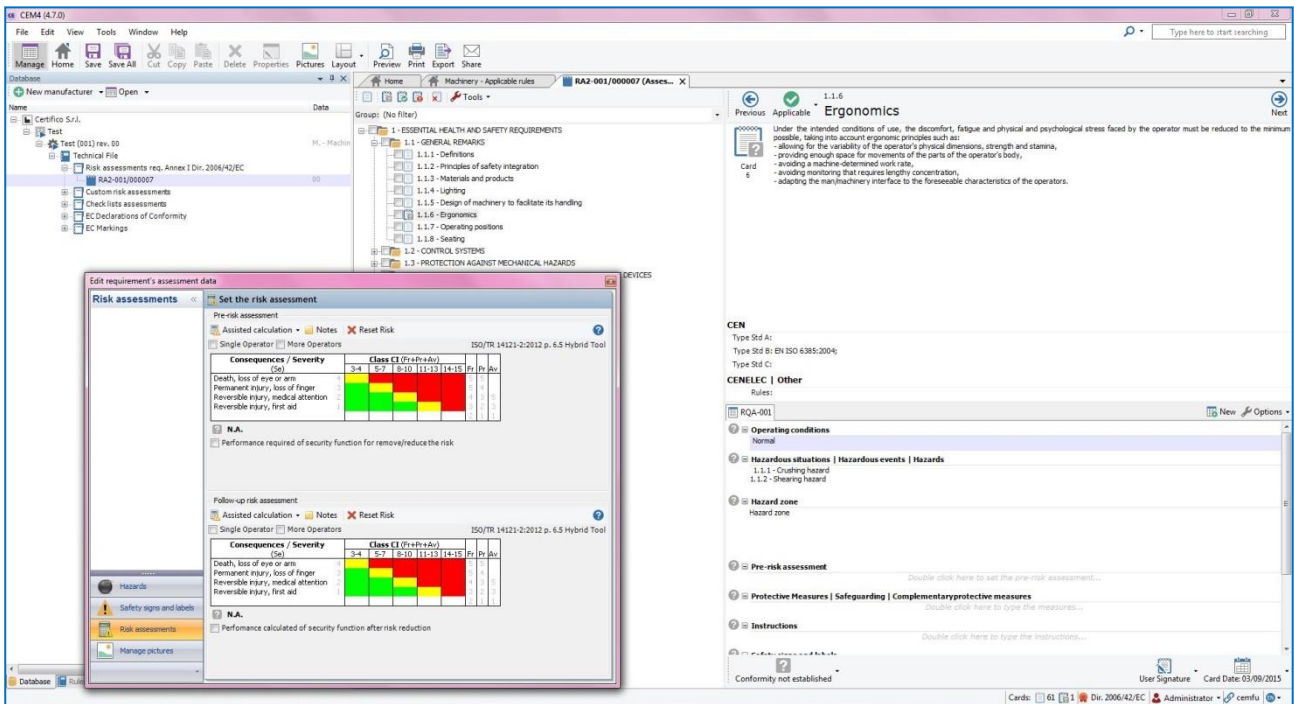
## Step 7

Describe where are located the Hazard zones of the machinery, with the ability to insert relating images.



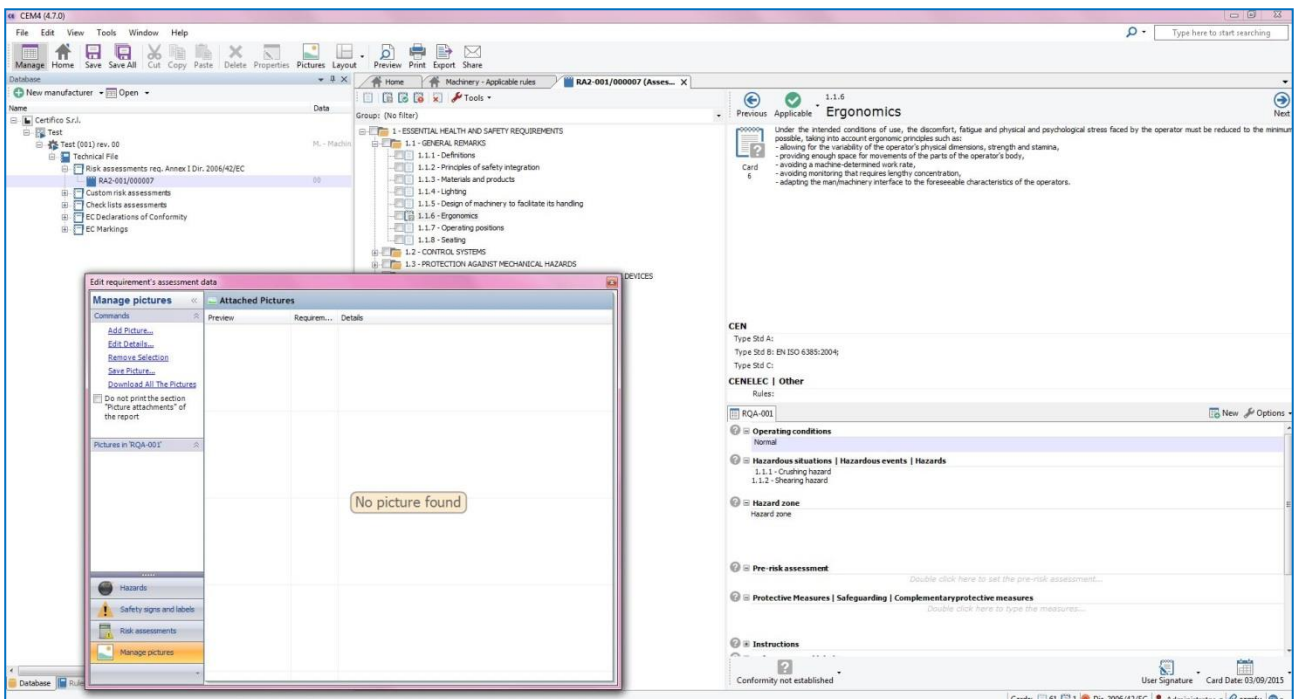
## Step 8

Make an preliminary risk assessment (pre-risk assessment) as required by the Technical Standard Harmonized **EN ISO 12100:2010** and **ISO/TR 14121-2:2012 p. 6.5** to begin the iterative process of risk assessment.



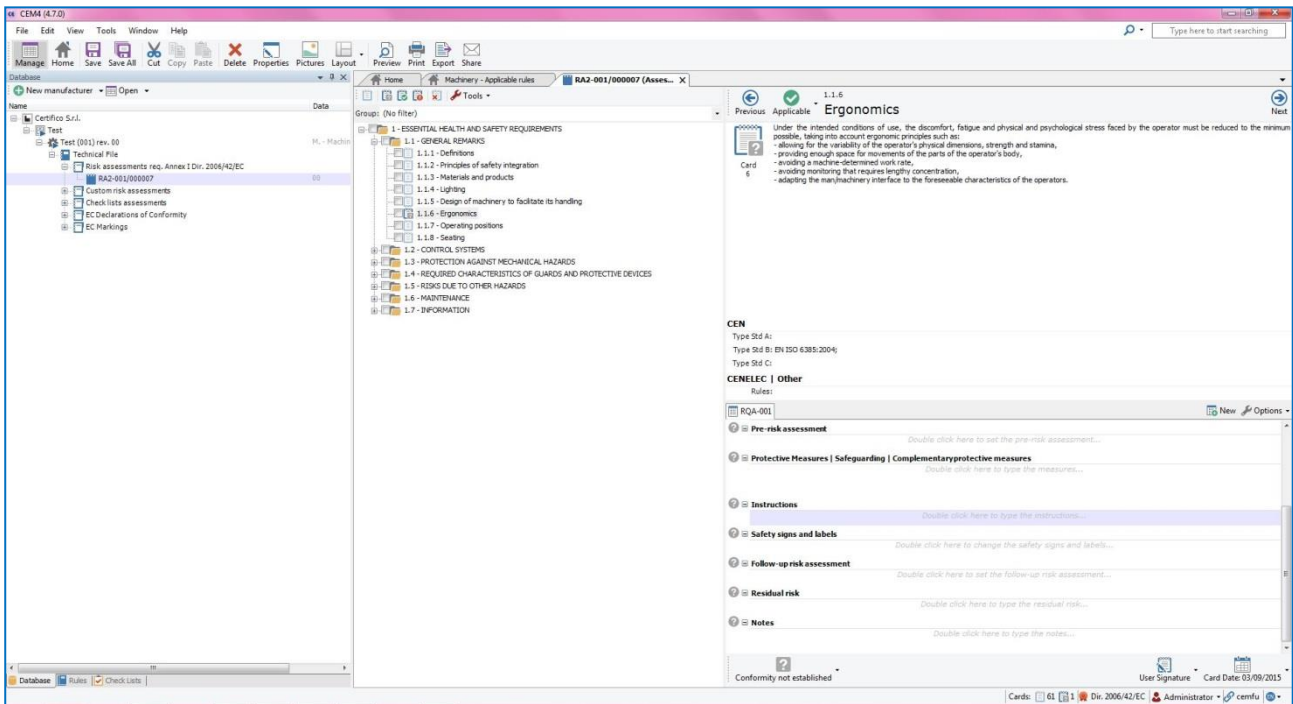
## Step 9

Describe the **Protection Measures/Safeguarding/Complementary protective measures** taken after pre-risk assessment with inserting images to describe them.



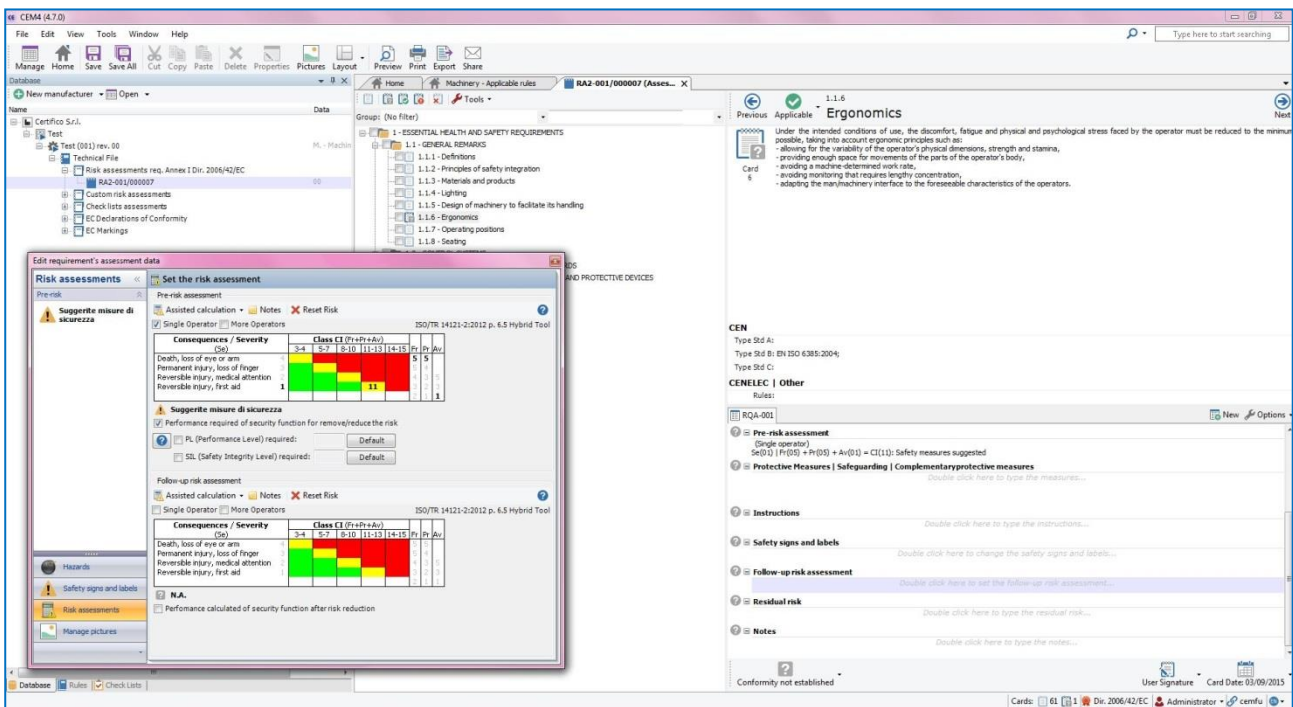
## Step 10

Describe safety instructions, entered in the User and Maintenance Manual, used to reduce risk.



## Step 11

Insert **the safety signs and labels** (if required) to be affixed according to the type of hazard, selecting them from database.





## Step 12

Make risk assessment (**follow-up risk assessment**), as required by the Technical Standard Harmonized EN ISO 12100:2010 and ISO/TR 14121-2:2012 p. 6.5 to define if the risk is sufficiently reduced.

The screenshot shows the 'Edit requirement's assessment data' dialog in Certifico Machine 4.6.2 PRO. The dialog is for requirement 'RA2-001/000035 (Asses...)'. It features a 'Risk assessments' section with a table for 'Consequences / Severity' and 'Class CI (Fr+Pr+Av)'. The table has columns for Class CI (3-4, 5-7, 8-10, 11-13, 14-15), Fr, Pr, and Av. A dropdown menu is open over the table, showing options for Probability (Very high, Likely, Possible, Rarely, Negligible) and Frequency (At least once each hour, At least once each day, At least once every two weeks, At least once every year, Sometimes). The 'Follow-up risk' section shows 'OK' and 'Safety measures required'. The 'Pre-risk assessment' section shows 'Assisted calculation' and 'Notes'. The 'Single operator' checkbox is checked. The 'More operators' checkbox is unchecked. The 'ISO/TR 14121-2:2012 p. 6.5 Hybrid Tool' is selected. The 'Performance calculated of security function after risk reduction' checkbox is checked. The 'Hazards' section shows 'Safety signs and labels'. The 'Risk assessments' section shows 'Manage pictures'. The 'Database' section shows 'Rules' and 'Check Lists'. The 'Conformity not established' status is shown at the bottom. The 'Cards' section shows '61', 'Dir. 2006/42/EC', 'Amministratore', and 'Card Date: 03/09/2014'.

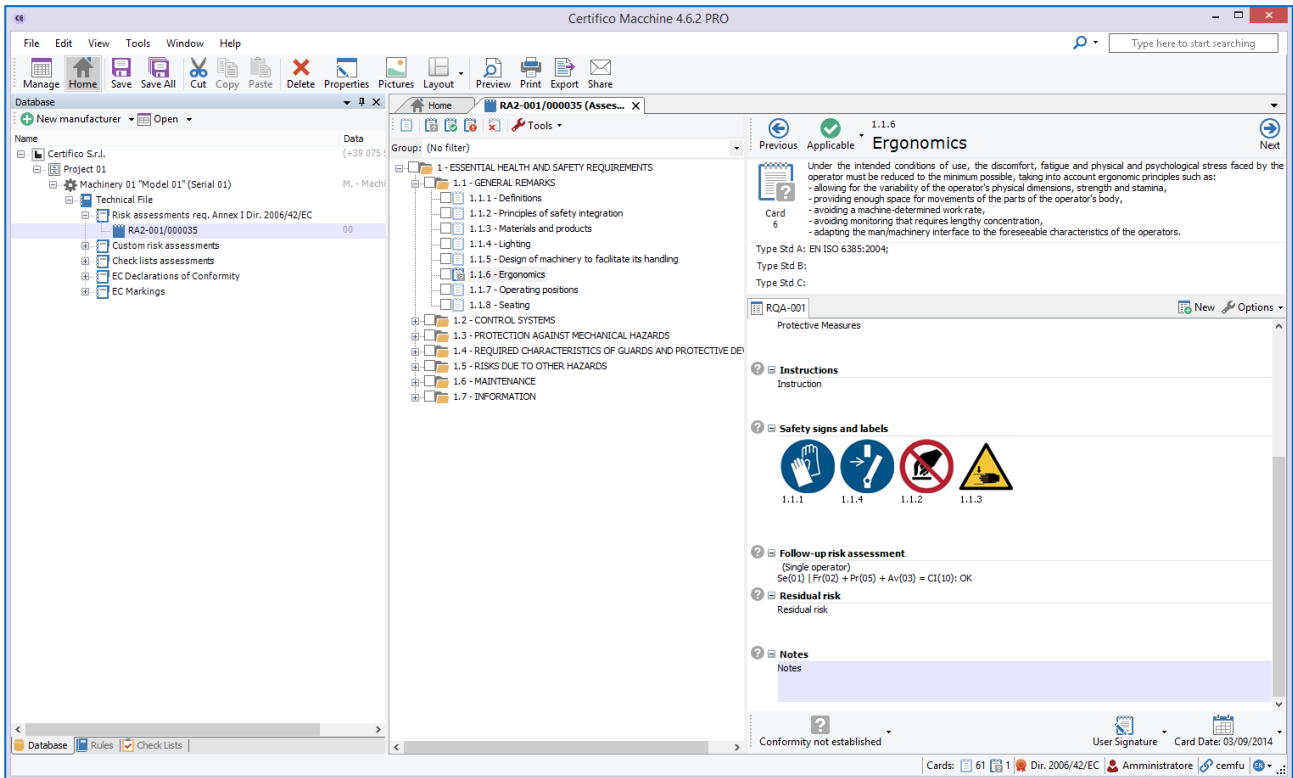
## Step 13

Describe the **Residual Risks** if necessary.

The screenshot shows the 'Edit requirement's assessment data' dialog in CEM4 (4.7.0). The dialog is for requirement 'RA2-001/000007 (Asses...)'. It features a 'Risk assessments' section with a table for 'Consequences / Severity' and 'Class CI (Fr+Pr+Av)'. The table has columns for Class CI (3-4, 5-7, 8-10, 11-13, 14-15), Fr, Pr, and Av. The 'Follow-up risk' section shows 'OK' and 'Safety measures required'. The 'Pre-risk assessment' section shows 'Assisted calculation' and 'Notes'. The 'Single operator' checkbox is checked. The 'More operators' checkbox is unchecked. The 'ISO/TR 14121-2:2012 p. 6.5 Hybrid Tool' is selected. The 'Performance calculated of security function after risk reduction' checkbox is checked. The 'Hazards' section shows 'Safety signs and labels'. The 'Risk assessments' section shows 'Manage pictures'. The 'Database' section shows 'Rules' and 'Check Lists'. The 'Conformity not established' status is shown at the bottom. The 'Cards' section shows '61', 'Dir. 2006/42/EC', 'Administrator', and 'Card Date: 03/09/2015'.

