Internal Audit Check list			
Technical Files V S 1			
Created:	17/May 1995	**Audit No 12**	VM3/COP VOP01
Revised:	19 August 2016	Last printed 30/04/2007 02:13:00 PM	Page 1 of 2
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Paper files are becoming obsolete as electronic documentation supersedes them.
All CE Technical files should be in Intrastats Document Index.
Emails can be found in Gmail, Goldmine and documentation in Intrastats.

Question	Comments	Response/ Answer
Check the list of current CE Files in Intrastats. Do all our products have a CE File. Review list and see if any are missing. ISO – Tech Files, top dark blue section ad the light blue OBL below.		Y
Check Cross reference in Intrastats - Family Types. ISO – Tech Files Are all the Products present review		Y
Do all files contain the Basic information required. Are there any Red areas. Cross reference. ISO – Tech files – second icon Cross ref families and files/regulations - ISO BSI Required – Viamed Products – Submit. Speak to quality controller and ask if there are any problem areas, the system is highly complex and understanding of this is not required by auditor.		No Problems
Are MDA guidelines are available for classification information. In ISO- Tech Files	This is an intrastats automatic process when developing a new product.	N/A
Check that form RG2 has been completed and submitted to MDA for any Class I products. ISO Tech Files, the bracketed number is the CE classification. This is in the check list for when we develop a new Viamed product.	Check the (1)'s and see if they have the MDA letter present.	N/A
Check the Canadian Medical Devices CMDCAS form is filled in annually. ISO – Tech Files (At present the microstims are our only products that we sell to Canada)		N/A

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Pick one of our Files in the ISO – Tech Files ~~Dark Blue~~ and answer the following VST Sensors		
Have there been any product changes since the last Audit		N
Have Risk assessments been completed on change		N/A
Have there been any classification changes		N
Any new accessories.		N
Any label changes	updated not changed	Y
Any User information changes	updated not changed	Y
Any sales leaflet changes	updated	Y
Any Data sheet changes	updated more info added	Y
Any maintenance or service manual changes	updated more info added	Y
Any other major changes effecting CE Files		N