Internal Audit Check list

Design

Created:	17/May 1995	Audit No 03	VM3/COP16 & 09 VOP 17
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Audit Date		Auditor	ISO 7.2 7.3

QUESTION:	RESPONSE:	Y/N
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	
Verify that EMC testing has been identified where required.	CE Files	
Are the latest BS ISO MDD, CMDCAS requirements are available	Library, Paperport	
Check that product classification is done to MDD, CMDCAS principles.	CE Files Intrastats	
Verify that each design was initiated from a job description & specification	Intrastats or QC22	
Has each design has received a job number and a job progress form	Intrastats or QC25	
Verify the existence of a design documentation checklist.	Intrastats or QC29	
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	Not normal	
Check that current status is identified on a regular basis.	Intrastat meetings	
Verify that design reviews are undertaken and that records are retained	Intrastat meetings	
Check that any amendments to design are logged	Intrastats or QC24	
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	CE Files	
Verify that design validation has been carried out as required by form QC30	CE Files	
Check that any design changes have been identified, recorded and approved	CE Files	
Have risk analysis has been carried out and recorded at all relevant stages	CE Files	
Check that CE files are complete, correct and maintained	Intrastats, Library	
Check and list current design files: Technical Library. Intrastats a) Red Plastic Holder b) Red Binder &/or Red CE mark Binder c) Hardware R & D or Archives		
Do all the files contain the master layout	Intrastats CE	Y
Are the sections in the master layout being filled in correctly		Y
Are the designated people filling in log sheets		N/A
Is information from the logs being copied to master files .	Intrastats CE	N/A
Are design components kept separate from stock and adequately stored		N/A
Are design component stocks labelled		N/A
Check the existence of design compliance forms		
Have risk analyses been carried out and recorded	CE Files	
Check that these files are maintained	Intrastats CE	
Verify that they are complete and correct	Intrastats CE	
If more space is required for answers use the reverse of this form		

NO Design for Products taken place in 2012 /2013.
Dlm