

LORENZ eValidator 5.3.0

(Incluye Nuevas Reglas de Validación Septiembre 2013)

[Nees New Validation Criteria v.4.0](#) 

[Ectd New Validation Criteria v.5.0](#) 

1. DESCARGA E INSTALACIÓN

Descarga desde:

Directamente pinchando en el enlace de la AEMPS

<http://www.lorenz.cc/eSolutions/eValidator/index.cfm?getFile=Yes>

o desde la pagina de Lorenz




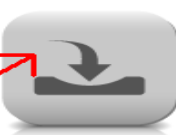
<http://www.lorenz.cc/eSolutions/eValidator/>

The World's Most Complete eValidator: eCTD, Nees, PDF Analysis and more.

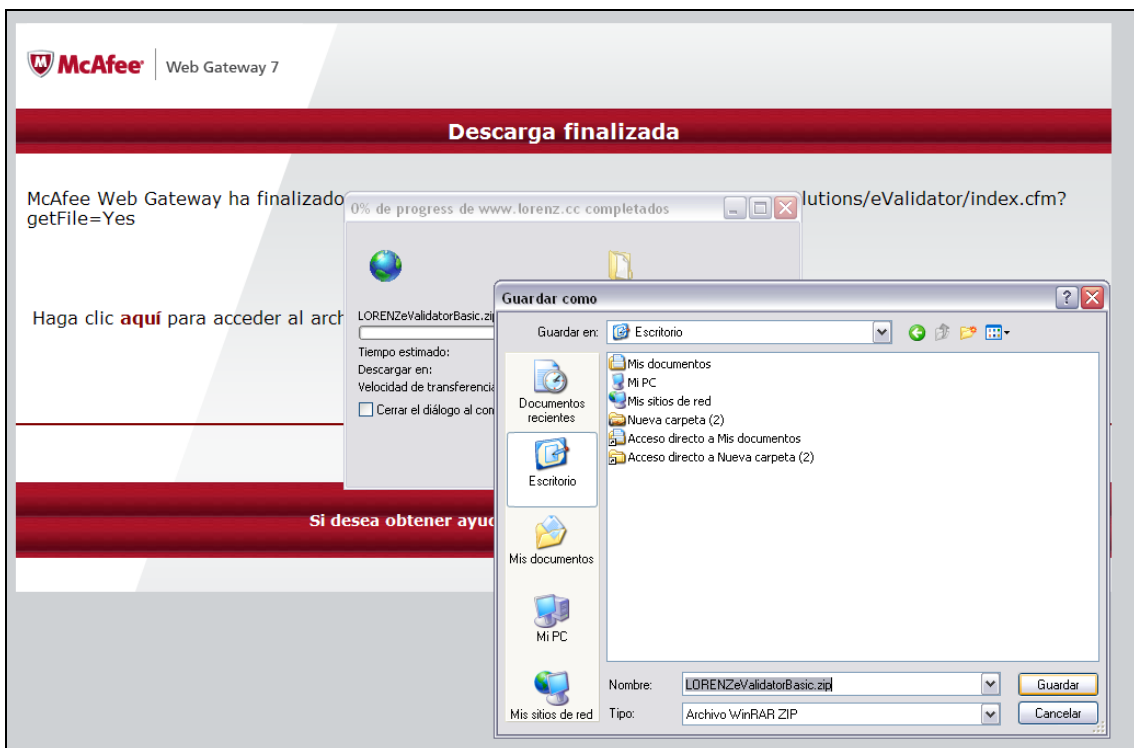
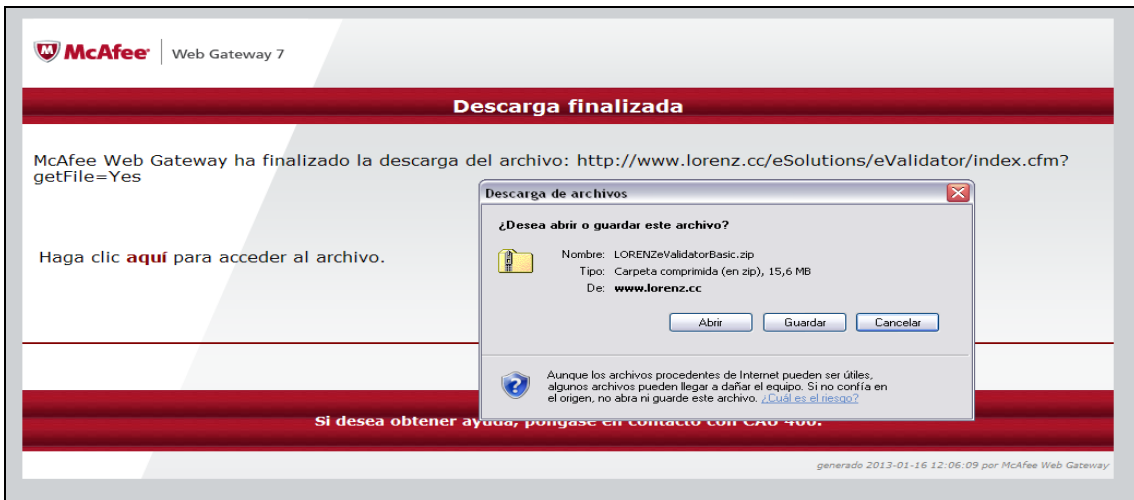
<h4>eValidator BASIC - Free</h4> <p>The world's most complete multi-region eValidator is yours - for free! Current version: 5.1 HF1</p> <p>Download Now</p>	<h4>eValidator PROFESSIONAL</h4> <p>For organizations that require more functionality, want to run multi-region validations in parallel and want to integrate the eValidator engine further into their operational processes, the eValidator Professional may be the tool for you. If you are interested in knowing more about benefits and prices, please contact your regional sales representative.</p> <p>Contact Me!</p>
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Download Free LORENZ eValidator Basic

