

VIAMET

## 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
<b>Check and list current CE Files in : Intrastats;</b>		
Does it agree with products being sold requiring CE File	Y	
Do all Products have a CE File		
<b>Check Cross reference in Intrastats :Family Types</b>		
Are all the Products present	Y	
<b>Do all files contain the Basic information required</b>		
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	+1 NEW PROCEDURE Required for this
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	Removing 800 Series Prod
Have Risk assessments been completed on change	N/A	Removing a product
Have there been any classification changes	✓	
Any new accessories.	✓	
Any label changes		PMS Review #2
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		

#1 ~ need report to check for RG2 Forms

#2 AUDIT NOT FIT FOR PURPOSE