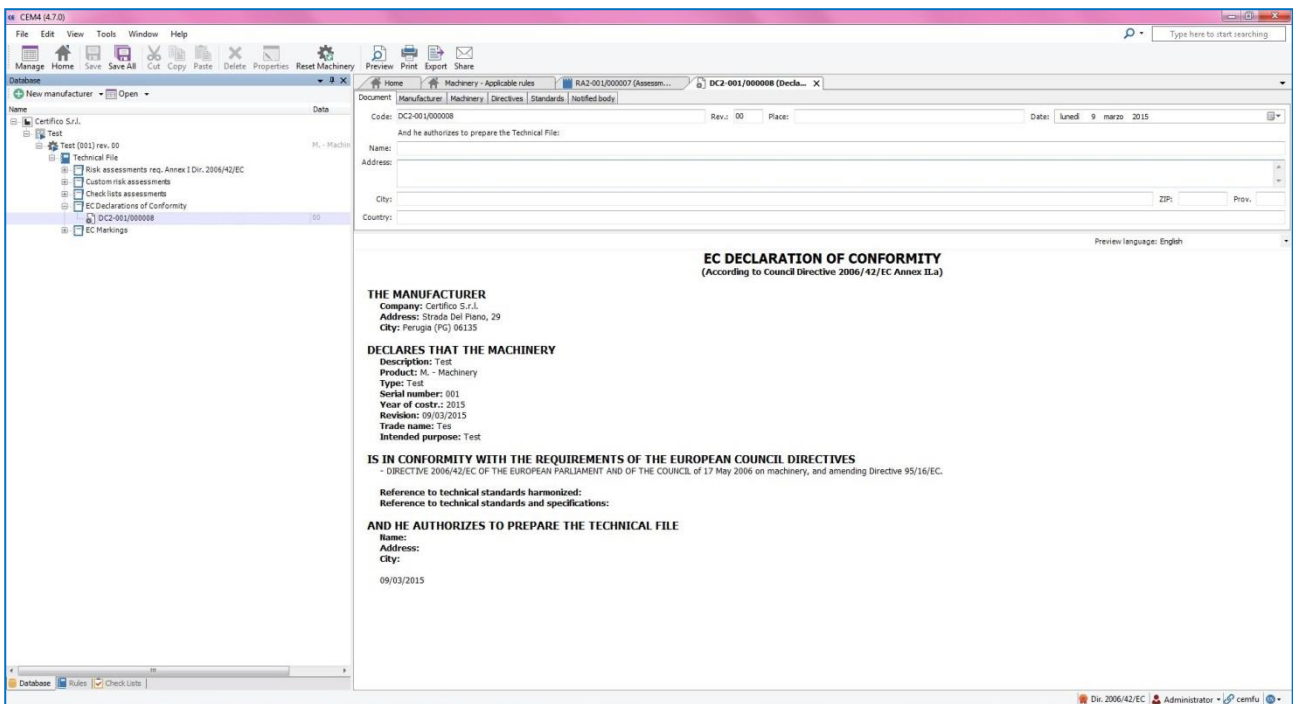
## Step 14

Insert **notes**.



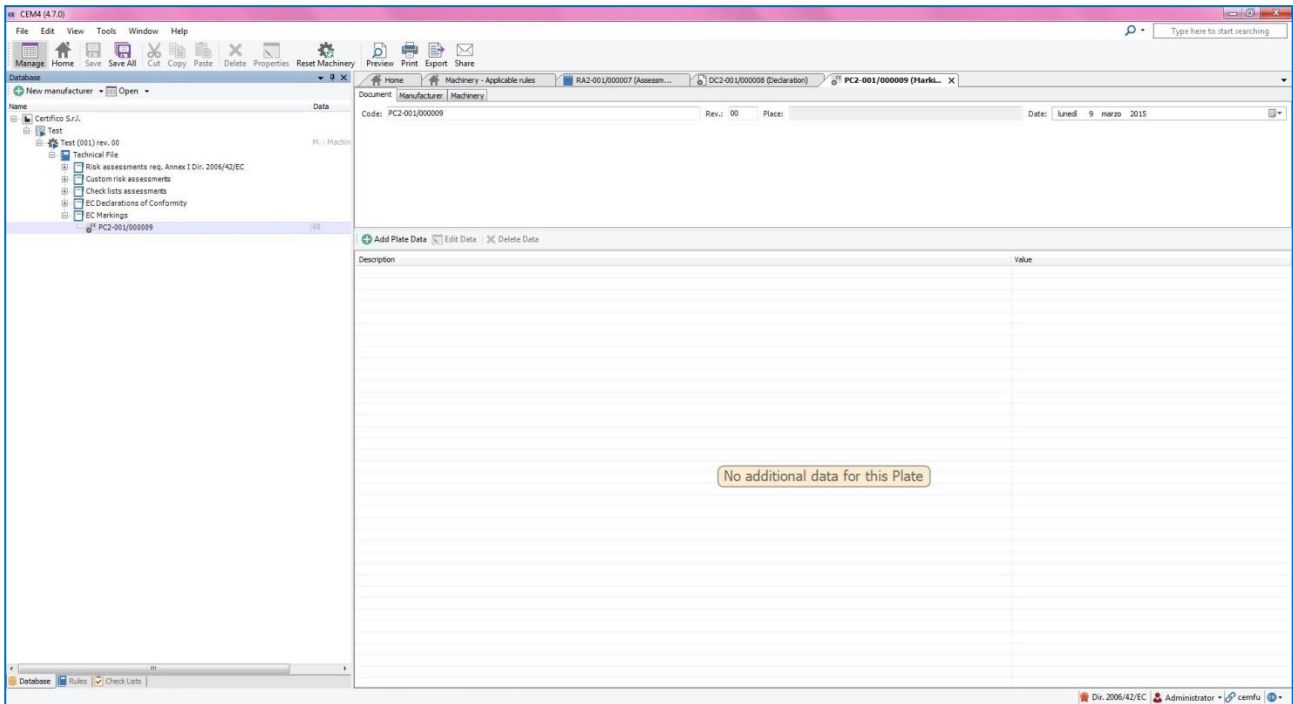
## Step 15

Compile **EC Declaration of Conformity** with missing data.



## Step 16

CEM4 automatically create model of CE mark. Click on **Add Plate Data** to insert more data.



# Report

## Report

This section of CEM4 manual describe the main reports edited by the software CEM4:

- Cover of the Technical File;
- Risk Assessment;
- Ec Declaration of Conformity;
- CE Mark;
- Etc.

The documents drawn up by the software CEM4 can be viewed , printed and distributed .

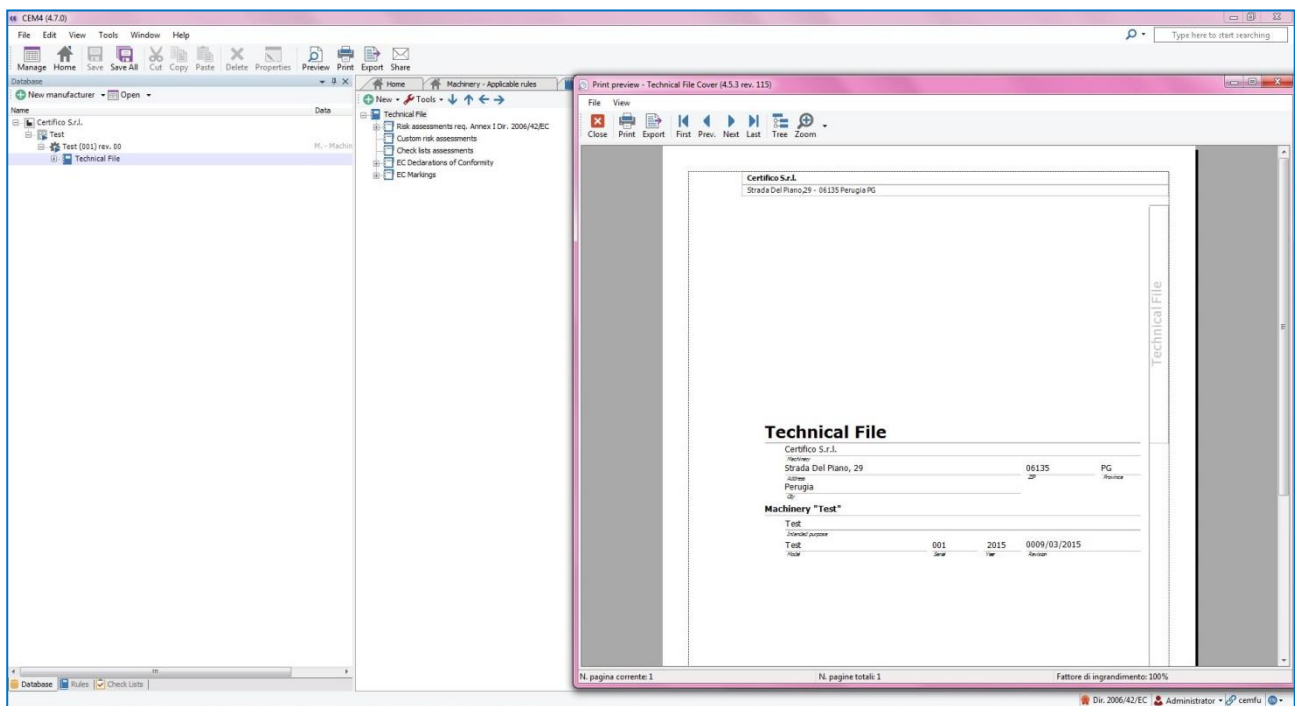
To print a document, proceed as follows :

- Select the machinery and the type of document;
- Click on print.

Before printing you can see the contents of the document clicking in Preview.

Some documents have more report templates. You can select the model you want to print from the drop-down menu.

The software also allows you to export documents in multiple formats including .pdf , .doc , .rtf , .epub.



# Customization

## Customization

In CEM4 you can customize the following sections:

- **Company Details**
- **Technical Standard;**
- **Checklist;**
- **Hazards;**
- **Signs and labels;**
- **Sections of the Technical File;**
- **User account.**

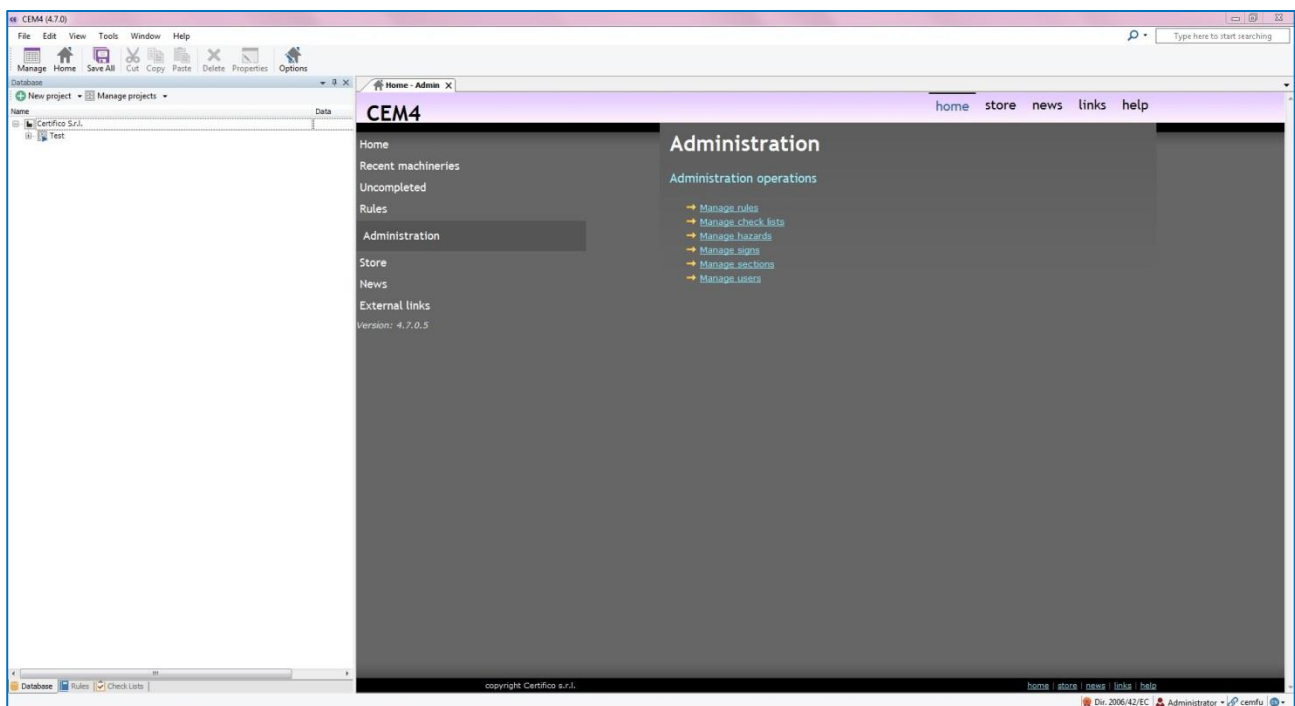
### 1. Company details - General

Specify details company to customize documents created by CEM4 before printing.

Set data of your company.

Data of your company will be printed in the footer of the documents.

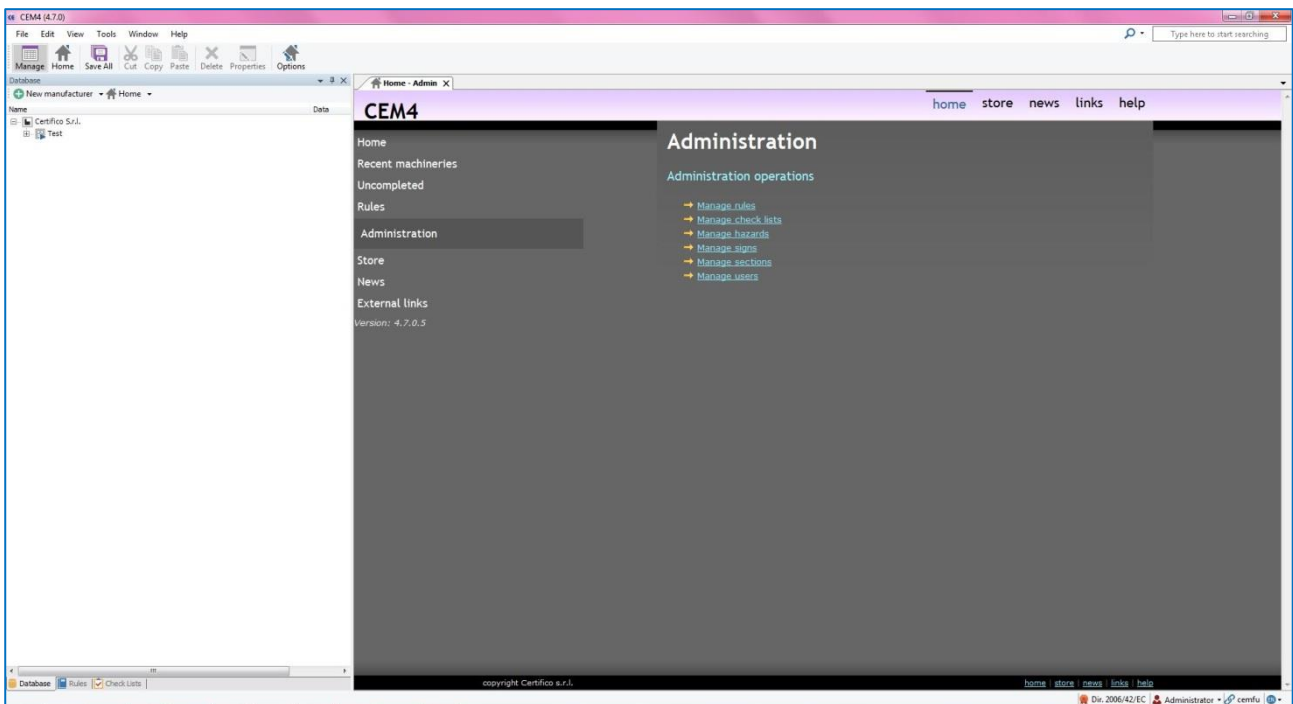
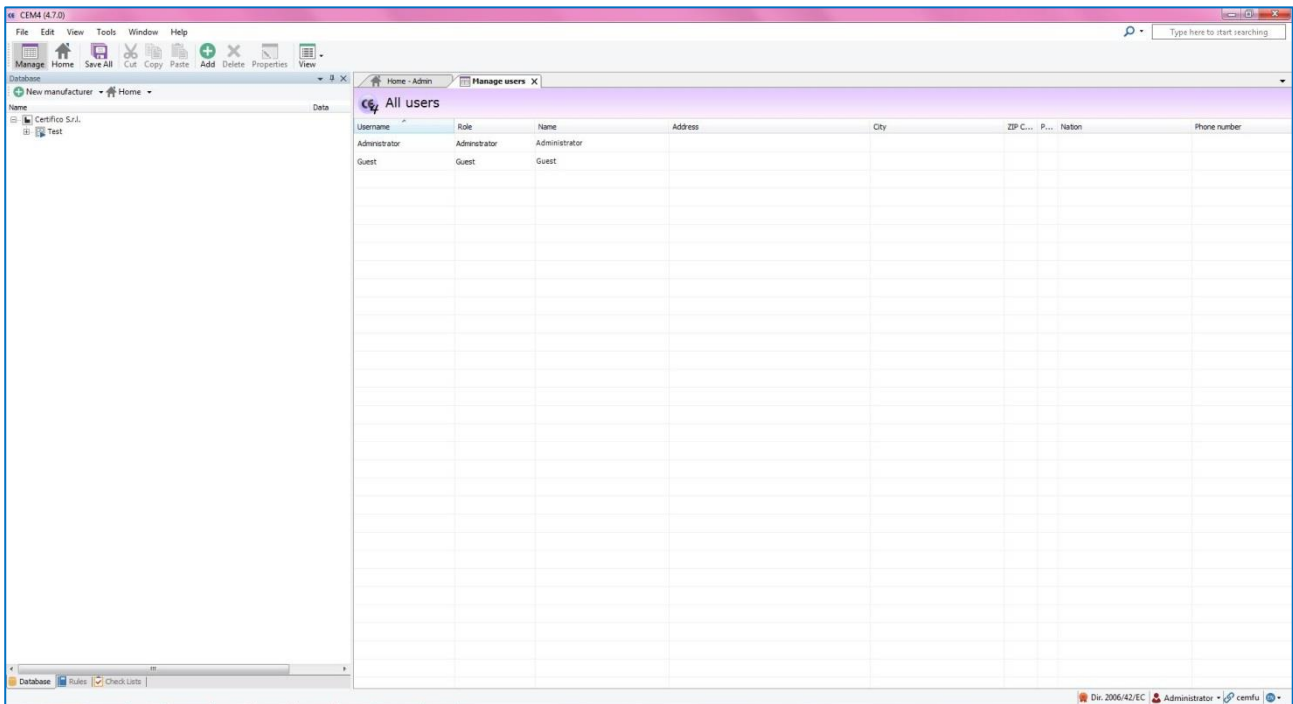
In this section It's possible to insert company brand.