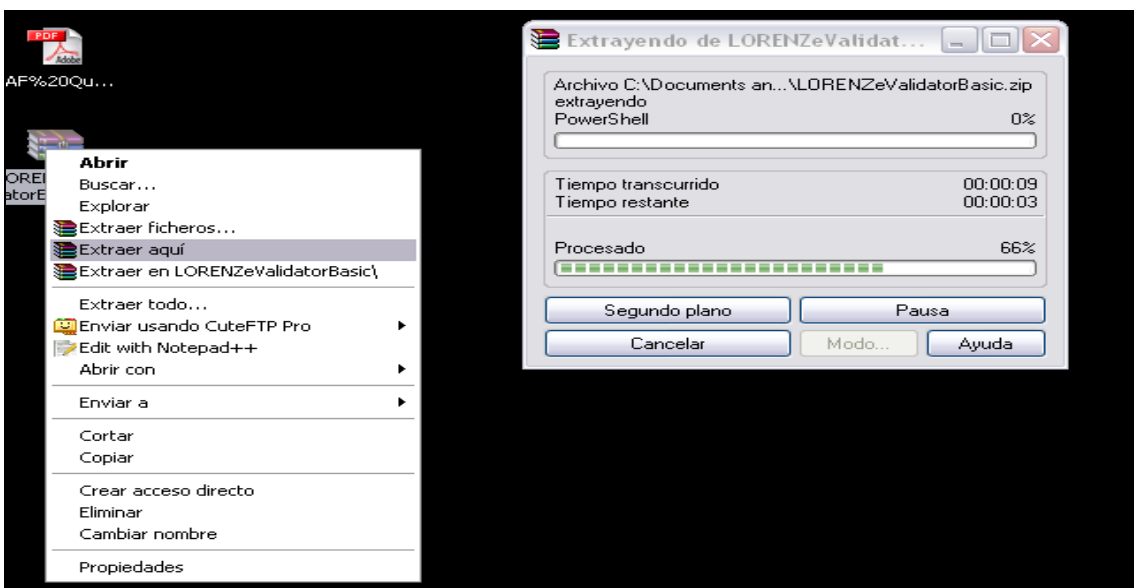
You have two options:

 <h4>Download with registration</h4> <p>Advantages:</p> <ul style="list-style-type: none">• Notification of updates• Access to video tutorials• Access to feature request system 	 <h4>Download without registration</h4> 
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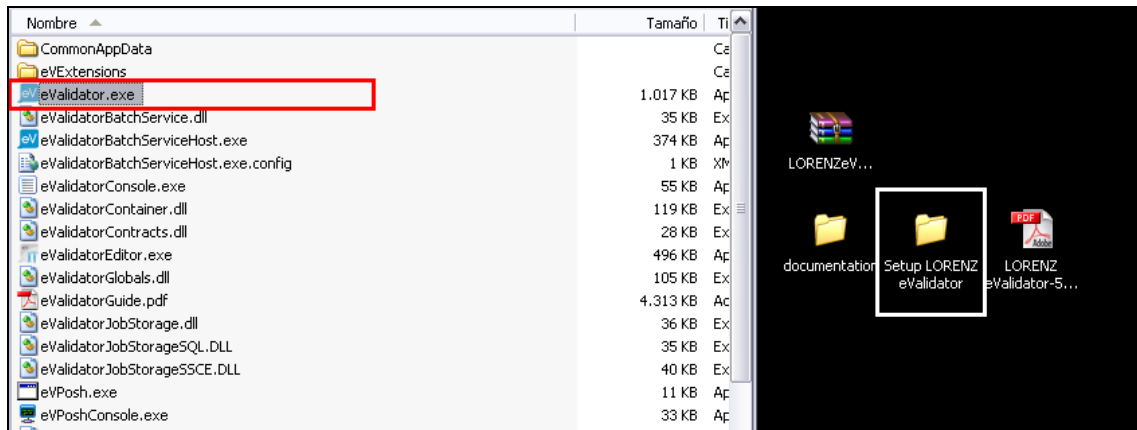
The version you will be downloading will contain all country and submission profiles available for the Basic version. Upon installation, you will be asked to choose one. The profiles are identical to the ones found with our regulatory agency customers.



Guardamos el archivo en el PC y lo descomprimos:



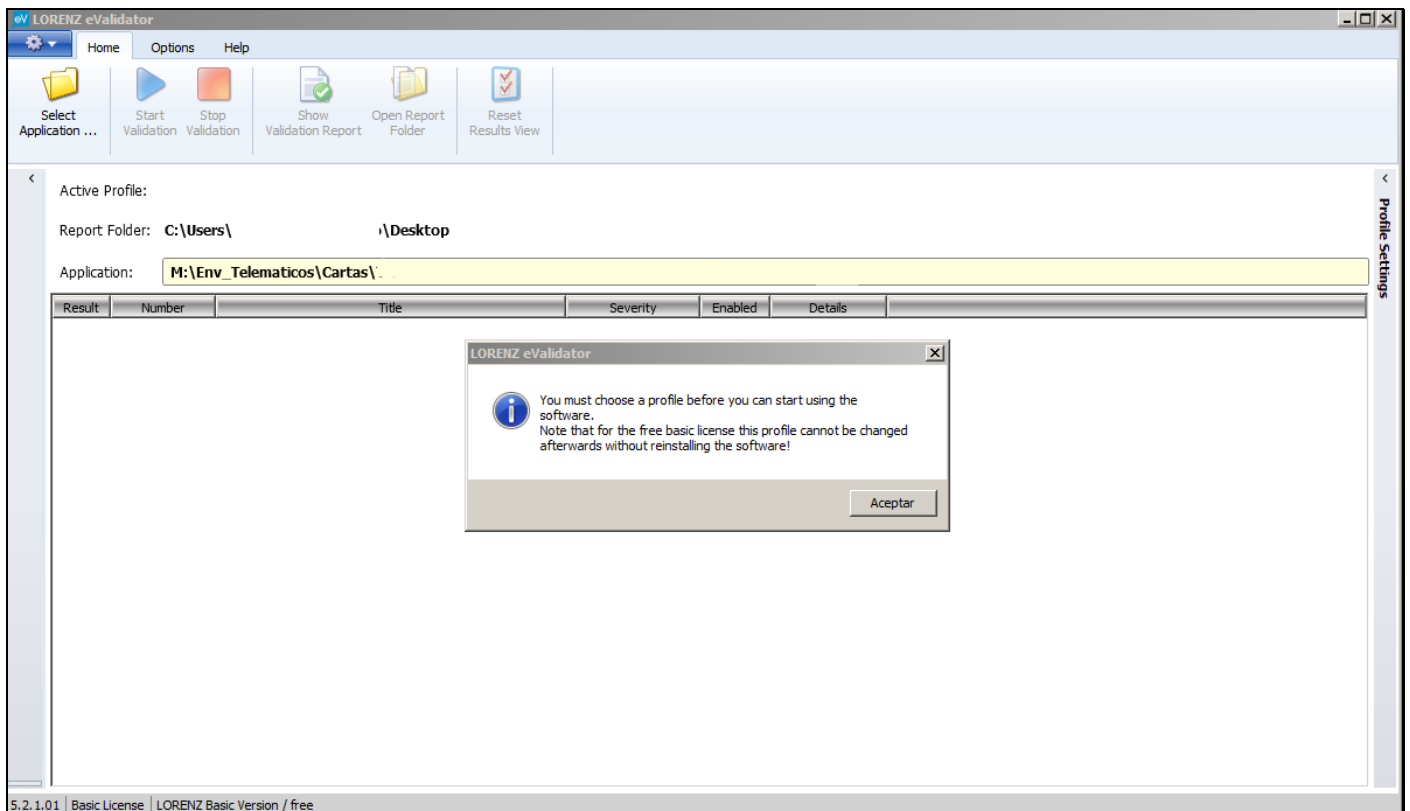
Tendremos tres carpetas, tras descomprimir el archivo. Localizamos en una de ellas " Setup LORENZ eValidator" el ejecutable "eValidator.exe"



