

Viamed #91362

Internal Audit Check list			
Technical Files			
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
Audit Date	13-4-17	Auditor Helen Lamb Bsc Hons	ISO

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 and the light blue OBL below.		Y
Check Cross reference in Intrastats - Family Types. ISO – Tech Files Are all the Products present reviewed	within spec all have dates	Y
Check that all Viamed Products (dark blue at the top) are Green for PMS – Post market surveillance. List those not and Issue to technical manager.		Y
Check that all Viamed Products and OBL's (dark blue and light blue the top two sections) are blue for Risk assessment. List those not and Issue to technical manager..		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.	MD explained Reds are present as they not required for ISO	N
Are MDA guidelines available for classification information. In ISO- Tech Files	This is an intrastats automatic process when developing a new product.	N/A

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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.	Y
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)		Y
Pick one of our Files in the ISO – Tech Files Dark Blue and answer the following <i>Perspex Oxygen heads Tenda</i>		
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	<i>Packaging label Handle with care</i>	Y
Any User information changes		N
Any sales leaflet changes		N
Any Data sheet changes		N
Any maintenance or service manual changes		N
Any other major changes effecting CE Files		N