

Internal Audit Check list

CE Files

Created:	17/May 1995	Audit No 12	VM3/COP VOP01
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Audit Date		Auditor	ISO

Paper files are becoming obsolete as electronic documentation supersedes them.

All CE Technical files should be in Intrastats Documentation centre.

All Archive electronic & scanned documents are stored electronically in Paperport

All Archive paper documents are in Paper CE Files.

Any documents missing from Intrastats can be found in Paperport or hard copy files.

Emails can be found in Goldmine and documentation in Intrastats

Question	Y/N	Response/Answer
Check and list current CE Files in : Intrastats;		*# 35290
Does it agree with products being sold requiring CE File	Y	
Do all Products have a CE File		
Check Cross reference in Intrastats :Family Types	Y	
Are all the Products present	Y	
Do all files contain the Basic information required Are there any Red areas	Y	*# 35291
Are MDA guidelines available for classification information. Library and electronically	Y	
Check that form RG2 has been completed and submitted to MDA for any Class I products	Y	no new products
Check that the files classification information for Canada is in their required format.	Y	
Have there been any product changes since the last Audit	Y	*# 35292
Have Risk assessments been completed on change	Y	- NEW POST MARKET SURV. CHANGES
Have there been any classification changes	N	
Any new accessories.		
Any label changes	Y	
Any User information changes	Y	
Any sales leaflet changes	Y	
Any Data sheet changes	Y	
Any maintenance or service manual changes	Y	
Any other major changes effecting CE Files	N	