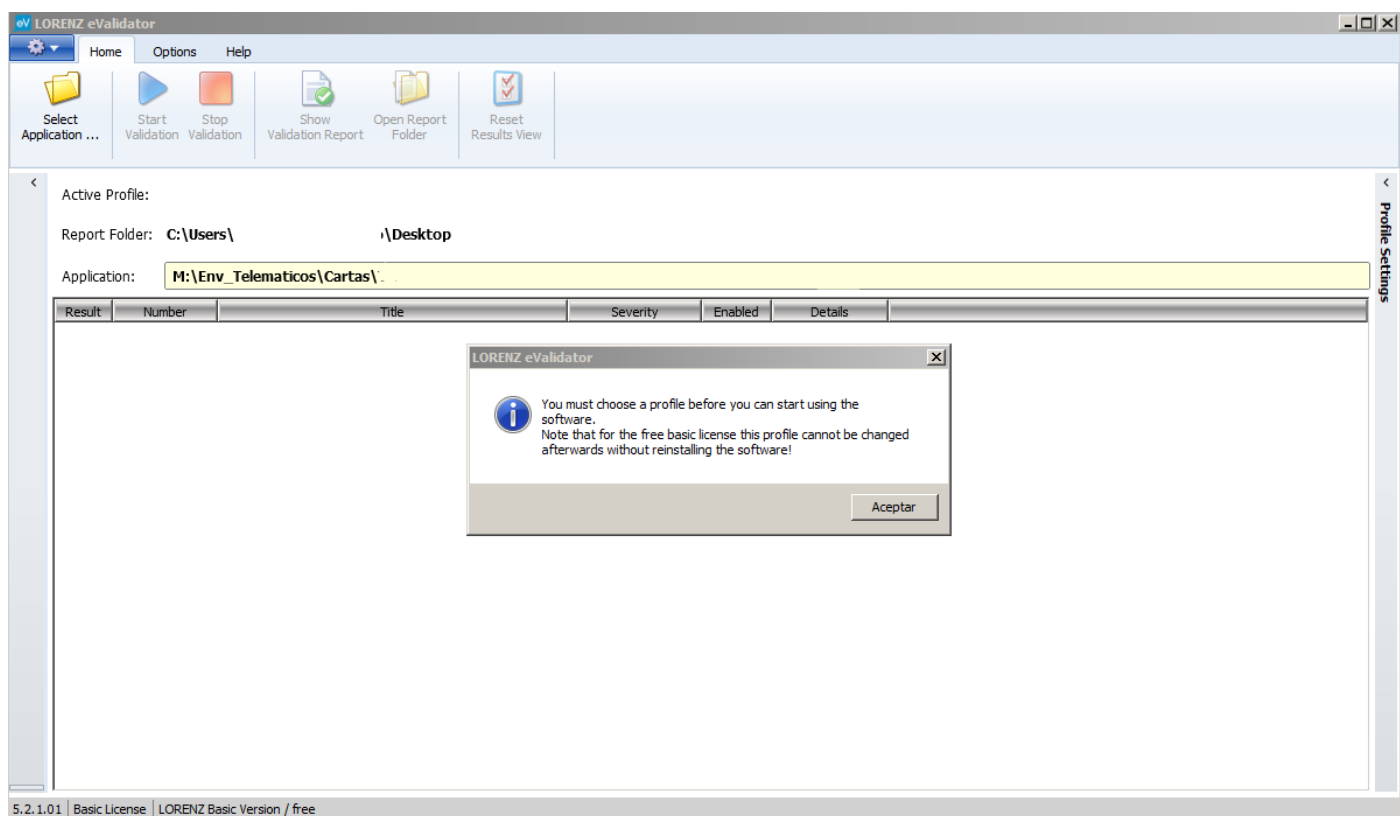
Iremos aceptando las diferentes pantallas que vayan apareciendo (Siguiente/Next) hasta finalizar

2. USO DEL VALIDADOR

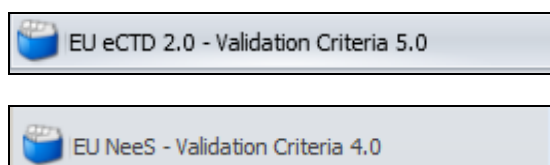
La primera vez que lo ejecutemos, nos pedirá indicar el perfil a utilizar. En esta versión gratuita será necesario reinstalar el programa para modificar el perfil seleccionado.



