Internal Audit Check list

Design

Created:	17/May 1995	**Audit No 03**	VM3/COP16 & 09 VOP 17
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Audit Date	22/05/2007	Auditor	ISO 7.2 7.3

QUESTION:	**RESPONSE:**	**Y/N**	
Check that the final design responsibility is a Sole Authority.	Top management	Y	
Check that all products are C.E. marked and have a C.E. file.	Intrastats	Y	
Verify that EMC testing has been identified where required.	CE Files	Y	
Are the latest BS ISO MDD, CMDCAS requirements are available	Library, Paperport	Y	
Check that product classification is done to MDD, CMDCAS principles.	CE Files Intrastats	Y	
Verify that each design was initiated from a job description & specification	Intrastats or QC22	Y	
Has each design has received a job number (No) and a job progress form	Intrastats or QC25	Y	
Verify the existence of a design documentation checklist.	Intrastats or QC29	Y	
Check that estimated times have been noted.	Intrastats	Y	
Have final testing requirements, and test criteria, been identified		Y	
Have concession notes have been raised on non-approved suppliers	Not normal Procedure		
Check that current status is identified on a regular basis.	Intrastat meetings	Y	
Verify that design reviews are undertaken and that records are retained	Intrastat meetings	Y	
Check that any amendments to design are logged	Intrastats or QC24	Y	
Check that design output records are verified against design input		Y	
Does design verification comply with COP 16 - 7.7.1 - .4		Y	
Check that clinical trials have been carried out and relevant records retained	CE Files	Y	
Verify that design validation has been carried out as required by form QC30		Y	
Check that any design changes have been identified, recorded and approved	Intrastats Meeting	Y	
Have risk analysis has been carried out and recorded at all relevant stages	CE Files	Y	
Check that CE files are complete, correct and maintained	Intrastats, Library	Y	*
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	Library	Y	
Do all the files contain the master layout	Hard Copy	Y	
Are the sections in the master layout being filled in correctly	"	Y	
Are the designated people filling in log sheets	Intrastat Logs		
Is information from the logs being copied to master files .	No	N/A	
Are design components kept separate from stock and adequately stored		Y	
Are design component stocks labelled and counted.			**
Check the existence of design compliance forms		Y	
Are these changes reviewed and approved		Y	
Have risk analyses been carried out and recorded	CE Files	Y	
Verify that all products have a C.E. file		Y	
Check that these files are maintained		Y	
Verify that they are complete and correct			*
If more space is required for answers use the reverse of this form			

* In process of complete review & transfer to Intrastats

** In progress of new components Sm. are required