### 2. Company details - Access CEM4

Click on tab program login to set the type of use of the software (single user or multi-user).

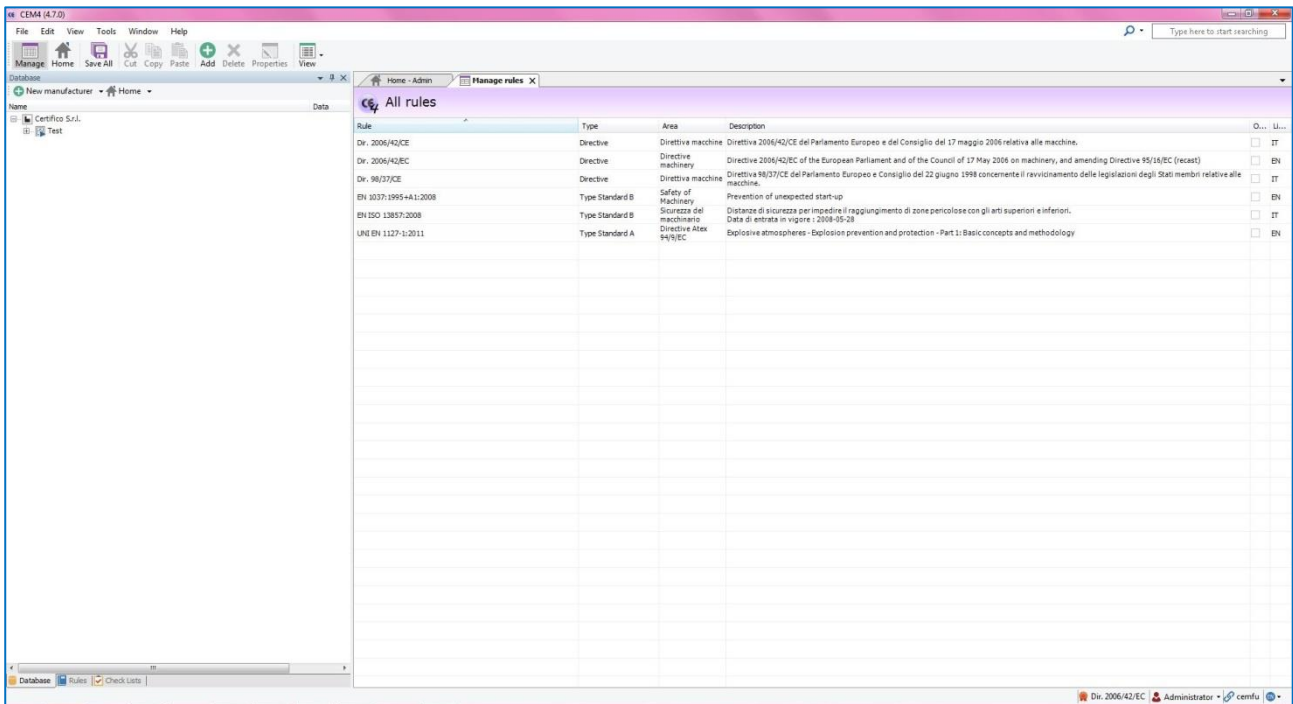
If you choose the single user setting, CEM4 user login will be disabled.



### 3. Administration - Manage Rules

In the section Rules Management you can organize the technical standards. The technical standards can be added in a custom risk assessment and in the EC Declaration of Conformity.

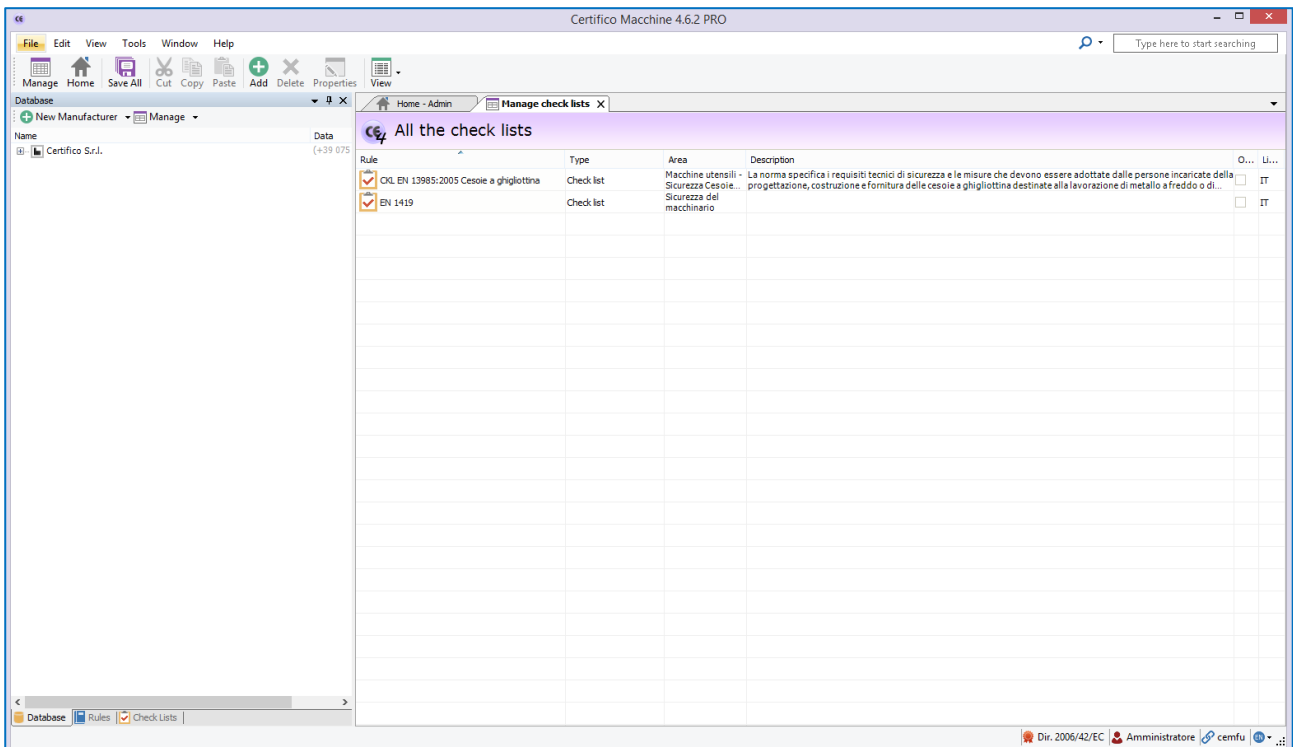
The database can be organized adding Technical Standards Requirements, Guidelines, etc..



## 4. Administration - Manage Check list

In the section **Check List Management** you can organize your check lists. The check lists can be added in a check lists assessment.

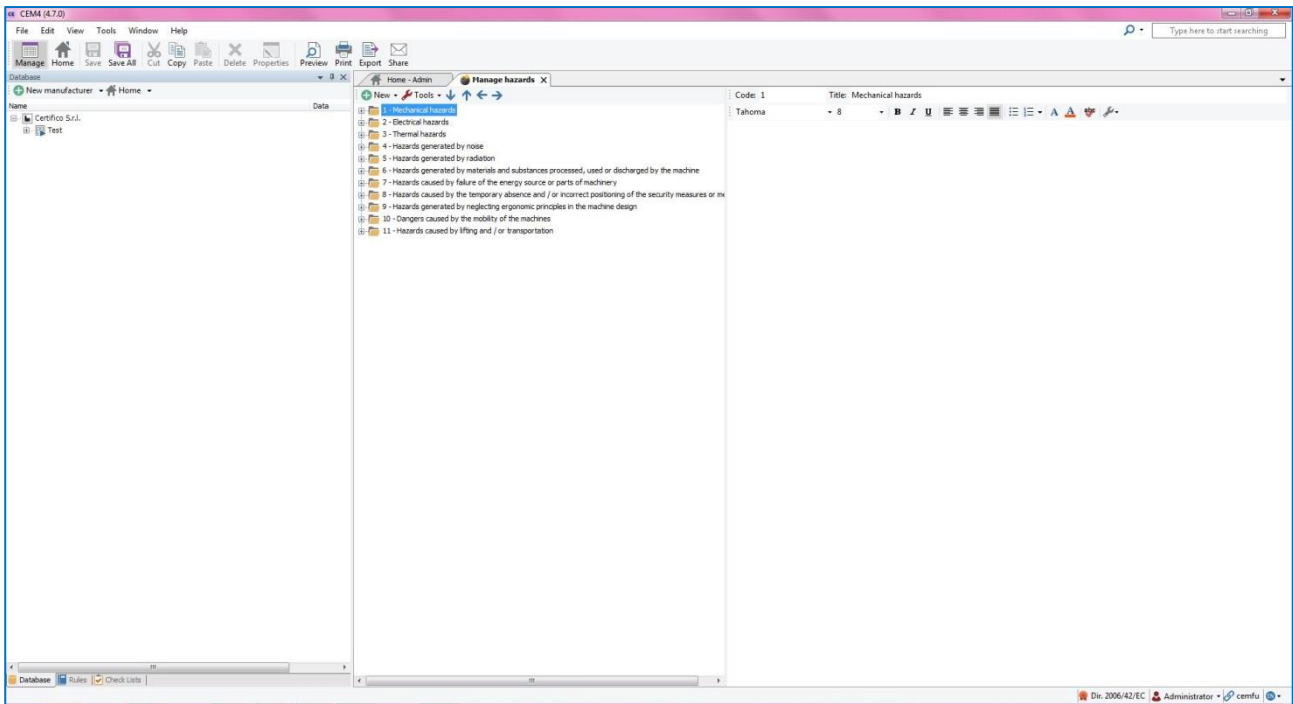
The database can be organized adding every check list you needed.



## 5. Administration - Manage Hazards

In this section you can organize your list of hazards. You can add to the list the hazards you needed by using the section tools.

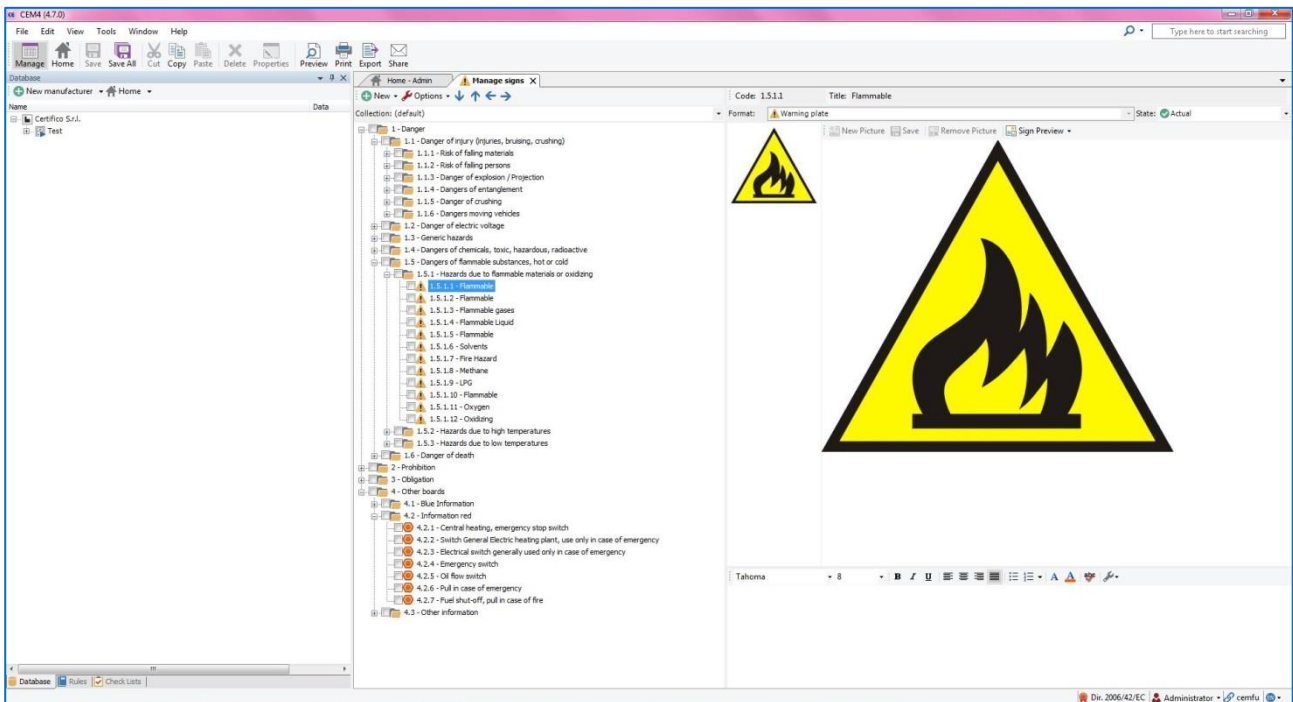
The list will be used during risk assessment process.



## 6. Administration - Manage signs

In this section you can organize your list of signs and labels. You can add to the list the signs you needed by using the section tools.

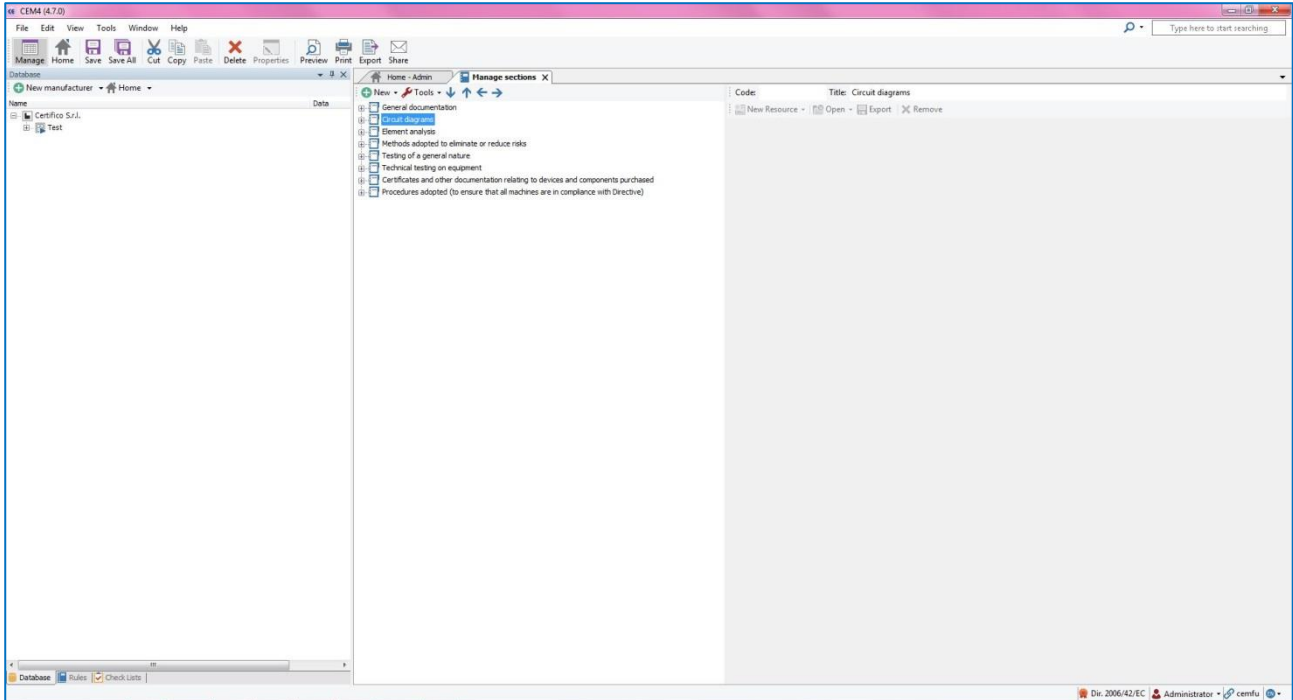
The list will be used during risk assessment process.





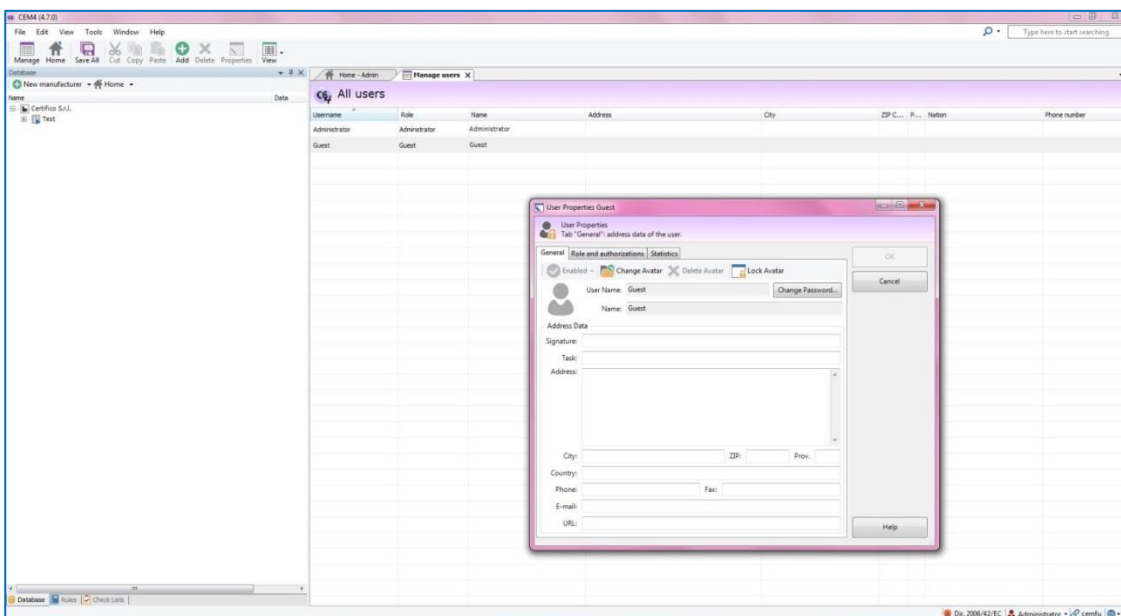
## 7. Administration - Manage Section

In this section you can organize the sections of the technical file by adding new ones. The user can add new sections or update the existing ones.