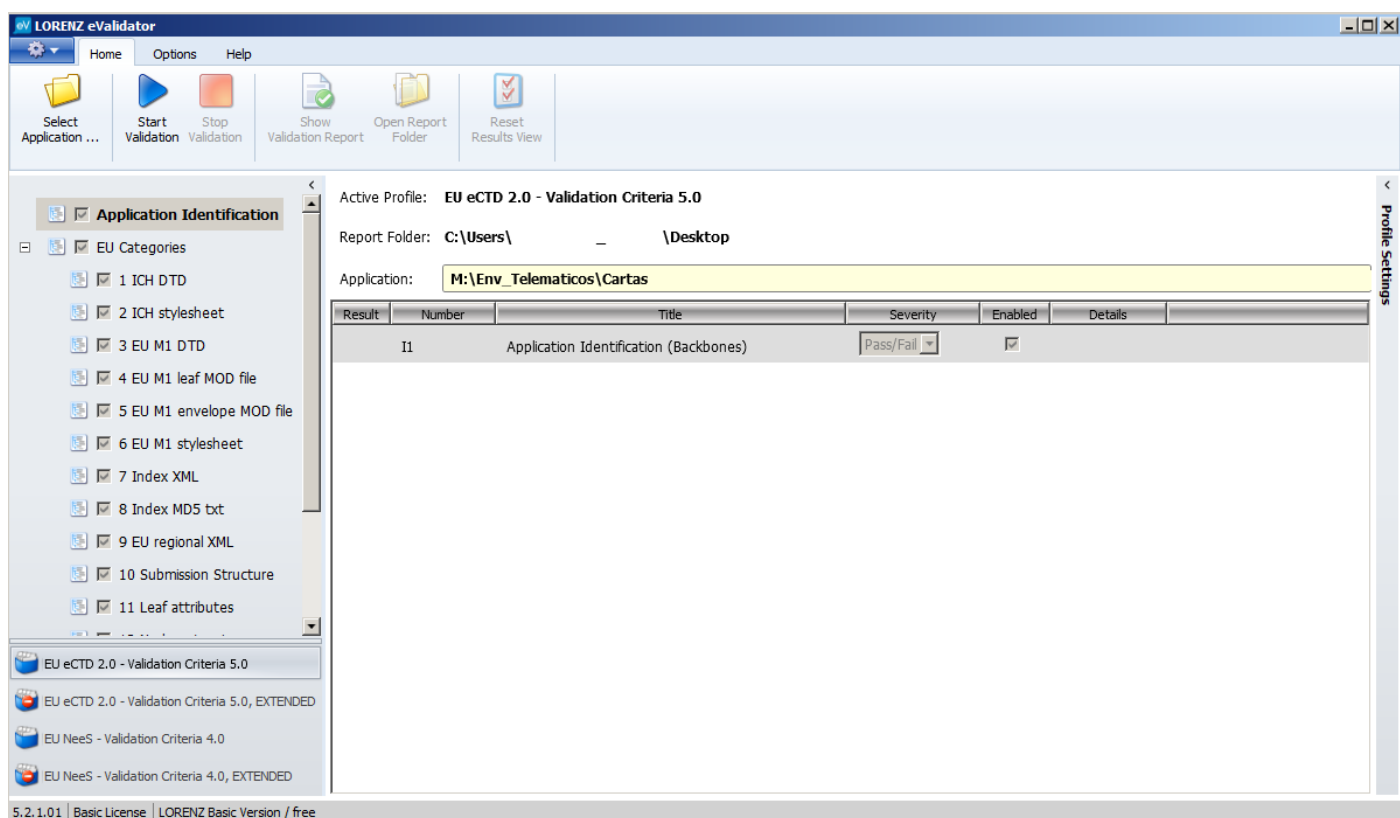
En nuestro caso seleccionaremos el perfil EU con las últimas reglas de validación aprobadas



