# 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/





Desc	
	arga finalizada
McAfee Web Gateway ha finalizado la descarga del a getFile=Yes	rchivo: http://www.lorenz.cc/eSolutions/eValidator/index.cfm?
Haga clic <b>aquí</b> para acceder al archivo.	Carga de archivos Cesea abiir o guardar este archivo? Nombre: LORENzeValidatorBasic.zip Tipo: Carpeta comprimida (en zip), 15,6 MB De: www.lorenz.cc Abrir Guardar Cancelar
Si desea obtener ayuua	Aunque los archivos procedentes de Internet pueden ser útiles; algunos archivos pueden llegar a dañar el equipo. Si no confía en el origen, no abra ni guarde este archivo. <u>Coal es el niesco?</u> prongase en contracto con coo <del>q</del> uo.

Web Gateway 7						
	Des	carga fina	alizada			
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	Tiempo estimado: Descargar en: Velocidad de transferencia Cerrar el diálogo al con	Guardar en: Documentos recientes Escritorio	Mis docume Mis docume Mi PC Mi sitios de Nueva carp Acceso dire Acceso dire	ntos red eta (2) cto a Mis documentos cto a Nueva carpeta (2)		
Si de	esea obtener ayud	Mis documentos				
		Mis sitios de red	Nombre: L Tipo: /	.ORENZeValidatorBasic.zip Archivo WinRAR ZIP		<ul> <li>✓ Guardar</li> <li>✓ Cancelar</li> </ul>

Guardamos el archivo en el PC y lo descomprimimos:

Adde		Extrayendo de LOREN	ZeValidat 💷 🗖 🔀
F%20Qu		Archivo C:\Documents an\l extrayendo PowerShell	LORENZeValidatorBasic.zip 0%
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<ul> <li>Extraer ficheros</li> <li>Extraer aquí</li> <li>Extraer en LORENZeValidatorBasic\</li> </ul>	-	Procesado	66%
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Enviar a Cortar Copiar	• •		
Crear acceso directo Eliminar Cambiar nombre			
Propiedades			

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

Nombre 🔺	Tamaño Ti 🔼
CommonAppData	Ca
C eVExtensions	Ca
eValidator.exe	1.017 KB Ap
👏 eValidatorBatchService.dll	35 KB Ex
eValidatorBatchServiceHost.exe	374 КВ Ар
eValidatorBatchServiceHost.exe.config	1 KB X/v LORENZeV
eValidatorConsole.exe	55 KB Ac
SeValidatorContainer.dll	119 KB Ex 🗏
🔊 eValidatorContracts.dll	28 KB Ex
Tr eValidatorEditor.exe	496 KB Ap documentation Setup LORENZ LORENZ
🔊 eValidatorGlobals.dll	105 KB Ex eValidator eValidator = 200 EVAL
🔁 eValidatorGuide.pdf	4.313 KB Ac
🔊 eValidatorJobStorage.dll	36 KB Ex
🔊 eValidatorJobStorageSQL.DLL	35 KB Ex
SeValidatorJobStorageSSCE.DLL	40 KB Ex
TeVPosh.exe	11 KB AC
👮 eVPoshConsole.exe	33 KB Ap

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.

Verter	V LORENZ eValidator	- 🗆 🗵
Active Profile:       Report Folder: C:\Users\	Select     Start     Stop     Show     Open Report     Reset       Application     Validation     Validation     Folder     Results View	
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# En nuestro caso seleccionaremos el perfil EU con las últimas reglas de validación aprobadas

V LORENZ eValidator	
Home     Options     Help       Select     Start     Stop       Application     Validation     Validation Report         Open Report     Reset       Results View	
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Application: M:\Env_Telematicos\Cartas\	they are a second secon
Note that for the afterwards without	I profile before you can start using the i pre basic license this profile cannot be changed t reinstalling the software!
5.2.1.01   Basic License   LORENZ Basic Version / free	

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



### En el caso de eCTD :

LORENZ eValidator								ļ	- <u>    ×</u>
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💽 🗾 3 EU M1 DTD	I1	Applicati	on Identification (Bac	kbones)	Pass/Fail 💌	$\checkmark$			
💽 🔽 4 EU M1 leaf MOD file									
🔄 🔽 5 EU M1 envelope MOD file									
🔄 🔽 6 EU M1 stylesheet									
🔄 🔽 7 Index XML									
🔄 🔽 8 Index MD5 txt									
🔄 🔽 9 EU regional XML									
🔃 🗹 10 Submission Structure									
🔄 🔽 11 Leaf attributes									
EU eCTD 2.0 - Validation Criteria 5.0									
資 EU eCTD 2.0 - Validation Criteria 5.0, EXTENDED									
EU NeeS - Validation Criteria 4.0									
EU NeeS - Validation Criteria 4.0, EXTENDED									
5.2.1.01   Basic License   LORENZ Basic Version / free									

