

VST

Internal Audit Check list

CE Files

Created:	17/May 1995	Audit No 12	VM3/COP VOP01
Revised:	11 July 2011	Last printed 30/04/2007 02:13:00 PM	Page 1 of 1
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; Does it agree with products being sold requiring CE File Do all Products have a CE File	✓		
Check Cross reference in Intrastats :Family Types Are all the Products present	✓	only 1 RANGE	
Do all files contain the Basic information required Are there any Red areas	✓		
Are MDA guidelines are available for classification information. Library and electronically		N/A	
Check that form RG2 has been completed and submitted to MDA for any Class I products		N/A	
Check that the files classification information for Canada is in their required format.		N/A	
Have there been any product changes since the last Audit		NO	
Have Risk assessments been completed on change		} PMS Yearly Review	
Have there been any classification changes			
Any new accessories.			
Any label changes			
Any User information changes			
Any sales leaflet changes			
Any Data sheet changes			
Any maintenance or service manual changes			
Any other major changes effecting CE Files			