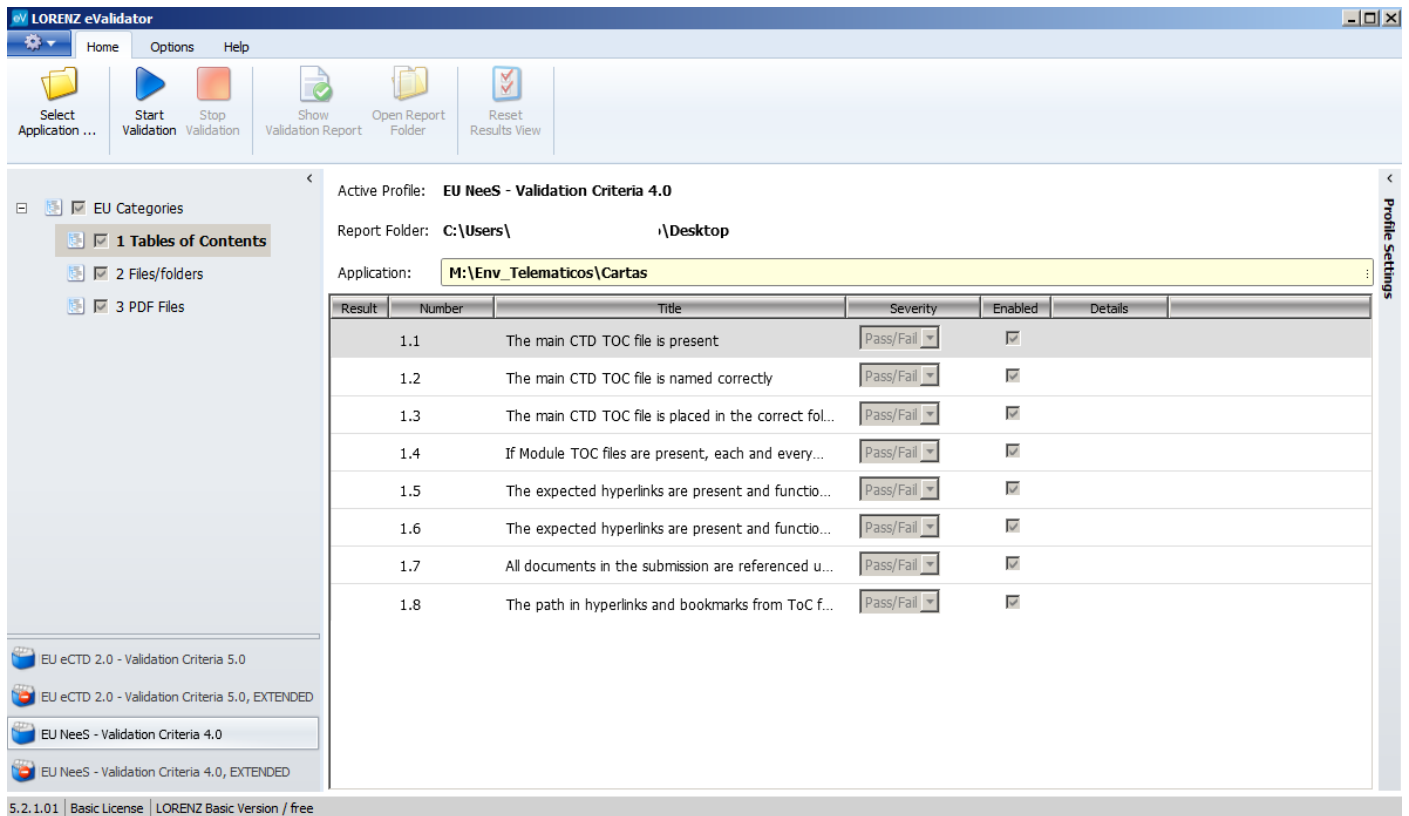
En función del formato de la secuencia a validar, seleccionaremos entre las opciones



En el caso de eCTD :



En el caso de formato Nees :



LORENZ eValidator

Home Options Help

Select Application ... Start Validation Stop Validation Show Validation Report Open Report Folder Reset Results View