#### En el caso de formato Nees :

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	1.2	The main (	CTD TOC file is named correctly	P	Pass/Fail 💌	V		
	1.3	The main	CTD TOC file is placed in the cor	ect fol	ass/Fail 💌	V		
	1.4	If Module	TOC files are present, each and	every	Pass/Fail 💌	V		
	1.5	The expec	cted hyperlinks are present and f	unctio	ass/Fail 💌	$\checkmark$		
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	1.7	All docume	ents in the submission are refere	nced u	ass/Fail 💌	$\checkmark$		
	1.8	The path i	in hyperlinks and bookmarks from	ToC f	Pass/Fail 💌	V		
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📁 EU NeeS - Validation Criteria 4.0								
😇 EU NeeS - Validation Criteria 4.0, EXTENDED								
5.2.1.01   Basic License   LORENZ Basic Version / free								



# Seleccionamos la ubicación de la secuencia a validar desde "Select Application"

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🔄 🔽 3 PDF Files	Result Nur	nber	Title	Severity	Enabled	Details		<b>1</b>
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## > Iniciamos la validación desde "Start Validation"

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	1.5	The expected h	yperlinks are present and functio	Pass/Fail 💌			
	1.6	The expected h	yperlinks are present and functio	Pass/Fail 💌			
	1.7	All documents in	the submission are referenced u	Pass/Fail 💌			
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EU NeeS - Validation Criteria 4.0							
EU NeeS - Validation Criteria 4.0, EXTENDED							
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# Comenzará entonces la validación, mostrándose barra de progreso en la parte inferior

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5.2.1.01 Basic License CORENZ Basic Version / free						



## > Una vez finalizado, accederemos al informe de validación mediante "Show Validation Report"

V LORENZ eValidator						_	
Home Options Help Select Application Validation Validation Validation	Open Repor Folder	rt Reset Results View					
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I   ● Rules passed ok (33)	Report Folder:	C:\Users\dhernandez_externo\EDOSSIER\000	8\0008				rofile §
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	1.5	The expected hyperlinks are present and f	unctio Pass/Fail 💌	V			
	1.6	The expected hyperlinks are present and f	unctio Pass/Fail 💌	V			
	1.7	All documents in the submission are refere	nced u Pass/Fail 💌	V			
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EU NeeS - Validation Criteria 4.0							
EU NeeS - Validation Criteria 4.0, EXTENDED							
5.2.1.01   Basic License   LORENZ Basic Version / free							

# 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, **amarilio** buenas prácticas y **azul** información a destacar.

<b>LORENZ</b> eValidator	LORENZ eValidator - Application Validation Report NeeS
Application name	0008
Full path of application	c:\users\idhernandez_externo\idesktop10008
Sequence	008
Preceding sequences found in application path	n'a
Other sequences referenced	n/a
Missing referenced sequences	n/a
Profile	EU NeeS - Validation Criteria 4.0
Profile Path	C:\ProgramData\LORENZ Life Sciences\eValidator\Profiles\Profile_EU_NeeS_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/Fatl     0

EU Categories		
EU Categories / 1 Tables of Contents		
1.1	ОК	The main CTD TOC file is present
1.2	ОК	The main GTD TOC file is named correctly
1.3	ОК	The main GTD TOC file is placed in the correct folder
1.4	ок	If Module TCC files are present, each and every module folder (im1, im2, etc.) contains the correctly named Module TOC file
1.5	ок	The expected hyperfinks are present and functioning in the main CTD TOC file.
1.6	ок	The expected hyperfinks are present and functioning in the Module TOC files, if present.
1.7	ок	All documents in the submission are referenced using a hyperfink in a TOC, either the main ctd-loc pdf or in a module-specific TOC, as appropriate.
1.8	ОК	The path in hyperfinite and bookmarks from TeO files should never contain the four digit NesS folder.
EU Categories / 2 Filesfolders		
2.1	ок	The files provided in the folders for Module 1 are in acceptable formats
2.2	ОК	The files provided in the folders for Module 2-6 are in acceptable formats