

BCMS ISO 22301:2012

Viamed runs a very tight ISO 9001 and ISO 13483 Management system.

Business continuity day to day is handled via these 2 systems and or Intrastats.

The ISO 22301:2012 has been reviewed, it has been determined not to be assessed by an external body as most sections of the Standard are DIRECTLY covered by ISO 13485/ISO 9001 of which Viamed is continuously review by British Standards 0086.

Viamed also has a basic Disaster plan found in the document index which addresses sections not covered by ISO 13485.

4.3.2

BCMS Requirements:

Computer Systems

Warehousing Stock

Service / Repair services

Financial Facility's

Customer and Supplier Order Processing

ISO Standards

4.4

Recurring Issue #266

5.2

All Management is committed to ISO 13485 and ISO 9001 Procedures and processes.

5.3

Policy's and Document control and staff notification is covered in ISO 13485

6.1

ISO13485 Audit system and Document control systems

7.1

ISO13485

7.2

Staff Training systems

7.3

a-c ISO13485

d/ the VM3COP60.04 Viamed Disaster continuity plan

7.4

ISO13485, and the Internal Issues communication system.

- 7.5
ISO13485 Documentation system
- 8.1
ISO13485 Viamed Company operating procedures and processes.
- 8.2
VM3COP60.04 Viamed Disaster continuity plan.
- 8.2.2
VM3COP60.04 Viamed Disaster continuity plan.
- 8.3
ISO 13485 (Resource management)
Intrastats Monitoring system.
- 8.4
VM3COP60.04 Viamed Disaster continuity plan.
- 8.4.3
ISO 13485, Customer Complaints systems.
- 8.4.4
ISO 13485, Customer Complaints systems.
- 8.4.5
VM3COP60.04 Viamed Disaster continuity plan.
- 8.5
Viamed is a small organisation in the scope of Testing BCMS,
Computer Backup testing occurs monthly.
- 9
Intrastats monitoring under ISO 13485.
- 9.1.2
Recurring Issue #266
- 9.2
ISO 13485 Internal Audits
- 9.3
ISO 13485 Management reviews
- 10
ISO 13495 Non conformity / corrective action procedures