Active Profile: **EU Nees - Validation Criteria 4.0**

Report Folder: C:\Users\... \Desktop

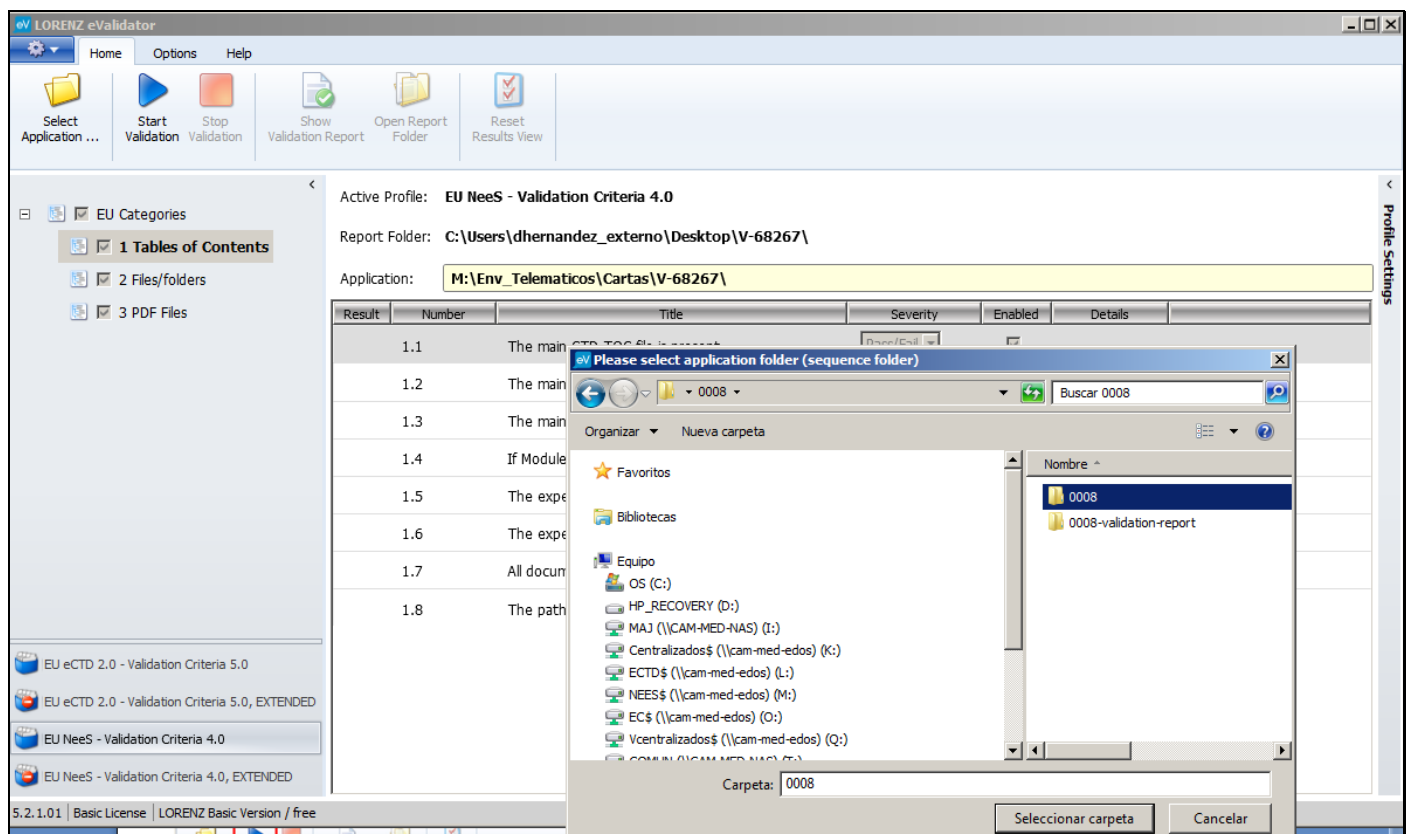
Application: **M:\Env_Telematicos\Cartas**

Result	Number	Title	Severity	Enabled	Details
	1.1	The main CTD TOC file is present	Pass/Fail	<input checked="" type="checkbox"/>	
	1.2	The main CTD TOC file is named correctly	Pass/Fail	<input checked="" type="checkbox"/>	
	1.3	The main CTD TOC file is placed in the correct fol...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.4	If Module TOC files are present, each and every...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.5	The expected hyperlinks are present and funcio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.6	The expected hyperlinks are present and funcio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.7	All documents in the submission are referenced u...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.8	The path in hyperlinks and bookmarks from ToC f...	Pass/Fail	<input checked="" type="checkbox"/>	

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Seleccionamos la ubicación de la secuencia a validar desde “Select Application”



LORENZ eValidator

Home Options Help

Select Application ... Start Validation Stop Validation Show Validation Report Open Report Folder Reset Results View

Active Profile: **EU Nees - Validation Criteria 4.0**

Report Folder: C:\Users\dherandez_externo\Desktop\V-68267\

Application: **M:\Env_Telematicos\Cartas\V-68267**

Result	Number	Title	Severity	Enabled	Details
	1.1	The main CTD TOC file is present	Pass/Fail	<input checked="" type="checkbox"/>	
	1.2	The main CTD TOC file is named correctly	Pass/Fail	<input checked="" type="checkbox"/>	
	1.3	The main CTD TOC file is placed in the correct fol...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.4	If Module TOC files are present, each and every...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.5	The expected hyperlinks are present and funcio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.6	The expected hyperlinks are present and funcio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.7	All documents in the submission are referenced u...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.8	The path in hyperlinks and bookmarks from ToC f...	Pass/Fail	<input checked="" type="checkbox"/>	

Please select application folder (sequence folder)

0008

Organizar Nueva carpeta

Nombre

- 0008
- 0008-validation-report

Carpetas: 0008

Seleccionar carpeta Cancelar

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➤ Iniciamos la validación desde "Start Validation"

The screenshot shows the LORENZ eValidator application window. The 'Start Validation' button is highlighted with a red arrow. The interface includes a menu bar (Home, Options, Help), a toolbar with icons for Select Application, Start Validation, Stop Validation, Show Validation Report, Open Report Folder, and Reset Results View. On the left, there is a tree view under 'EU Categories' with '1 Tables of Contents', '2 Files/folders', and '3 PDF Files' selected. The main area displays the 'Active Profile: EU Nees - Validation Criteria 4.0' and a table of validation criteria.