## 7. Administration - Manage User

In this section you can organize rules and authorizations of the users. You can assign different kind of authorizations to the users of CEM4. With different authorizations you can assign projects and machines to different users.



# Copy

## Copy Features

Copy functions allow copying, duplication, documents revision.

### Manage - Copy Manufacturer

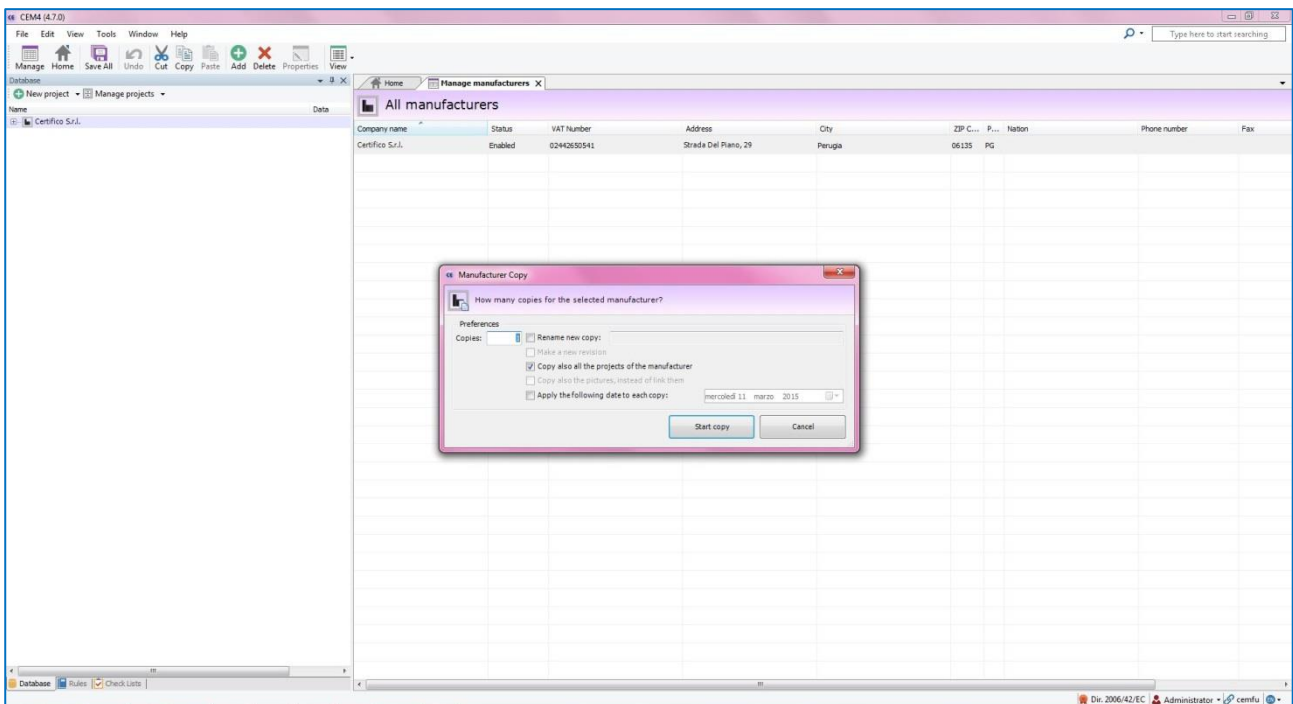
This function creates a copy of the selected Manufacturer.

By copy of the manufacturer, all his projects will be copied.

In this case you get a copy with the same contents of the original.

To copy manufacturer, you must click on **manage** tool and after click on manufacturer you want to copy in "All Manufacturers" list.

Copy tool will be activated.



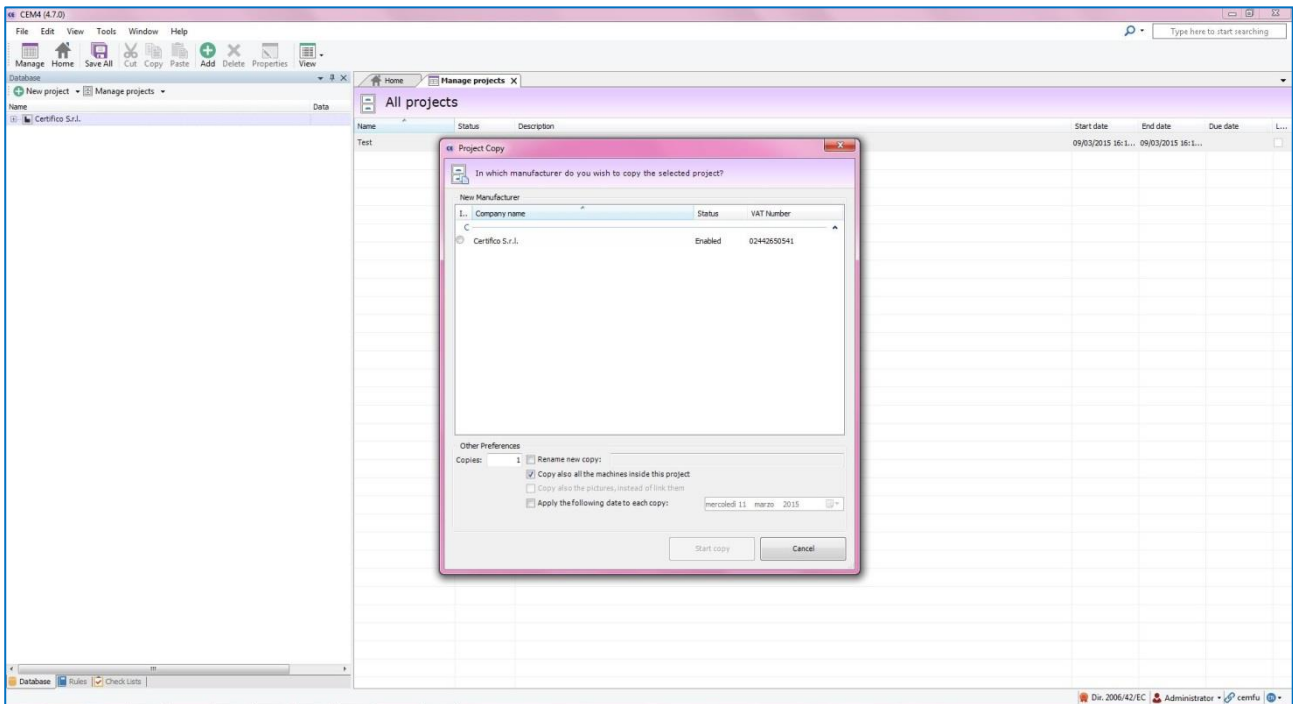
### Manage - Copy Project

This function creates a copy of the selected Project.

To copy a project, you must click on manufacturer to which the project was assigned and after click on project you want to copy in "All Projects" list.

Copy tool will be activated.

You can establish if you want to copy the projects in the same manufacturer section or assign the project to another manufacturer.



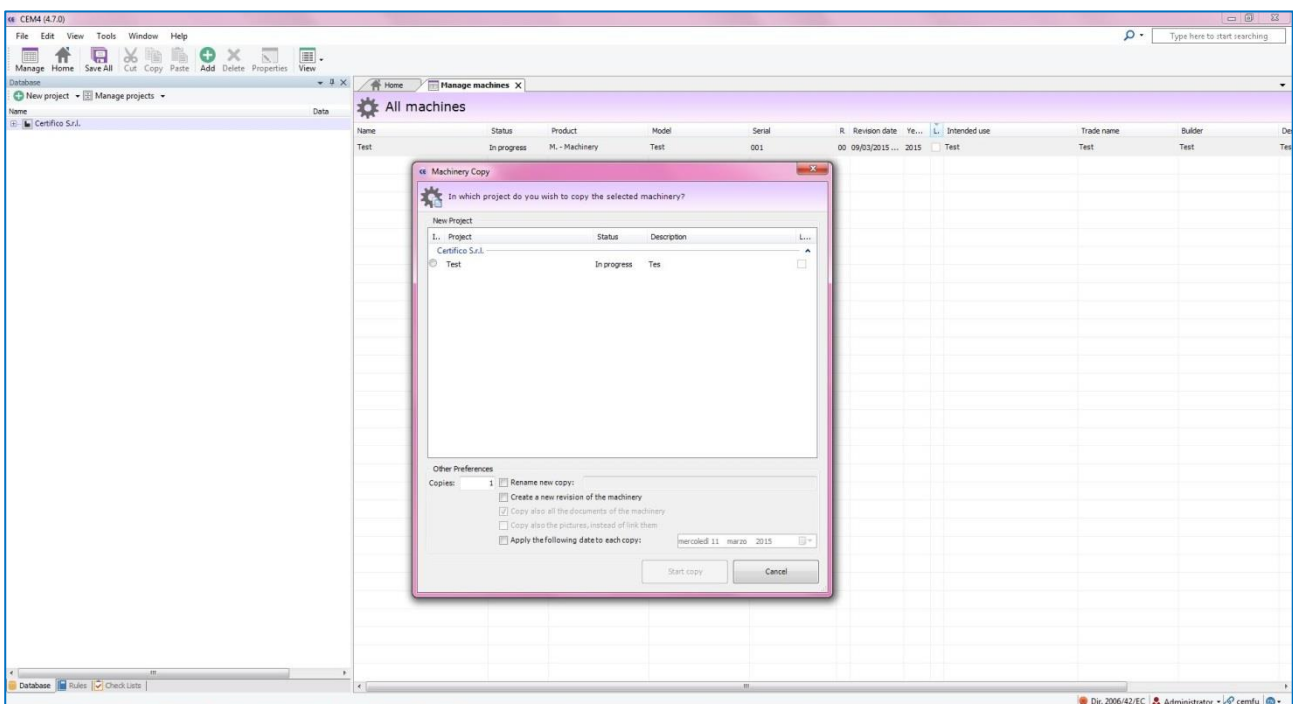
## Manage - Copy Machinery

This function creates a copy of the selected Machinery.

To copy a machinery, you must click on project to which the machinery was assigned and after click on machinery you want to copy in "All Machineries" list.

Copy tool will be activated.

You can establish if you want to copy the machinery in the same manufacturer section or assign the machinery to another project.



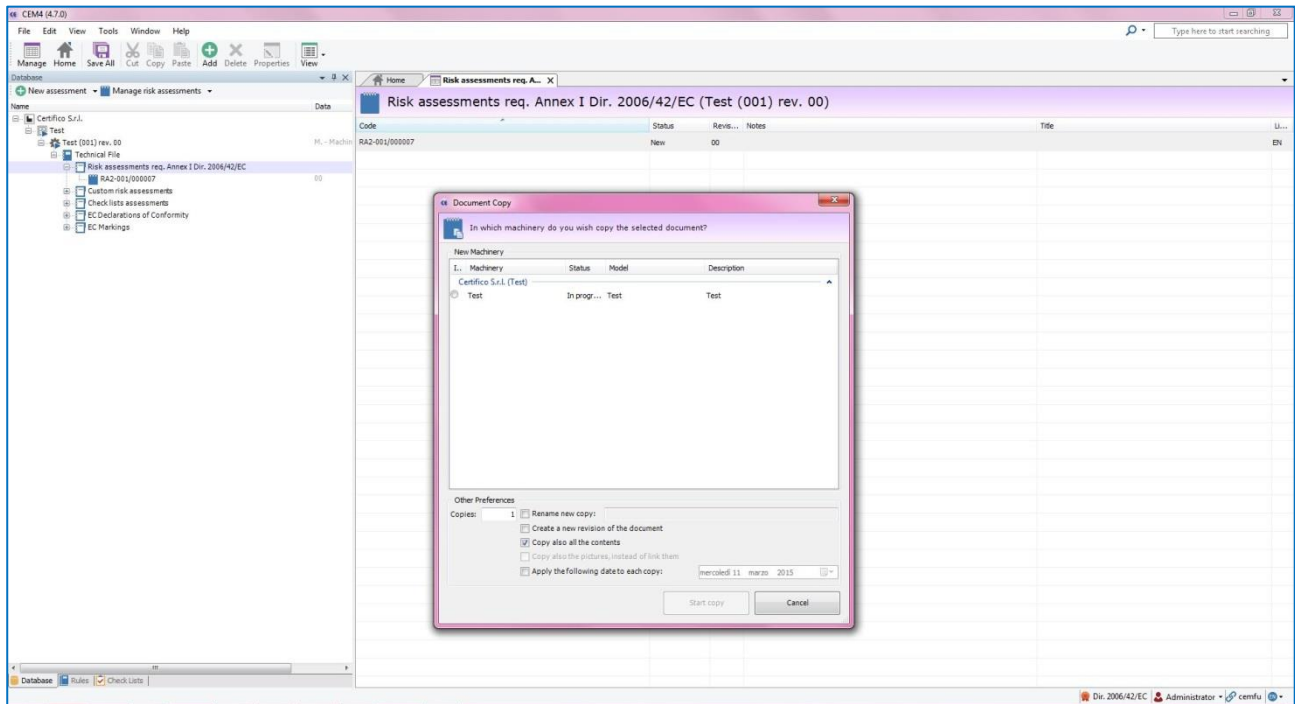
## Manage - Copy document (Risk Assessment)

This function creates a copy of the selected document of risk assessment.

To copy a risk assessment document, you must click on section containing RAX-XX/XXXXXX file and after click on RAX-XX/XXXXXX file you want to copy showed in list to the right of the screen.

Copy tool will be activated.

You can establish if you want to copy the file in the same section or to another section.



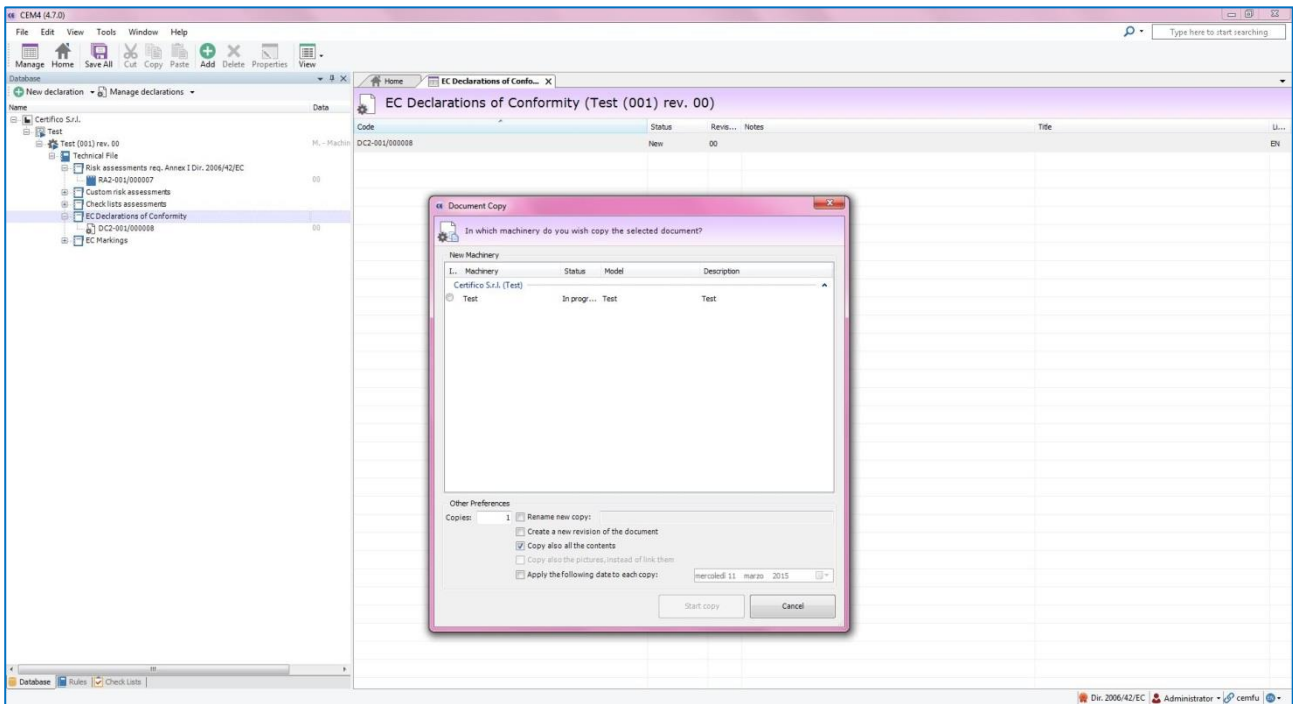
## Manage - Copy EC Declaration of Conformity

This function creates a copy of the selected document of EC Declaration of Conformity.

To copy a EC Declaration of Conformity document, you must click on section containing DCX-XX/XXXXXX file and after click on DCX-XX/XXXXXX file you want to copy showed in list to the right of the screen.

Copy tool will be activated.

You can establish if you want to copy the file in the same section or to another section.



