

Internal Audit Check list

CE Files

Created:	17/May 1995	Audit No 12	VM3/COP VOP01
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Audit Date	19/8/09	Auditor <i>David</i>	ISO

Paper files are becoming obsolete as electronic documentation supersedes them.

All CE Technical files should be in Instrastats 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 Instrastats can be found in Paperport or hard copy files.

Emails can be found in Goldmine and documentation in Instrastats

Question	Y/N	Response/Answer
Check and list current CE Files in : Instrastats;		
Does it agree with products being sold requiring CE File	Y	
Do all Products have a CE File		
Check Cross reference in Instrastats :Family Types	Y	
Are all the Products present		
Do all files contain the Basic information required Are there any Red areas		
Are MDA guidelines are 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	
Check that the files classification information for Canada is in their required format.	Y	
Have there been any product changes since the last Audit	N/A	
Have Risk assessments been completed on change	Y	
Have there been any classification changes	No	
Any new accessories.	✓	
Any label changes	✓	
Any User information changes	✓	
Any sales leaflet changes	—	<i>Lots Auto filled via interface</i>
Any Data sheet changes	N/A	
Any maintenance or service manual changes	—	<i>Auto update.</i>
Any other major changes effecting CE Files	✓	