


ValidationExec			
	Responsible:	Date/Sign:	
	SVC-EURSNEXT	02 July 2024	
Submission folder:		C:\ Users\ SVC-EURSNEXT\ AppData\ Local \ Temp\ ValidationExec\ 240702-092026\ ValidationExec\ extedo	
Validation Set:		EU-eCTD v2.1 (DTD 1.3) eCTD 3.2 with EU M 1.3 regional part Version: EU validation criteria release 2.1 Last modification date: 26 January 2015	
Validation Comp. / Lib. Version:		24.3.24082.2 / 24.3.24082.2	
Check Result:		Invalid	

Envelope Information:
















Envelope country	emea
Applicant	Merck Serono Europe Ltd.
Application number(s)	EMA/H/C/071/IA/105
Agency code	EU-EMA
Submission	var-type1a
Invented name	Gonal-f
Procedure type	centralised
Sequence number	0000
Submission description	Change in the name and/or address of the marketing authorisation holder

Summary:

Total files	18
Valid files	16
Valid files with minor issues	0
Invalid files	2
Skipped files	0
Failed submission level tests	0
MD5 Checksum	4c67e4e0cb44241edbff17f3cccb15c1
Validation Start	02 July 2024, 12:20:27
Validation End	02 July 2024, 12:20:27

Validation Report:

[illegible]

Status	Path/File	Rules	Severity
	/m1/eu/10-cover/emea emea-cover-ia105.pdf		
     	/m1/eu/12-form/emea emea-form-annex53105.pdf emea-form-annex54105.pdf emea-form-annexpichanges105.pdf emea-form-applicationform105.pdf emea-form-ia105.pdf emea-form-requirements105.pdf		
 	/m1/eu/13-pi/131-spclabelpl/emea/en emea-combined-ia105106annotated.pdf emea-combined-ia105106clean.pdf		
   	/util/dtd eu-envelope.mod eu-leaf.mod eu-regional.dtd ich-ectd-3-2.dtd		
 	/util/style ectd-2-0.xsl eu-regional.xsl		

Legend:



Valid



Valid with minor Issues



Invalid