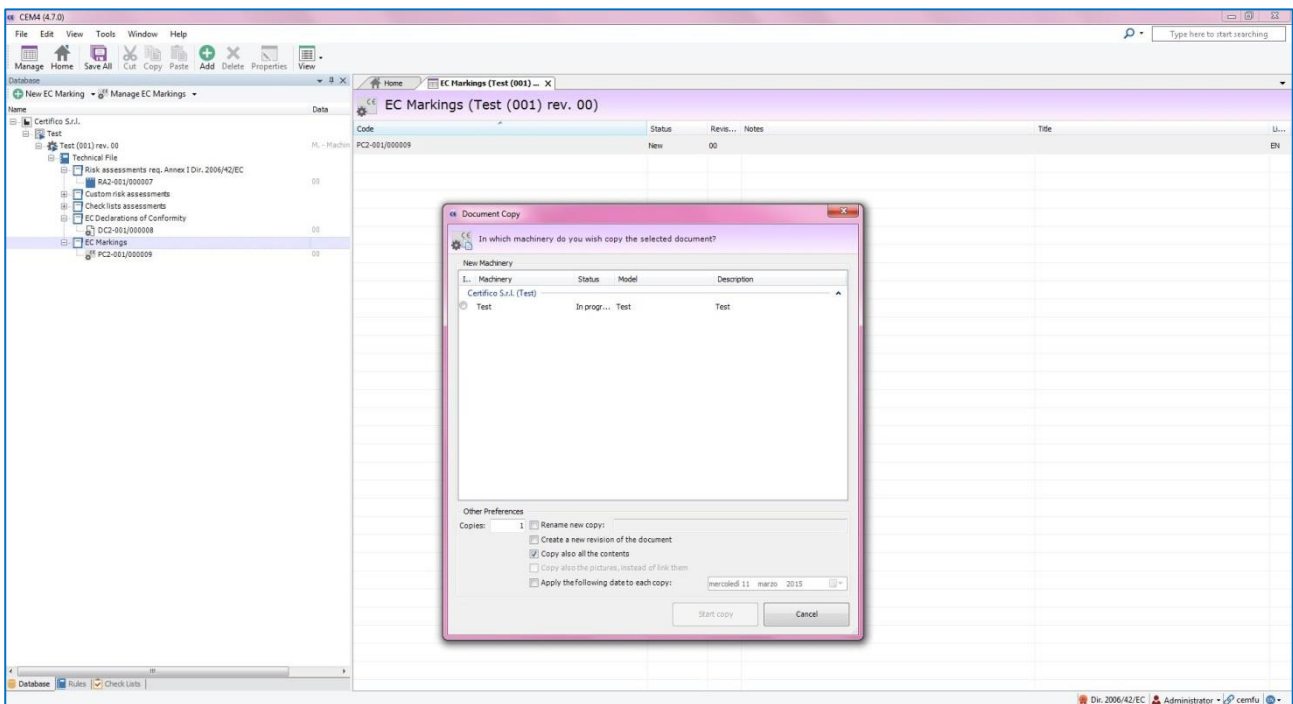
## Manage - Copy document CE marking

This function creates a copy of the selected document of CE Mark.

To copy a CE Mark document, you must click on section containing PCX-XX/XXXXXX file and after click on PCX-XX/XXXXXX file you want to copy showed in list to the right of the screen.

Copy tool will be activated.

You can establish if you want to copy the file in the same section or to another section.



# Manage rules

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## Manage rules

With the management rules tools you can:

- 1 - Insert the headline and/or requirements of the Technical Standards , of the Directives or other Requirements Specific.
- 2 - Import Technical Standards Requirements created by Certifico S.r.l.

## Inserting Technical Standards by the User

Initially, database does not contain Technical Standards Requirements, you must add them.

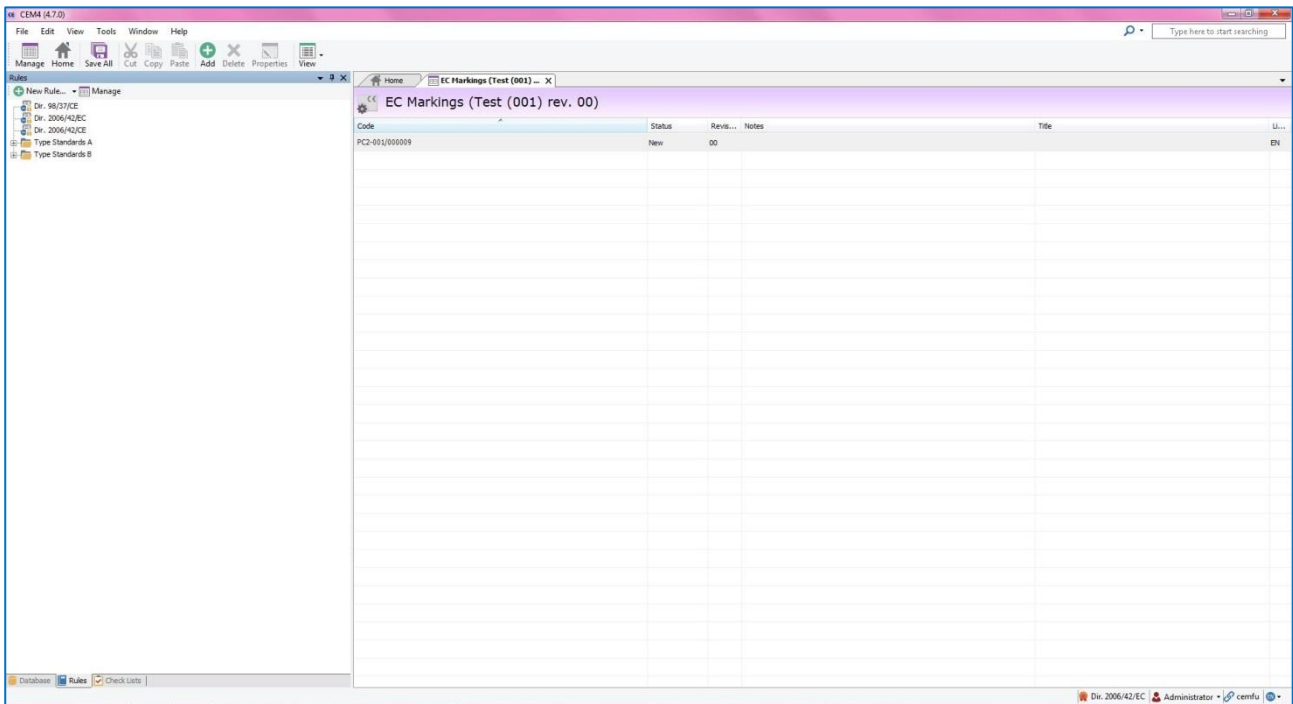
To add requirements of the Technical standards you can:

- 1 – Create the requirements of standards with CEM4 editor, clicking on “New rule” tool.
- 2 – Import the standards clicking on “Import from Exchange files” tool in the drop-down file menu.

## Property Rules

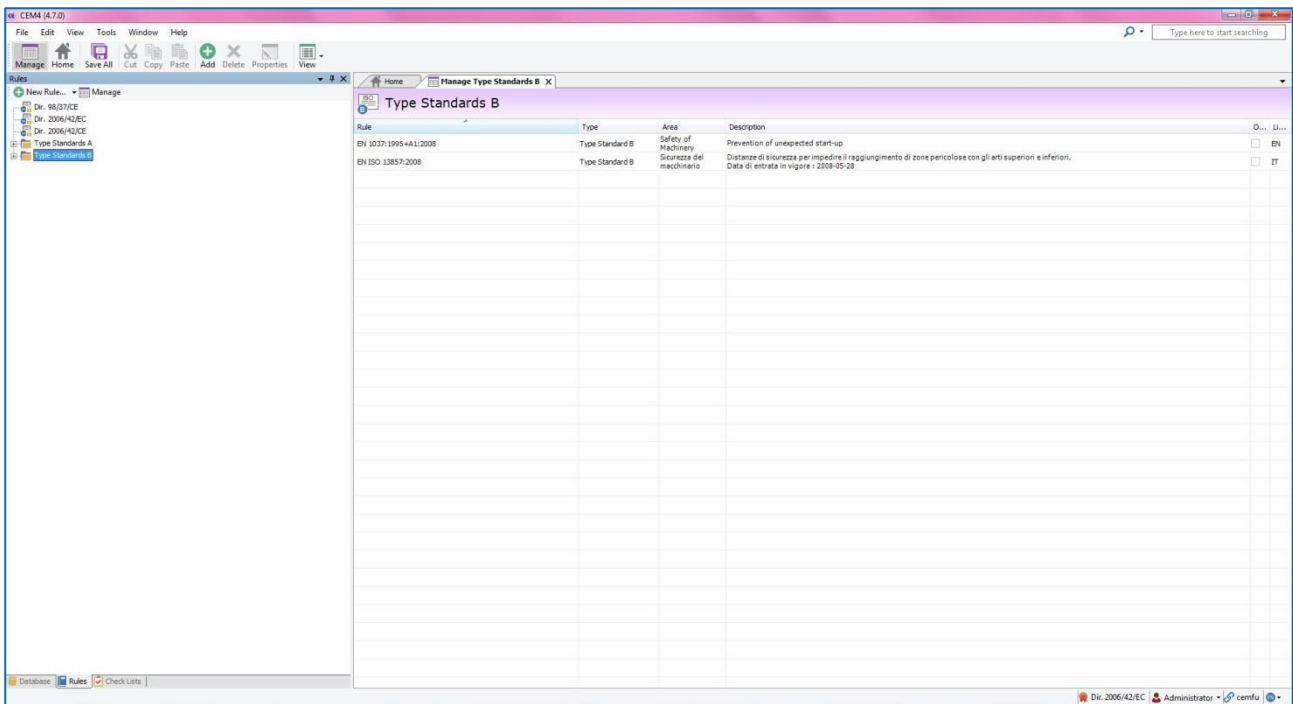
The technical standards entered by the user can be changed at any time and may be rendered obsolete (in case of withdrawal, of substitution, etc. ).

Box "Obsolete rule" , if selected, indicates that users do not use the technical standard, as it is no longer in force and is maintained only for historical archive.



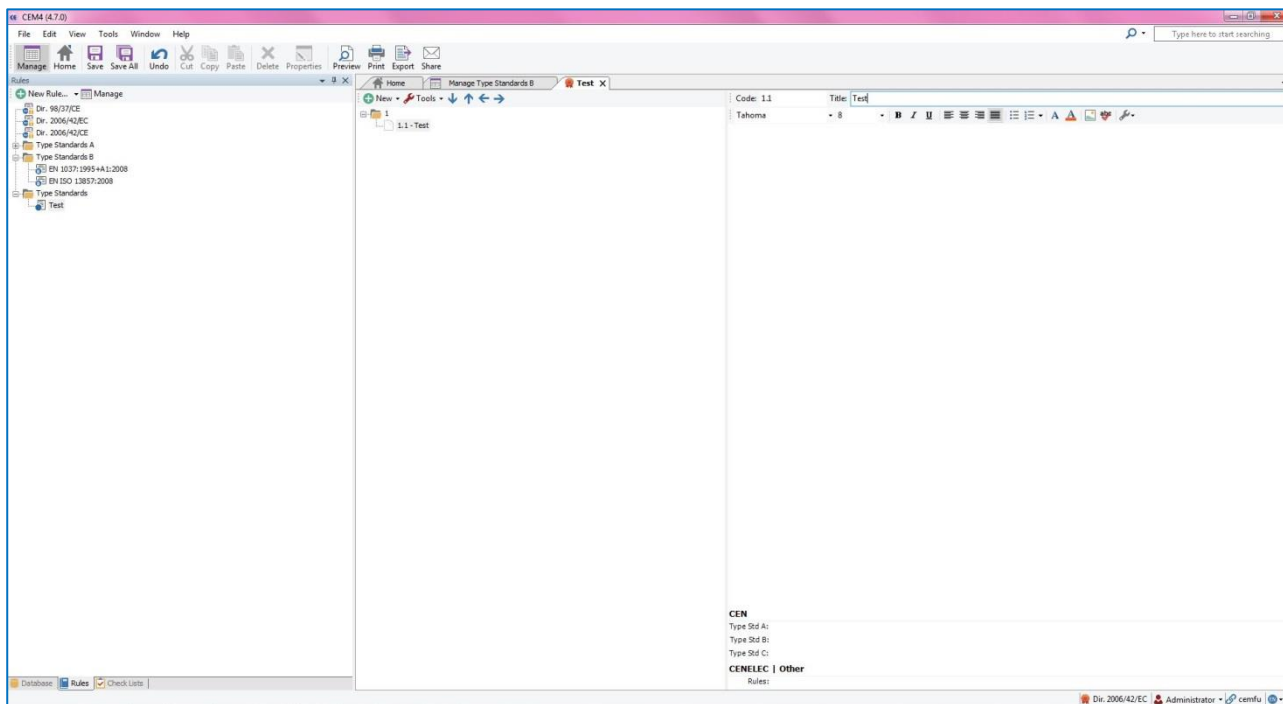
## Management standards

Once you have created the new standard, this appears in the rules management tool.



## Requirements Standards insert

To insert a new requirement you must create a chapter and then a new requirement by using "New Chapter" tools and "New Requirements" tools.





# Support

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## 1. Helpdesk

### Help desk TeamViewer Certifico.

It excludes any liability arising from the use of TeamViewer QuickSupport with other users, and in contravention of the conditions of TeamViewer GmbH.



[TeamViewer](#) | [Protection](#)

## 2. How to Backup / Restore

### Installing libraries to support backup / restore database

The functions of backup / restore CEM4 are operated by 4 with some libraries calls Microsoft SQL Server Management Objects (SMO).

These libraries generally are not always present on the user's computer , as is usually the setup of SQL Server simply install the service and little else.

This guide and ' tested to CEM4 4.2.0, but it could also work for older versions (4.0.x , 4.1.x).

The packages to install, taking for granted the presence of .NET Framework are as follows:

(Note: IA64 -based systems are not officially supported by certify machines , the link packet and ' reported only for completeness of information)

#### 2.1) System CLR Types Microsoft SQL Server

32-bit systems ( SQLSysClrTypes.msi ) - 1588

KB: <http://go.microsoft.com/fwlink/?LinkId=123721&clcid=0x410>

64-bit systems ( SQLSysClrTypes.msi ) - 1981 KB

: <http://go.microsoft.com/fwlink/?LinkId=123722&clcid=0x410>

IA64 systems ( SQLSysClrTypes.msi ) - 3289 KB

: <http://go.microsoft.com/fwlink/?LinkId=123724&clcid=0x410>

#### 2.2) Microsoft SQL Server 2008 Management Objects

(they work for both SQL Server 2005 and SQL Server 2008).

32-bit systems ( SharedManagementObjects.msi ) - 3225 KB

: <http://go.microsoft.com/fwlink/?LinkId=123708&clcid=0x410>

64-bit systems ( SharedManagementObjects.msi ) - 3895 KB

: <http://go.microsoft.com/fwlink/?LinkId=123709&clcid=0x410>

IA64 systems ( SharedManagementObjects.msi ) - 5640 KB

: <http://go.microsoft.com/fwlink/?LinkId=123710&clcid=0x410>

Only in the case where the two setups above should not start or should report the error messages, install these three additional packages and re-install the two previous packages.

### 2.2.1) Microsoft Windows Installer 4.5

<http://go.microsoft.com/fwlink/?LinkId=123373>

### 2.2.2) Microsoft Core XML Services (MSXML ) 6.0

<http://www.microsoft.com/downloads/it-it/details.aspx?FamilyId=d21c292c-368b-4ce1-9dab-3e9827b70604&displaylang=it>

(page there are three packages respectively for 32 /64 bit and IA64) .

### 2.2.3) Microsoft SQL Server 2008 Native Client

32-bit systems ( sqlncli.msi ) - 4549 KB: <http://go.microsoft.com/fwlink/?LinkId=123717&clcid=0x410>

64-bit systems ( sqlncli.msi ) - 7963 KB: <http://go.microsoft.com/fwlink/?LinkId=123718&clcid=0x410>

IA64 systems ( sqlncli.msi ) - 11112 KB: <http://go.microsoft.com/fwlink/?LinkId=123719&clcid=0x410>

If, despite everything, you are still unable to use the backup function, download and install Microsoft SQL Server Management Studio Express and use the backup and restore function available in this application:

<http://www.microsoft.com/downloads/it-it/details.aspx?FamilyID=08e52ac2-1d62-45f6-9a4a-4b76a8564a2b>

## 3. How to manage images

Note the size of the image inserted in the rich text fields

Some fields CEM4 (called fields RTF) allow the insertion of formatted text and images (for example, the text of the requirements, the assessment of the condition of the fields , the notes of the dangers and signs).

It was found that the insertion of images with high resolution, regardless of the format in which they were saved , they can occupy a lot of space in the database and thus cause errors during data loading or excessive delays.

It is recommended to insert relatively small images (such es. formule mathematical tables with a few lines , small schemes ) and avoid oversized images , such as scanned pages , photos from digital cameras that have not been reduced , etc..

To get a rough idea of how much space could occupy an image embedded in a rich text field , multiply the image area for 6.

It follows then that an image could occupy approximately 500x500 1.5 MB (these values are to be considered purely indicative: images of the same size but with a few colors or definitions below may occupy less space).

We recommend that you do not exceed 5 MB in total per field RTF.

If not sure how much space occupies a rich text field, follow this procedure (version 4.0.5 or higher):

- 1 ) From the toolbar to format the text field, click on the "Other Functions" (icon a tool blue);
- 2 ) From the menu contextual, select the command "save text files on the external";
- 3) Specify a file name and the menu drop down "Save as type" choose "Rich Text Format Document";
- 4) In the properties file, check the size of the saved file.

With the advanced feature "**about: config**" was introduced the ability to set the maximum size of the image inserted in the RTF fields.

## 4. How to install CEM4 systems with OS Window XP 32-bit

Packages to be installed in case of problems with SQL Server 2008 on Windows XP

On Windows XP can 'happen that SQL Server 2008 R2 has some problem to install. First, verify that Service Pack 3 and all updates to the system are properly installed.

Then, try to install (or reinstall if already) the following packages:

4.1) Microsoft Windows Installer 4.5

<http://go.microsoft.com/fwlink/?LinkId=123373>

4.2) Microsoft Core XML Services (MSXML ) 6.0

<http://www.microsoft.com/downloads/it-it/details.aspx?FamilyId=d21c292c-368b-4ce1-9dab-3e9827b70604&displaylang=it>

( page there are three packages respectively for 32 /64 bit and IA64) .

4.3) Microsoft SQL Server 2008 Native Client

32-bit systems ( sqlncli.msi ) - 4549 KB: <http://go.microsoft.com/fwlink/?LinkId=123717&clcid=0x410>

64-bit systems ( sqlncli.msi ) - 7963 KB: <http://go.microsoft.com/fwlink/?LinkId=123718&clcid=0x410>

IA64 systems ( sqlncli.msi ) - 11112 KB: <http://go.microsoft.com/fwlink/?LinkId=123718&clcid=0x410>

Next, the setup of the software, in the "Component Selection", select only the following option:  
"Microsoft Visual C + + 2008 Service Pack 1 Redistributable Package ATL Security Update"

After installation is complete , restart the setup of the software and in the "Component Selection", only select the following option:

"Microsoft SQL Server 2005 R2 Express Edition SP2"

On the "Settings MS SQL Server" make the following choice:

- "Custom installation for advanced users"

Follow the prompts on the screen of the SQL Server.

