INTERNAL PROCESS VERIFICATION

Audit No: 1:   **Date:** 29/9/14   **Auditor:**

MANAGEMENT SYSTEM

VIAMED

#	Question	O.K.?
1	Establish that the management system applications are a series of process controls, and that they are in place throughout the organisation..	✓
	Can processes be identified	✓
	Are charts produced to this effect? And are they in place in strategic locations for use by personnel.	✓
	Are regular analyses undertaken to identify any outstanding requirements Is it still on Meeting Agenda	✓
	Are necessary changes implemented where and when required ongoing	
	Is any outsourcing done	no
2	Check the documented system for its policies and objectives, and its control of the above processes and procedures.	✓
	Is the Process Manual is up-to-date. Check issue date 2014 : 14342 Has it been reviewed at a management meeting on going	✓
	Are amendments are controlled by Version & Date issue. Check amendments page is filled in	Y
	Does it continue to indicate the company's objectives	Y
	Is there sole responsibility for company procedures and other documentation.	Y
	Is documentation is checked prior to formal approval and issue.	Y
	Are Electronic procedures in place and available, to all. Do all personnel have access to their relevant areas of the documentation. Check electronic access	Y
	Are Technical Drawings, available and controlled Check electronic access	Y
	Are standards available and controlled Check electronic access	Y
	Are manufacturers data sheets are supplied as the latest issue. Has manufacture been approached for latest issue within last 12 months Check electronic access	Y
	Are operators Manuals available and controlled Check electronic access	Y
	Establish that all documentation is valid and of the latest status, and that any document changes are controlled.	Y
	Are documents controlled by date status; Check 6 at random	Y
	Are documents being checked by operators before use Check that printed copies of production procedures are of the latest issue status Check Repair & production areas	Y
	Check that there is a system in operation for the request for amendments.	Y
	Verify that amendments are updated "Electronically " and old copies removed.	Y
	Check that they are also updated in the company master file & old copies removed.	Y
	Establish that any records produced are controlled and filed for identity and easy retrieval etc. Check Record files are up to date including: QA	Y

Audit No: 106   **Date:**   **Auditor:**

MANAGEMENT SYSTEM

Production Goods returned Quarantine Warranty		
	Are sales orientated records filed and archived by Hospital name (and customer name).	Y
	Are records of inspections filed	Y
	Has organisation Chart changed	
	Has personnel responsibility descriptions changed	Y
	Check that the C.E. files are maintained by sole responsibility.	Y
	Check that obsolete data in the files is either Archived or retained.	Y
	Check that the Notified body is informed of major changes to Documentation Check if here have been major changes	Y
	Check that electronic documents are regularly backed up and secure off-site	Y
	Check that documents are filed where they say they are and the responsibility is true	Y
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