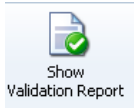
Result	Number	Title	Severity	Enabled	Details
	1.1	The main CTD TOC file is present	Pass/Fail	<input checked="" type="checkbox"/>	
	1.2	The main CTD TOC file is named correctly	Pass/Fail	<input checked="" type="checkbox"/>	
	1.3	The main CTD TOC file is placed in the correct fol...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.4	If Module TOC files are present, each and every...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.5	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.6	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.7	All documents in the submission are referenced u...	Pass/Fail	<input checked="" type="checkbox"/>	
	1.8	The path in hyperlinks and bookmarks from ToC f...	Pass/Fail	<input checked="" type="checkbox"/>	

Comenzará entonces la validación, mostrándose barra de progreso en la parte inferior

The screenshot shows the LORENZ eValidator application window during the validation process. The 'Start Validation' button is now disabled, and the 'Stop Validation' button is active. The progress bar at the bottom of the table is partially filled with blue. The status bar at the bottom of the window displays the version and license information.

Result	Number	Title	Severity	Enabled	Details
●	1.1	The main CTD TOC file is present	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.2	The main CTD TOC file is named correctly	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.3	The main CTD TOC file is placed in the correct fol...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.4	If Module TOC files are present, each and every...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.5	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.6	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.7	All documents in the submission are referenced u...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.8	The path in hyperlinks and bookmarks from ToC f...	Pass/Fail	<input checked="" type="checkbox"/>	

[EU Categories] [3 PDF Files]
[27/01/2014 11:21:58] [3.BP7][The bookmarks pane should be visible if bookmarks are included within a PDF document]



➤ Una vez finalizado, accederemos al informe de validación mediante “Show Validation Report”

The screenshot shows the LORENZ eValidator application window. The 'Show Validation Report' button is highlighted with a red arrow. The interface displays the following information:

- Active Profile: EU Nees - Validation Criteria 4.0
- Report Folder: C:\Users\dhernandez_externo\EDOSSIER\0008\0008
- Application: C:\Users\dhernandez_externo\Desktop\0008\0008

Result	Number	Title	Severity	Enabled	Details
●	1.1	The main CTD TOC file is present	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.2	The main CTD TOC file is named correctly	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.3	The main CTD TOC file is placed in the correct fol...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.4	If Module TOC files are present, each and every...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.5	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.6	The expected hyperlinks are present and functio...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.7	All documents in the submission are referenced u...	Pass/Fail	<input checked="" type="checkbox"/>	
●	1.8	The path in hyperlinks and bookmarks from ToC f...	Pass/Fail	<input checked="" type="checkbox"/>	

Se abrirá una ventana en el navegador con el informe donde se muestran los errores encontrados cuya importancia ira en función del código de color siendo el **rojo** motivo de rechazo, **amarillo** buenas prácticas y **azul** información a destacar.

LORENZ eValidator - Application Validation Report

NeesS

Application name	0008
Full path of application	c:\users\dhernandez_externo\desktop\0008
Sequence	0008
Preceding sequences found in application path	n/a
Other sequences referenced	n/a
Missing referenced sequences	n/a
Profile	EU NeesS - Validation Criteria 4.0
Profile Path	C:\ProgramData\LORENZ Life Sciences\evValidator\Profiles\Profile_EU_NeesS_Val4-0.xml
Profile status	Profile is protected (signed). - v1.1
User name	dhernandez_externo
License information	LORENZ Basic Version / free
Date/time of validation (UTC)	27/01/2014 10:21:57
Date/time of validation (local time)	27/01/2014 11:21:57
Runtime (hh:mm:ss)	00:00:02
Total files	15
Total folders	15
Total size (MB)	4,75
Total PDF documents	15
Total PDF pages	174

Information	0
Best Practice	18
Pass/Fail	0

EU Categories

EU Categories / 1 Tables of Contents

1.1	OK	The main CTD TOC file is present
1.2	OK	The main CTD TOC file is named correctly
1.3	OK	The main CTD TOC file is placed in the correct folder
1.4	OK	If Module TOC files are present, each and every module folder (m1, /m2, etc.) contains the correctly named Module TOC file
1.5	OK	The expected hyperlinks are present and functioning in the main CTD TOC file.
1.6	OK	The expected hyperlinks are present and functioning in the Module TOC files, if present.
1.7	OK	All documents in the submission are referenced using a hyperlink in a TOC, either the main ctd-toc.pdf or in a module-specific TOC, as appropriate.
1.8	OK	The path in hyperlinks and bookmarks from Toc files should never contain the four digit NesS folder.

EU Categories / 2 Files/folders

2.1	OK	The files provided in the folders for Module 1 are in acceptable formats
2.2	OK	The files provided in the folders for Module 2-5 are in acceptable formats