If the problem continues with SQL Server 2008 , and can still download and install SQL Server 2005:

<http://www.microsoft.com/it-it/download/details.aspx?id=15291>

## 5. How to install SAP Crystal Reports runtime for .NET Framework

Packages to be installed in case of problems with SAP Crystal Reports.

In case of errors during the installation of the Crystal Reports runtime errors or viewing reports within the software certify you are advised to follow the following procedure:

5.1) From the "Control Panel" in Windows "Programs and Features", uninstall the "SAP Crystal Reports runtime engine for. NET Framework", if any.

5.2) Download the updated runtime.

Version for 64-bit

systems:[http://downloads.businessobjects.com/akdlm/cr4vs2010/CRforVS\\_redist\\_install\\_64bit\\_13\\_0\\_6.zip](http://downloads.businessobjects.com/akdlm/cr4vs2010/CRforVS_redist_install_64bit_13_0_6.zip)

Version for 32-bit

systems:[http://downloads.businessobjects.com/akdlm/cr4vs2010/CRforVS\\_redist\\_install\\_32bit\\_13\\_0\\_6.zip5](http://downloads.businessobjects.com/akdlm/cr4vs2010/CRforVS_redist_install_32bit_13_0_6.zip5).

3) Unzip the package and run the setup installer.

SAP periodically releases updates the runtime of Crystal Reports that go to fix problems or add new features.

The table updates can be viewed at the following address: <http://scn.sap.com/docs/DOC-7824>

The runtime packages are available in the columns headed "MSI 32-bit" and "64-bit MSI."

# Example

# Risk assessment

## Risk assessment

1. Create a "New Company"

es.

Company Name: **Certifico Srl**

Status: **Enabled**

Other fields are not mandatory, however changed at any time

2. Create a "New Project" assign it to a "**Certifico Srl**"

es:

Project Code: **Project CEM01**

Status: **In progress**

Company membership: **Certifico Srl**

Other fields are not mandatory, however changed at any time

3. Create a "**New Machinery**" assign to "**Project CEM01**"

Machine Name: **Machinery 01**

Model: **Model 01**

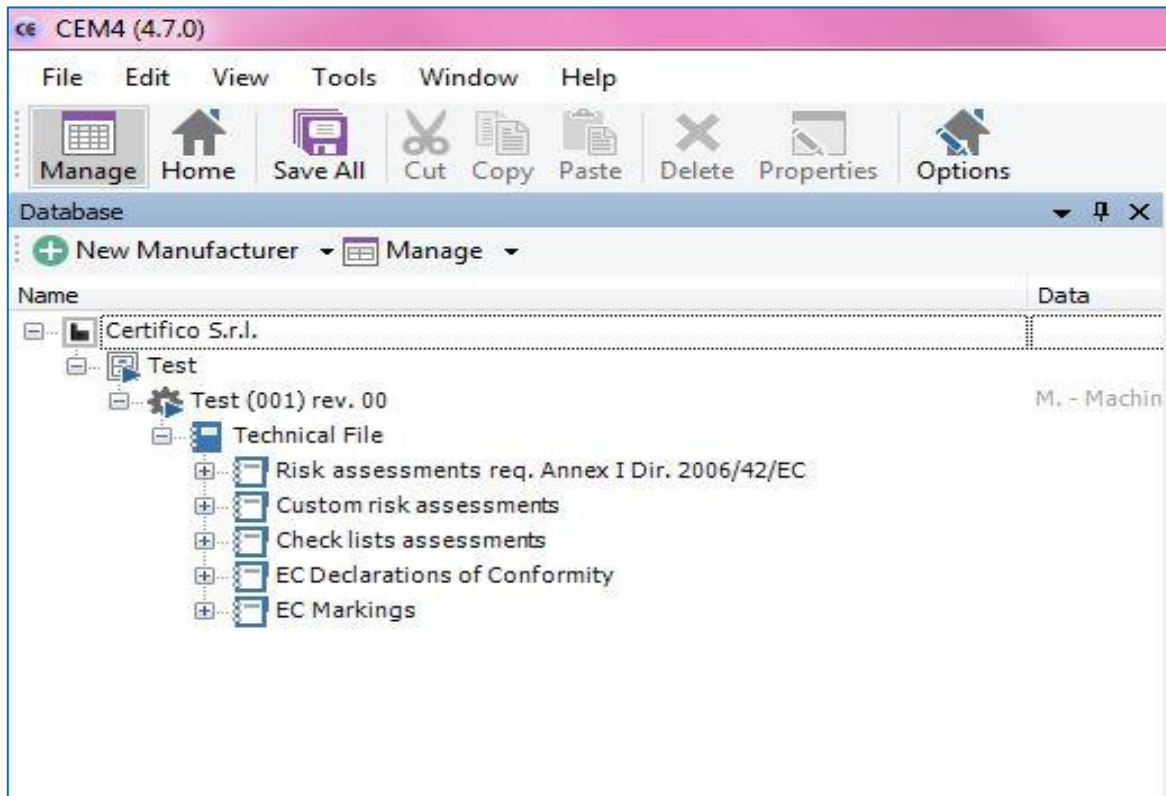
Serial number: **Serial 01**

Status: **In progress**

Project affiliation: **Project CEM1**

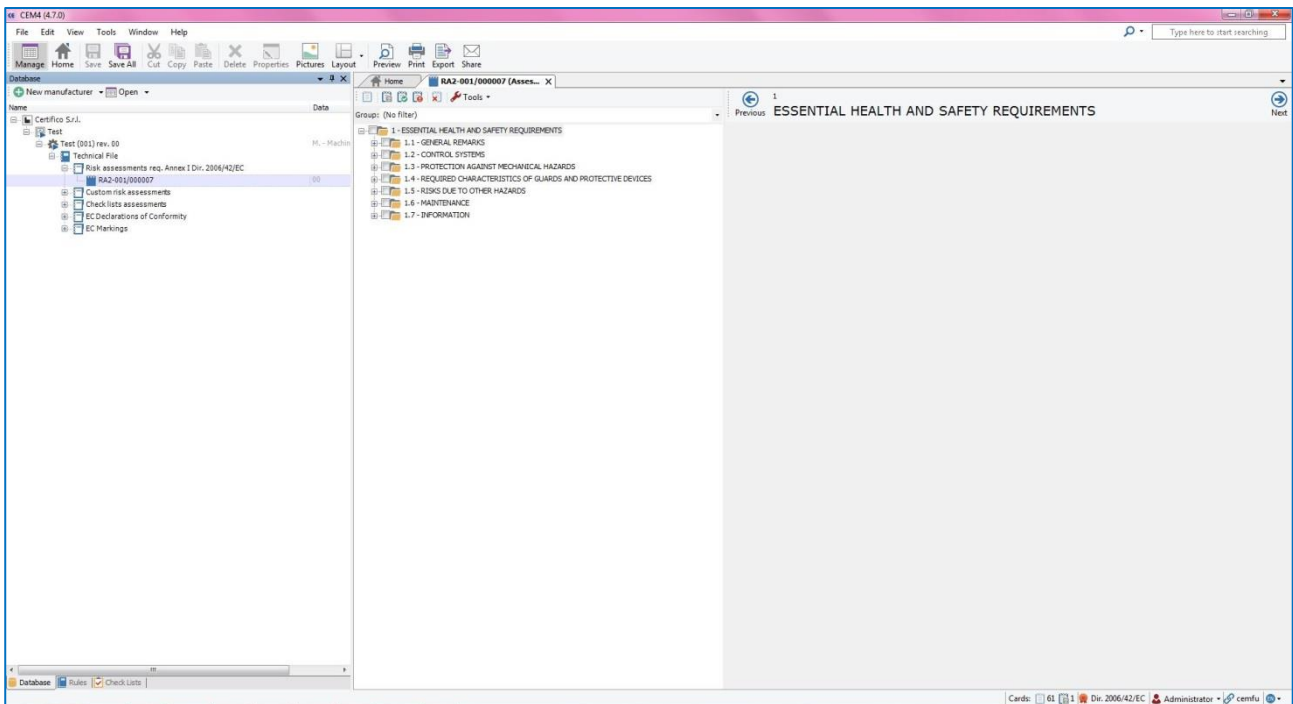
Other fields are not mandatory, however changed at any time

4. Open the tree of the **Certifico Srl - Project CEM01 - Machinery 01** folders will be displayed:



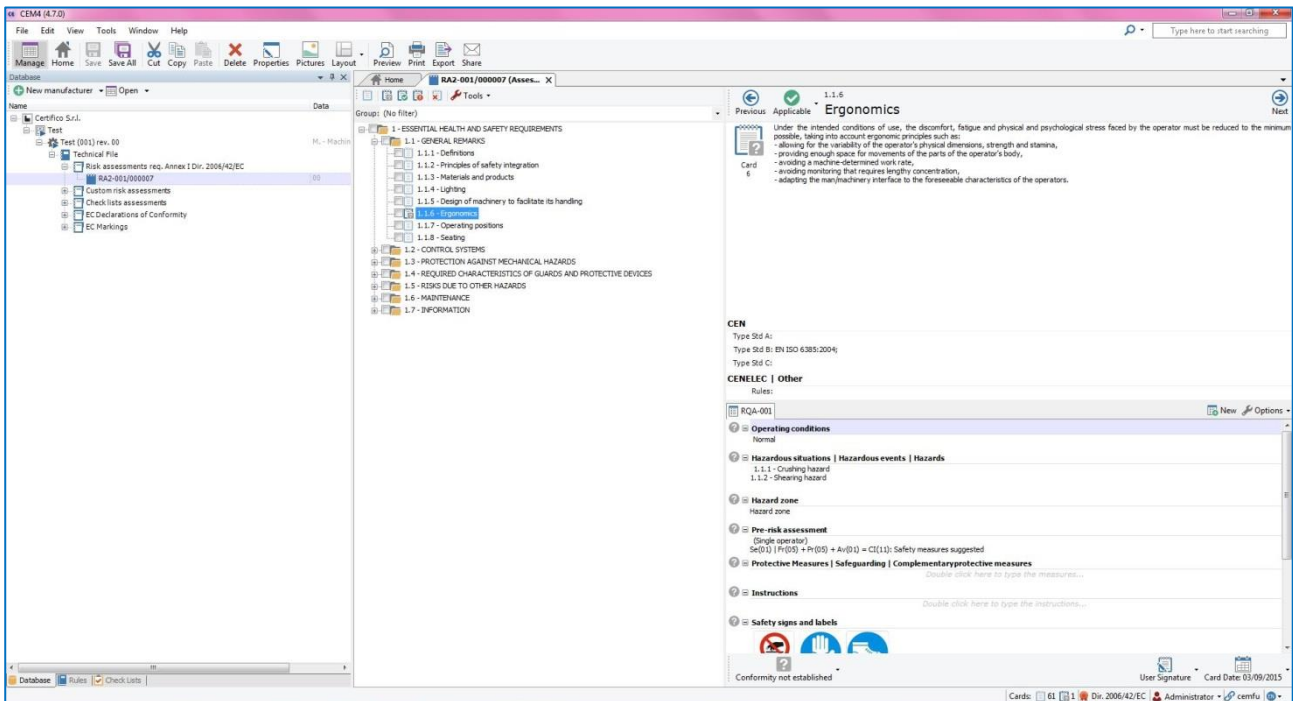
5. Open Folder "**Risk assessments**"

6. Clic "**RA2-001/000016**" and open one EHSR:



7. In the next screen the steps of Risk Assessment with feedback to the Applicability of the EHSR (A), the harmonized standards Presumption of Conformity (N), the Evaluation Sheet RA (in accordance with EN ISO 12100) and the Compliance EHSR (C).

For other hazards related EHSR will be multiple tabs open RA.



8. In the next screen, initial and final/residual Risk estimation, in agreement with the **Hybrid Tool of Technical Report ISO/TR 14121-2 p. 6.5:**

The screenshot displays the CEM4 (4.7.0) software interface. The main window shows a project tree on the left with 'RA2-001/000007 (Asses...)' selected. The central pane displays a hierarchical list of requirements under '1 - ESSENTIAL HEALTH AND SAFETY REQUIREMENTS', including '1.1 - GENERAL REMARKS' and '1.2 - CONTROL SYSTEMS'. A 'Risk assessments' dialog box is open, showing two tables for risk estimation. The top table is for 'Pre-risk assessment' and the bottom table is for 'Follow-up risk assessment'. Both tables use a color-coded matrix to represent risk levels based on Class CI (F+P+Av) and Class CII (F+P+Av). The right pane shows 'Ergonomics' requirements, such as '1.1.6 - Ergonomics', which states that operator stress must be reduced. The bottom status bar indicates 'Conformity not established' and shows user information: 'User: Administrator', 'Card Date: 03/09/2013'.

# Custom risk Assessment

---

## Custom risk assessment

With CEM4 is possible to build the customized risk assessment, for example:

- Risk Assessments of technical standards
- Risk Assessments of Requirements / Specifications, etc..

It's possible directly generate the document on which to make the assessment that import it directly from the site cem4.eu, section "**CEM file**", carefully read the [Disclaimer CEM file](#).

## Import CEM file (type Standards)

Import CEM file "**Standards.cem**"

1. Unzip the file **.zip** on the extracted file is **Standards.cem**
2. Open the menu "**File**" CEM4 select "**Import from file Standards**"
3. Select the file "**Standards.cem**"
4. Start
5. After import, the file will be visible in the "**Standards**" of CEM4.

## Custom risk assessment

1. Create a "**New Company**"

es.

Company Name: **Certifico Srl**

Status: **Enabled**

Other fields are not mandatory, however changed at any time

2. Create a "New Project" assign it to a "**Certifico Srl**"

es:

