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 / 24.3.240	82.2	
Check Result:	Invalid		

## **Envelope Information:**

Envelope country	emea
Applicant	Merck Serono Europe Ltd.
Application number(s)	EMEA/H/C/071/IA/105
Agency code	EU-EMEA
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:

Status	Path/File	Rules	Severity
	(Submission)		
2	Submission level tests		
	1		
8	index.xml		
	The sequence number has an incorrect format.	No. 0025	A
	Hint: The sequence number is 4 digits (i.e. numbers between 0000 and 9999).		
<b>2</b>	index-md5.txt		
	/m1/eu		
8	eu-regional.xml		
	One or more referenced files have wrong checksum	No. 0010	С
	10-cover/emea/emea-cover-ia105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: '525c6161e48ef3c11f95e96667bc4479'		
	12-form/emea/emea-form-annex53105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: 'e37a28fb0d2825dd3c98a9160bfce342'		
	12-form/emea/emea-form-annex54105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: '437eb27506f0fabe0ad082f6011c91b7'		
	12-form/emea/emea-form-annexpichanges105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: 'b96ce7ae774813e26deb19a55e61b24a'		
	12-form/emea/emea-form-applicationform105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: 'f2614b9efece05da3371632391cdfc03'		
	12-form/emea/emea-form-ia105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: 'c1fa59ad7fef1d7b39db0b1b2cf5ab43'		
	12-form/emea/emea-form-requirements105.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: '0695a1da4a67e358e39c944276447833'		
	13-pi/131-spclabelpl/emea/en/emea-combined- ia105106annotated.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: 'a9c78d82e8ba688d77958a1b3c37f0ae'		
	13-pi/131-spclabelpl/emea/en/emea-combined- ia105106clean.pdf: checksum calculated for document: '75fbab8258adb3a8e81338e5b1a84ed9', checksum stored in index: '9e028841e79bfbbbd31caab22f1871'		
	invalid-count : 9		
	Hint: The regenerated checksum for every referenced file is the same as each associated checksum provided in the backbone file (e.g. euregional.xml).		
	The sequence number has an incorrect format.	No. 0025	A
	Hint: The sequence number is 4 digits (i.e. numbers between 0000 and 9999).		
	The test was skipped.	No. 0026	Skipped
	The sequence folder doesn't match the envelope sequence number.	No. 0027	Α
	Hint: The sequence folder name matches the sequence number in the euenvelope in eu-regional.xml.		

Status	Path/File	Rules	Severity
	/m1/eu/10-cover/emea		
<b>4</b>	emea-cover-ia105.pdf		
	/m1/eu/12-form/emea		
<b>2</b>	emea-form-annex53105.pdf		
2	emea-form-annex54105.pdf		
2	emea-form-annexpichanges105.pdf		
2	emea-form-applicationform105.pdf		
2	emea-form-ia105.pdf		
<b>⊘</b>	emea-form-requirements105.pdf		
	/m1/eu/13-pi/131-spclabelpl/emea/en		
	emea-combined-ia105106annotated.pdf		
<b>4</b>	emea-combined-ia105106clean.pdf		
	/util/dtd		
<b>2</b>	eu-envelope.mod		
2	eu-leaf.mod		
2	eu-regional.dtd		
<b>4</b>	ich-ectd-3-2.dtd		
	/util/style		
<b>4</b>	ectd-2-0.xsl		
<b>4</b>	eu-regional.xsl		

## Legend:

