VST #86243

Internal Audit Check list

Design

Created:	17/May 1995	**Audit No 03**	VM3/COP16 & 09 VOP 17
Revised:	25 August 2015	Last printed 02/06/2006 02:27:00 PM	Page 1 of 1
Audit Date	19-1-17	Auditor Helen Lamb	ISO 7.2 7.3

QUESTION:	**RESPONSE:**	**Y/N**
Technical File Reviewed ID:		
Check that the final design responsibility is a Sole Authority.	Top management	
Check that all products are C.E. marked and Viamed products have a C.E. file.	Intrastats	
Pick 5 Products from the Files product list		
Declaration on Conformance Certificates present		
Verify that EMC testing has been identified where required.		
Are the latest BS ISO MDD, CMDCAS requirements are available List DOCIDS		
Check that product classification is done to MDD, CMDCAS principles.		
Verify that each design was initiated from a job description & specification		
Has each design has received a job number and a job progress form		
Verify the existence of a design documentation checklist.		
Check that estimated times have been noted. Electronic timing being introdced		
Have final testing requirements, and test criteria, been identified		
Have concession notes have been raised on non-approved suppliers		
Check that current status is identified on a regular basis.		
Verify that design reviews are undertaken and that records are retained		
Check that any amendments to design are logged		
Check that design output records are verified against design input		
Does design verification comply with COP 16 - 7.7.1 - .4		
Check that clinical trials have been carried out and relevant records retained		
Verify that design validation has been carried out as required by form QC30		
Check that any design changes have been identified, recorded and approved		
Have risk analysis has been carried out and recorded at all relevant stages		
Check that CE files are complete, correct and maintained		
Are design components kept separate from stock and adequately stored		
Are design component stocks labelled		
Check the existence of design compliance forms		
Have risk analyses been carried out and recorded		
Check that these files are maintained		
If more space is required for answers use the reverse of this form		

This is only done when producing a new product. Production + Dereleopement

None at time of Audit.