Project Code: **Project CEM01**

Status: **In progress**

Company membership: **Certifico Srl**

Other fields are not mandatory, however changed at any time

3. Create a "**New Machinery**" assign to "**Project CEM01**"

Machine Name: **Machinery 01**

Model: **Model 01**

Serial number: **Serial 01**

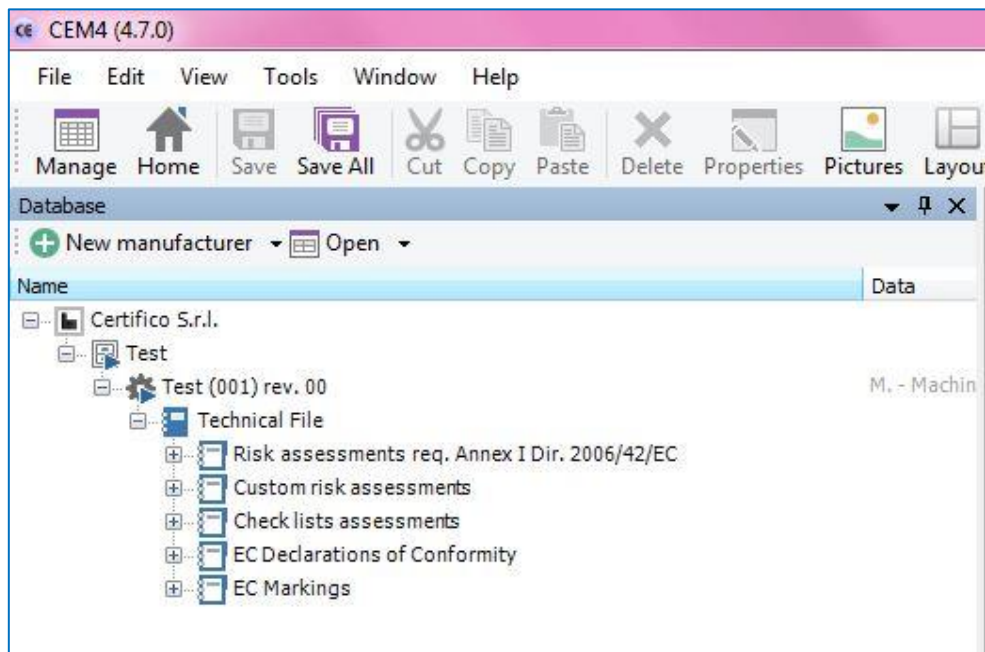
Status: **In progress**

Project affiliation: **Project CEM1**

Other fields are not mandatory, however changed at any time

4. Open the tree of the **Certifico Srl - Project CEM01 - Machinery 01** folders will be displayed:

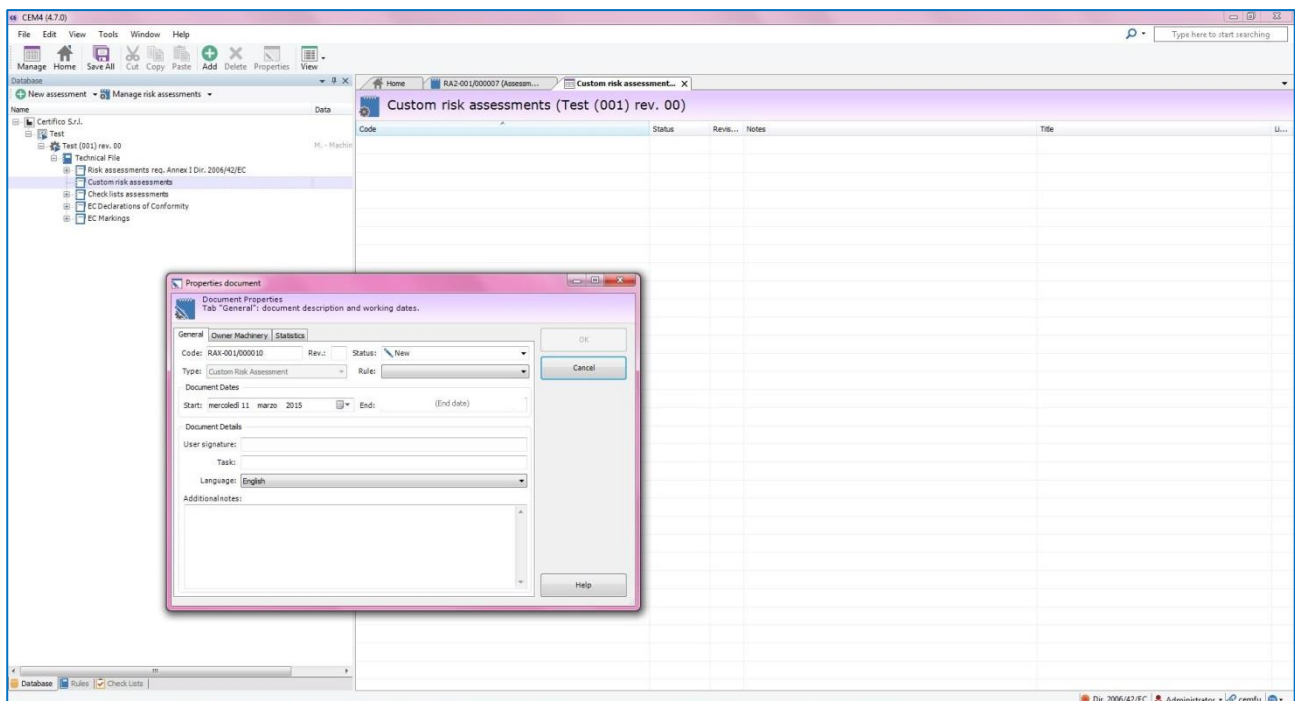




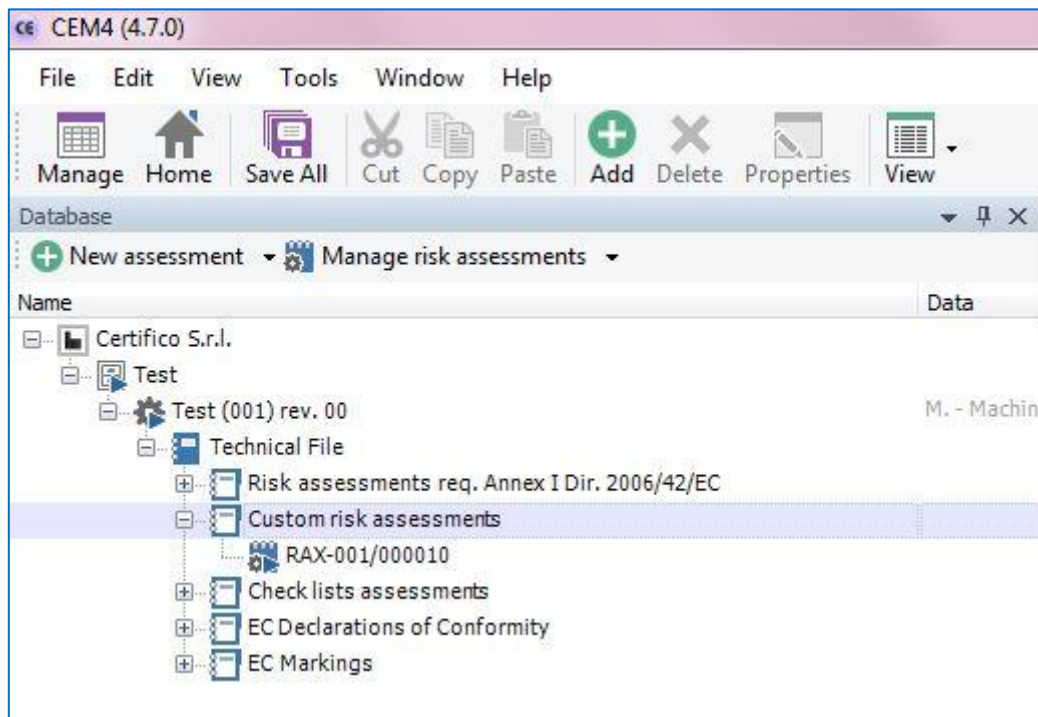
5. Open folder "**Custom risk assessment**"

6. Click on the "**(+) Add**" in the main menu at the top, it will open a window "**Document Properties**"

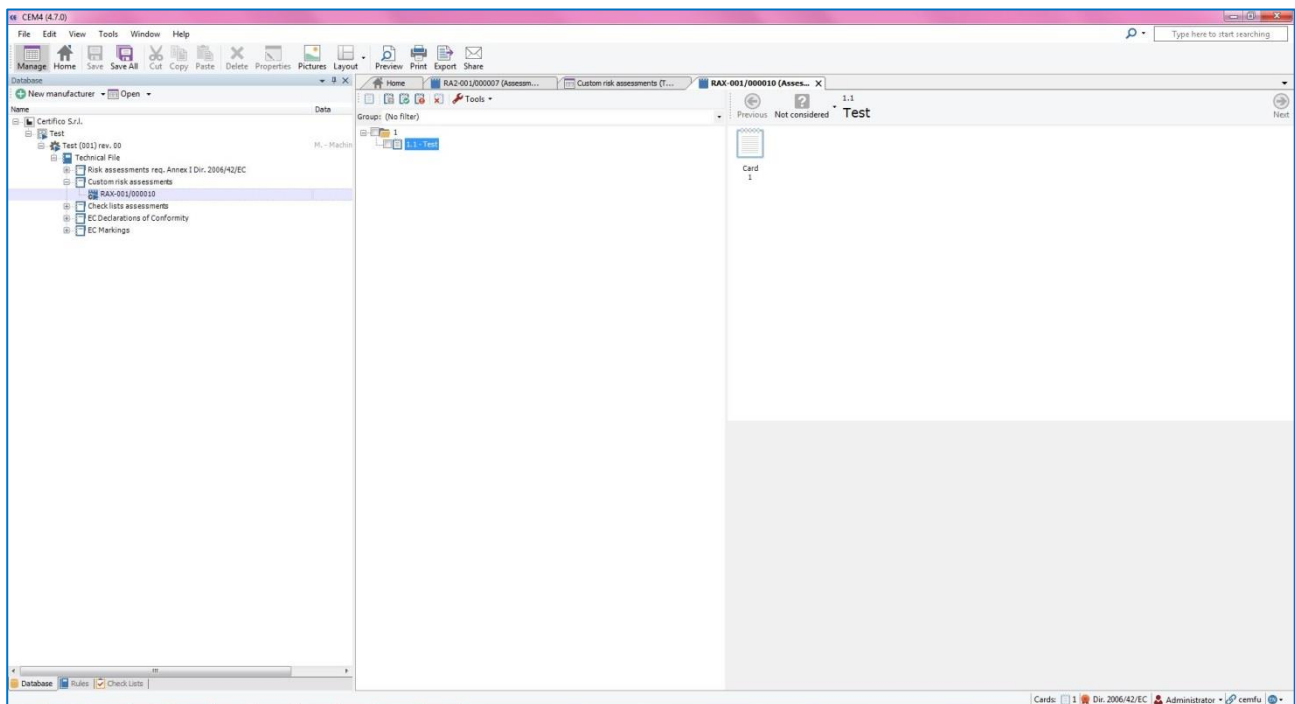
7. On the "Document Properties" will appear by default Code (es) RAX **001/000011** of the document, select in the drop-down menu a "**custom risk assessment**":



8. In the folder "Checklist assessment" will present the new document **CLK 001/000011** on which to make a rating:



9. Open document **RAX 001/000021** you will see the screen working for the **Custom risk assessment** as shown below:



# Assessment check list

---

## Check-list assessment

[Disclaimer CEM file](#)

## Import CEM file (type check list)

### Import a file CEM. "check\_list.cem"

1. Unzip the file **.zip** on the extracted file is **check\_list.cem**
2. Open the menu "File" CEM4 select "**Import from file Checklist**"
3. Select the file "**check\_list.cem**"
4. Start
5. After import, the file will be visible in the "**checklist**" of CEM4.

## Assessment check-list

### 1. Create a "New Company"

es.

Company Name: **Certifico Srl**

Status: **Enabled**

Other fields are not mandatory, however changed at any time

### 2. Create a "New Project" assign it to a "Certifico Srl"

es:

Project Code: **Project CEM01**

Status: **In progress**

Company membership: **Certifico Srl**

Other fields are not mandatory, however changed at any time

### 3. Create a "New Machinery" assign to "Project CEM01"

Machine Name: **Machinery 01**

Model: **Model 01**

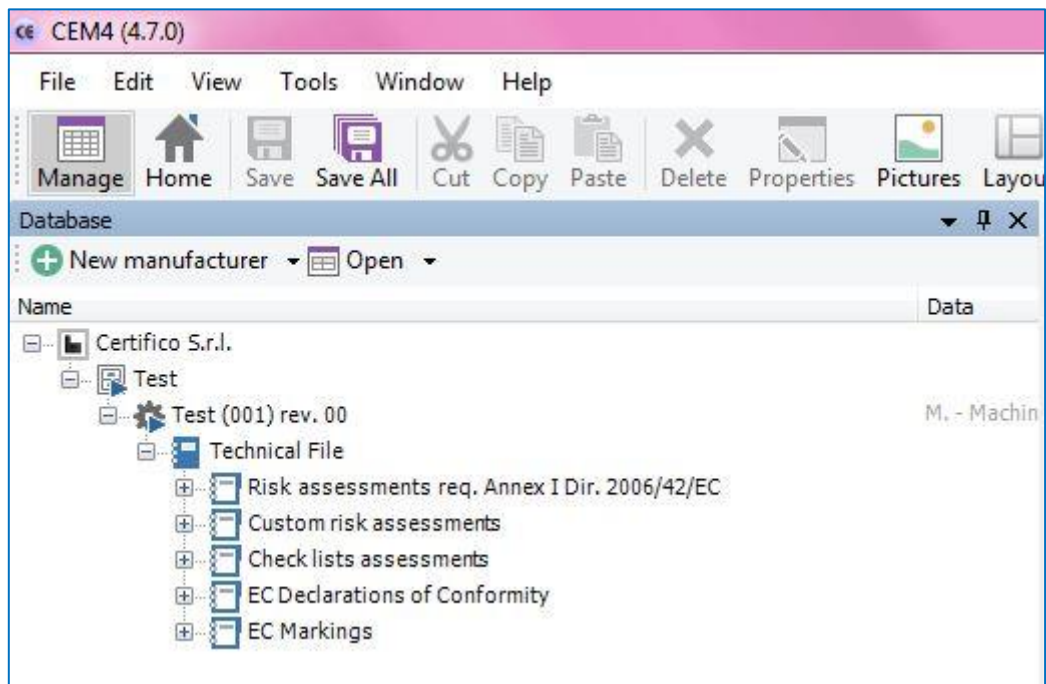
Serial number: **Serial 01**

Status: **In progress**

Project affiliation: **Project CEM1**

Other fields are not mandatory, however changed at any time

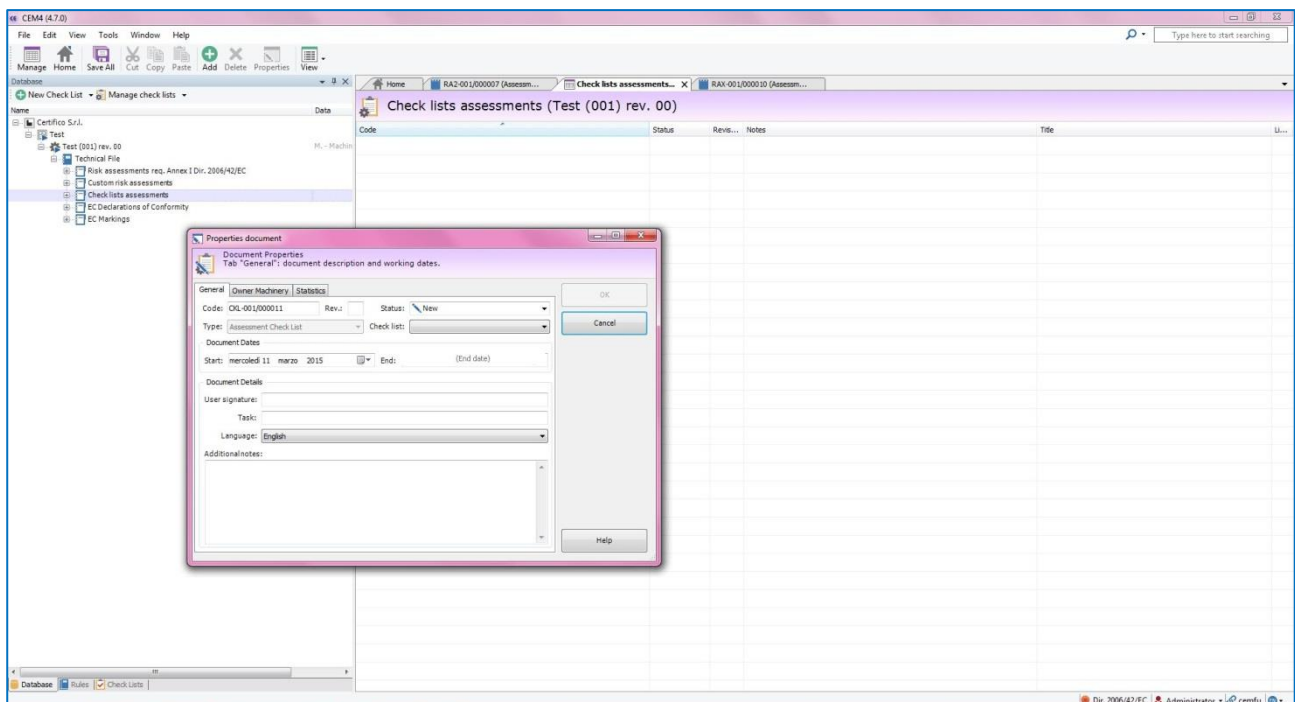
### 4. Open the tree of the **Certifico Srl - Project CEM01 - Machinery 01** folders will be displayed:



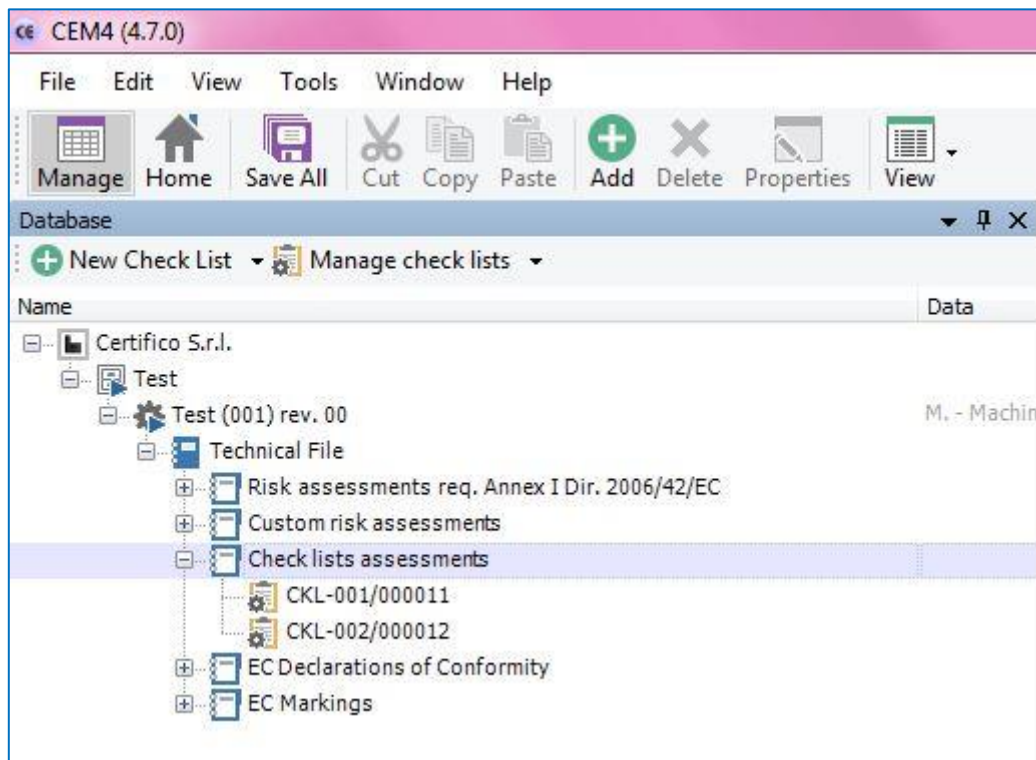
5. Open folder "**Check list assessment**"

6. Click on the "**(+) Add**" in the main menu at the top, it will open a window "**Document Properties**"

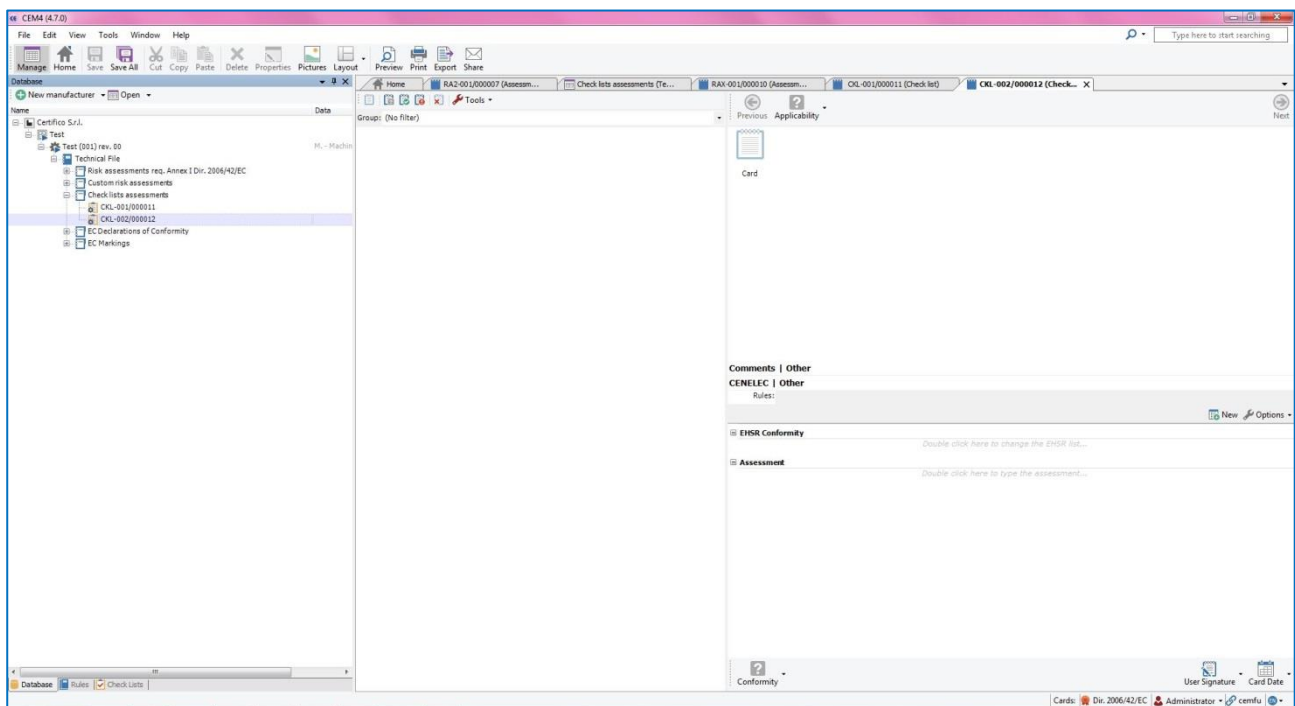
7. On the "Document Properties" will appear by default Code (es) **CLK 001/000011** of the document, select in the drop-down menu a "**check lists**":



8. In the folder "Checklist assessment" will present the new document **CLK 001/000011** on which to make a rating:



9. Open the document **CLK 001/000011** you will see the screen working for the **Assessment Checklist** as shown below:



# Technical file

## Technical file

The **Technical Construction File - FTC**, or more simply, the **Technical File - FT** is, in short, " all documents " that the manufacturer must prepare to comply with the requirements of the Machinery Directive (see what says the [Machinery Directive](#)) .

