Internal Audit Check list

Technical Files

Viamed.

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		Auditor Helen Lamb	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 ad the light blue OBL below.		Yes Seem Complete
Check Cross reference in Intrastats - Family Types. ISO – Tech Files Are all the Products present review		Yes
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.	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
		Y
		Y

add all Viamed products Dark blue.
all PMS should be green / Review
all Risk ass must be blue.
Dark + light Viamed + OBL
List those Send issue

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Pick one of our Files in the ISO – Tech Files Dark Blue and answer the following Resuscitation Unit and TC600 Viamed Product		
Have there been any product changes since the last Audit	nothing since 2011	N
Have Risk assessments been completed on change		N/A
Have there been any classification changes		N
Any new accessories.		N
Any label changes		N
Any User information changes		N
Any sales leaflet changes	New Leaflet 18-11-15 Id 15970	Y
Any Data sheet changes		N
Any maintenance or service manual changes	21-9-15 Id 15681	Y
Any other major changes effecting CE Files		N

Internal Audit Check list

Technical ~~CE~~ Files

Created:	17/May 1995	Audit No 12 named	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 Intraststats Documentation centre. Index
~~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
GMail

Question	Y/N	Response/Answer	
Check and list current CE Files in : Intrastats; ISO - tech files ~~Does it agree with products being sold requiring CE File~~ Do all Products have a CE File ~~our~~ Dark blue + top section Light blue OBL.		Review list for errors look for what is missing	
Check Cross reference in Intrastats :Family Types ISO - tech files Are all the Products present Review Families + files Negative Second areas			
1x **Do all files contain the Basic information required** Are there any Red areas ~~- Cross Ref - ISO FBS1~~	Required - named products. Submit		
Are MDA guidelines are available for classification information. ~~Library and electronically~~ in tech	files	Intrastats Automatic process when developing new product.	
Check that form RG2 has been completed and submitted to MDA for any Class I products Q2			
Check that the files classification information for Canada is in their required format. Q3			
Have there been any product changes since the last Audit			
Have Risk assessments been completed on change			
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			

Dichange of our files
ISO - ~~Tech~~ files
Dark blue

#1 Speak to quality controller + ask if any problem areas (System highly complex. Auditor not reserved to understand workings).

#2 ISO technical files — branched numbers classification.

this is in the ~~tech~~ check list for when we ~~create~~ develope a new named product

can check (1)'s and see if MDA letter present.

CMDCAS

#3 Checks Canadian medicare licences

form is filled is annually.

in ISO - tech files - ~~Rob~~ (microsoft only one at present).