The **Technical File** shall be made available to the competent authorities of the Member States for **at least 10 years** from the date of manufacture of the last unit produced in the case of mass production.

The section of the **Technical File**, present in the Tree Archive, allows you to generate an **index of the documents** contained the FT.

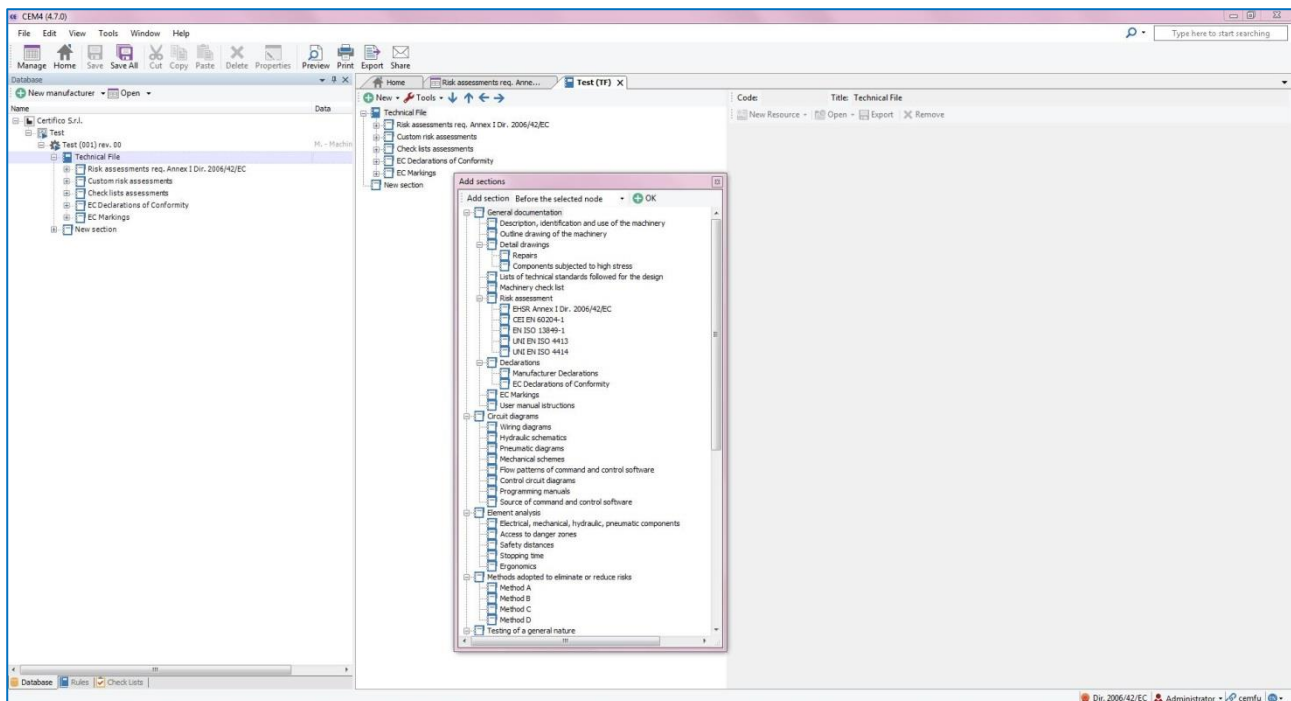
**CEM4** also allows you to manage documents created with other software (es, technical drawings, documents, photographs , etc.). , Through import in the database, or simply link.

It's possible print a complete **index** of the material in the **Technical File**, and you can also print the section separators to organize their **Technical File**.

The documents can be organized in a tree structure according to the section , subsection, to which they belong.

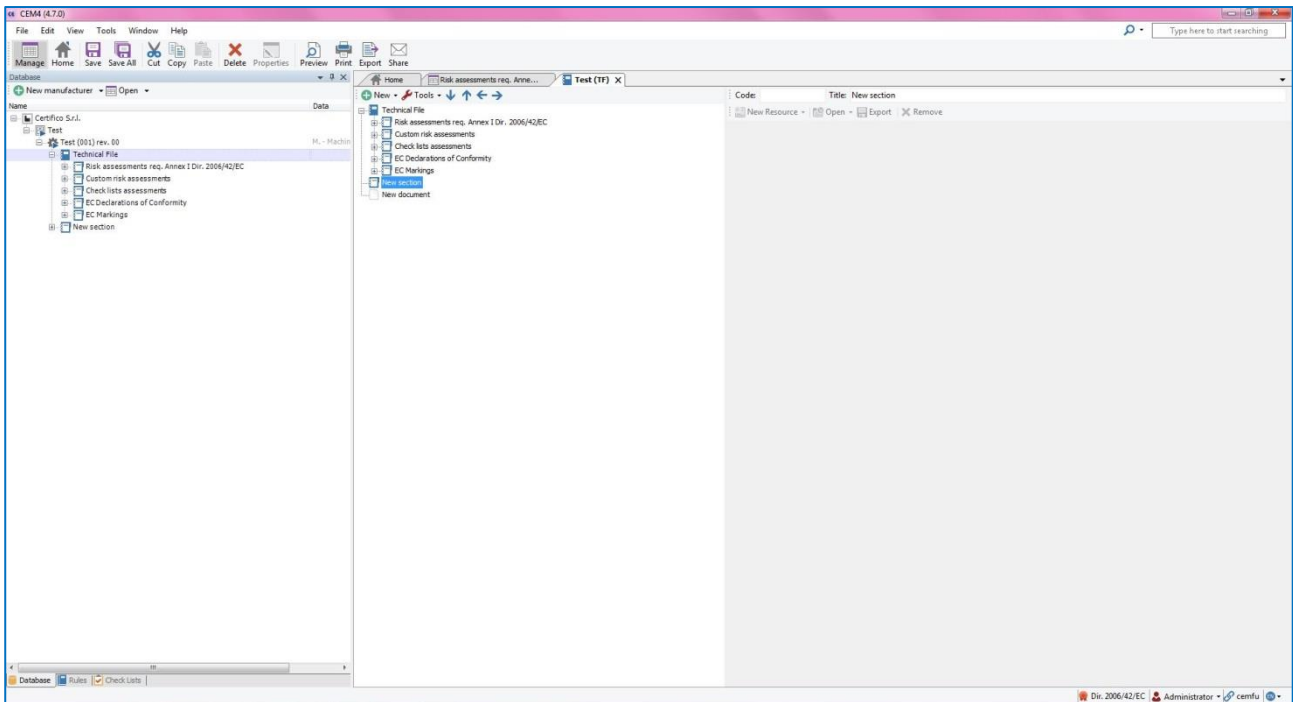
## New Section

To create a new section of the **FT**, select New from the Tree of the central FT one of the entries : **New Section**, etc., or to add this to a Model:



## New Document

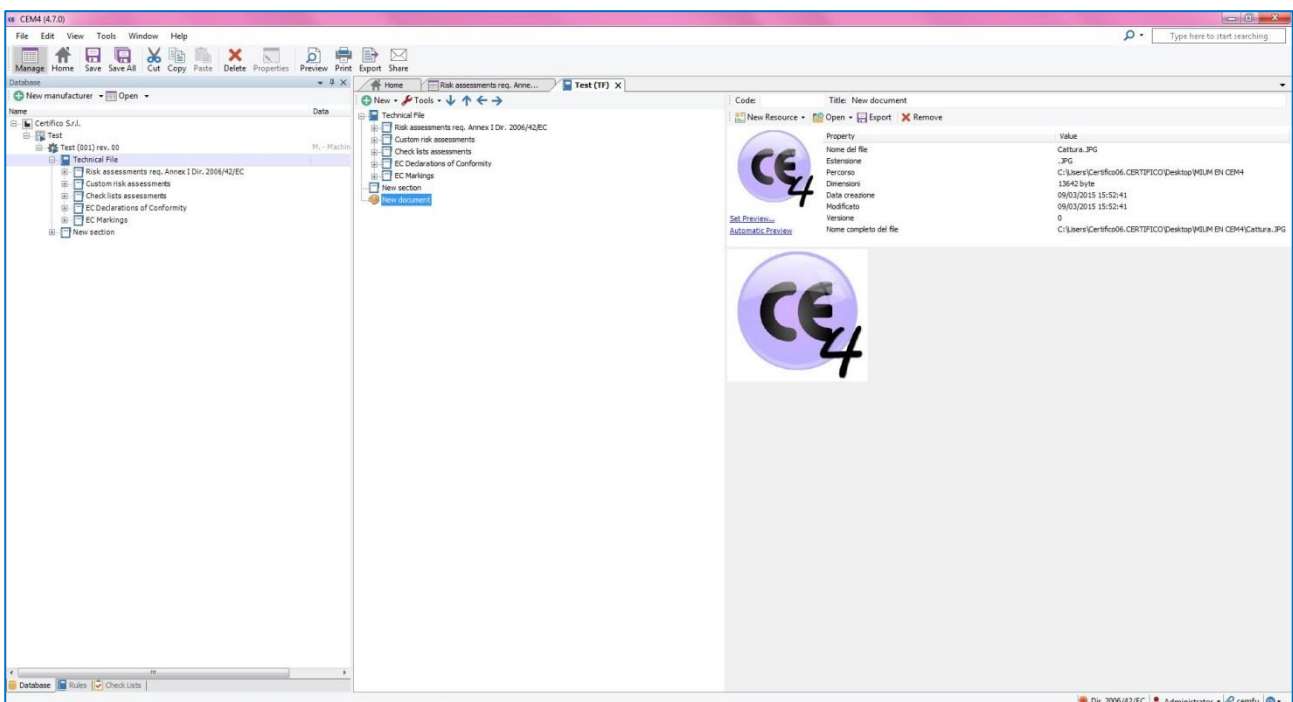
To insert a document in the Tree of the **FT**, select "**New**" from the menu, the voice of the "New Document" should appear on the right of the Tree of the FT, that item will reference a resource. It's possible to insert documents outside or inside sections (chapters):



## Related Resources

The document generated in the FT can be connected to a resource, both as a simple link that CEM4 **imported** into the database, this resource will be open from CEM4 read/write with the launch of its application.

The resource can be an image, a text document, and so on.:



# CEM Standards Update file

## General Standards Update file

Upgrade CEM4 Rel 4.6.4, adds an important feature of the **Update of Harmonized Standards**.

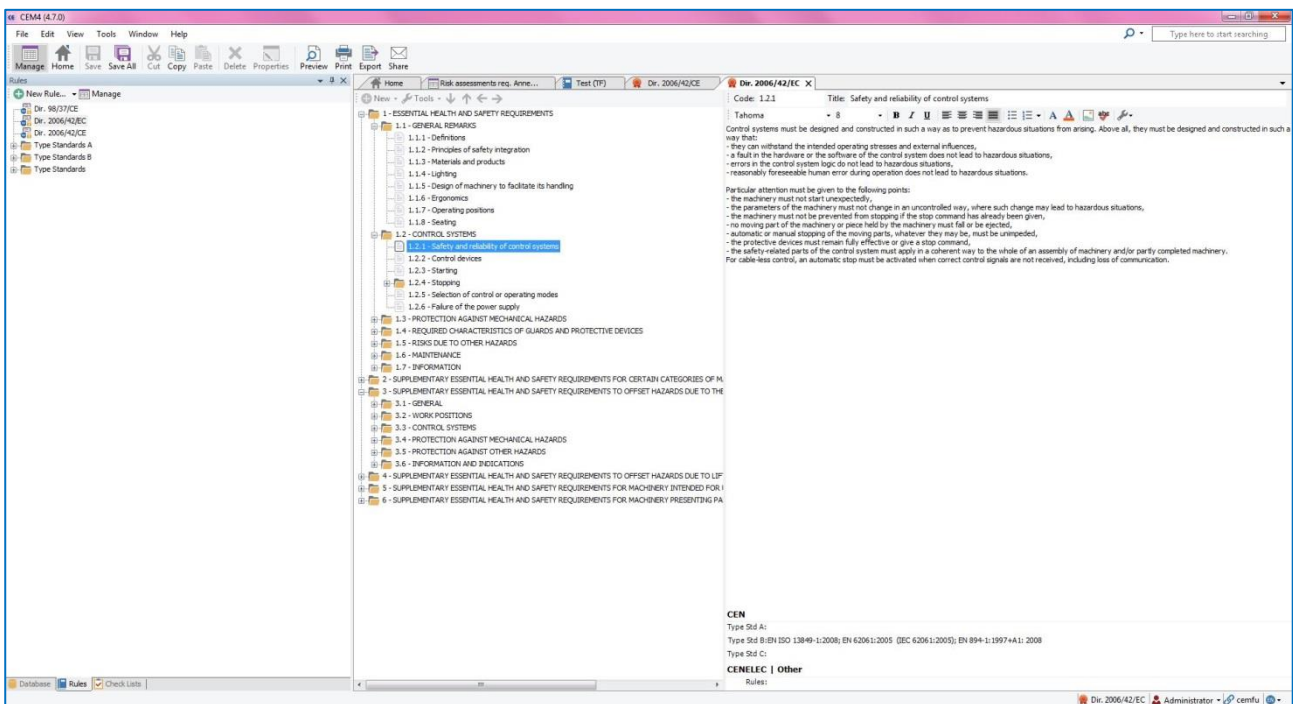
It will be so prepared and maintained a file of **Update Standards type "CEM"**, with which we can provide an update desynchronized type of **"Rules CEM"** by an update of the type **"software exe"** to CEM4 .

With the **Update Standards**, you can update the DB with data retrieval of the standards used in the management of the **Risk Assessment** in **"Presumption of Conformity"** there by guaranteeing a better standards control over the raw data.

Any changes to the rules given in the document concerned, whether due to user customizations or previous file import Update CEM standards, will be "frozen" and will also adopt a system of **"Change Tracking"** related to modifications, substitutions and terminations of standards in time.

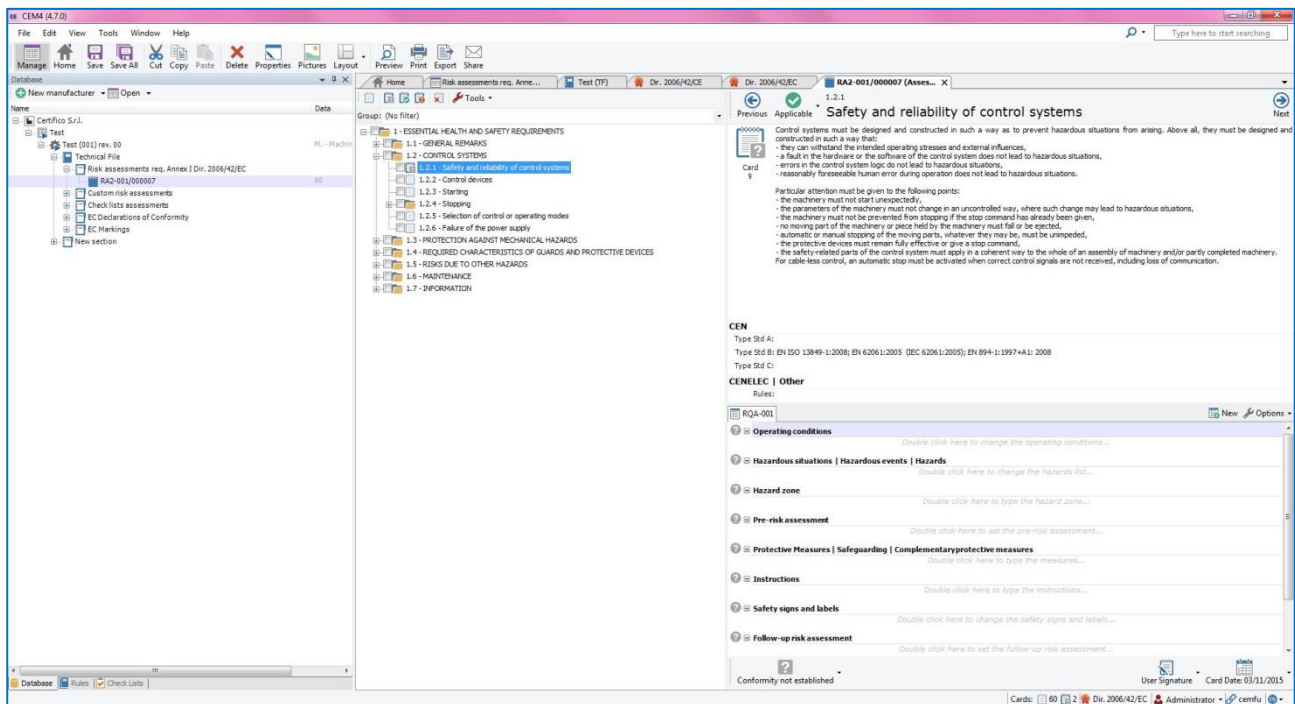
**CEM4 Update standards** by importing the file will be updated to reference standards (heading and possible description) that underlie each **EHSR**.

The new view of technical standards for **EHSR** in **"Rules"** is as follows :





The new view of technical standards for **EHSR** in "**Risk Assessment**" is as follows:



The Technical Standards Harmonized EN for the Machinery Directive 2006/42/EC, subdivided into **type A/B/C (EN CEN )** and **CENELEC EN Uncategorized**, have been renovated in readability in an organic way, and in this form, **as Communication from the Commission on November 28, 2013.**

Harmonized standards Machinery Directive Communication Last February 13, 2015 are on our website [www.cem4.eu](http://www.cem4.eu) :

[Online Standards Harmonized](#) | [Download Standards Harmonized](#).

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