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VIAMED Ltd.

15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, UK.

Website: www.viamed.co.uk. Email: info@viamed.co.uk.

Tel: +44 (0)1535 634542. Fax: +44 (0)1535 635582.

Control of documents

a) review and approve documents for adequacy prior to issue;

Procedure Documents controlled by the Managing Director

b) review, update as necessary and re-approve documents;

Document requiring review have Expiry date set forcing review

c) ensure that the current revision status of and changes to documents are identified;

Intrastats Controlled

d) ensure that relevant versions of applicable documents are available at points of use:

Intrastats Controlled

e) ensure that documents remain legible and readily identifiable;

Digital document non degradable

f) ensure that documents of external origin, determined by the organization to be necessary

for the planning and operation of the quality management system, are identified and their

distribution controlled;

Intrastats Controlled Document requiring review have Expiry date set forcing review

g) prevent deterioration or loss of documents;

Digital document non degradable

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

Intrastats Controlled

The organization shall ensure that changes to documents are reviewed and approved either by the

original approving function or another designated function that has access to pertinent background

information upon which to base its decisions.

Areas Linked to Document are displayed in the Document Admin in Intrastats

The organization shall define the period for which at least one copy of obsolete documents shall be

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retained. This period shall ensure that documents to which medical devices have been manufactured

and tested are available for at least the lifetime of the medical device as defined by the organization,

but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable

All Obsolete Documents are available to Document Admin

- I) Calibration Records maintained via the calibration index in Intrastats, all Calibration certificates for each Item maintained indefinatly in the Issue system.
- J) QA records and Serivce records maintained in Intrastats, logged against each barcode in the QA / Service sections of intrastats.

Signed: Date	18/01/17	
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D. I. Lamb Managing Director.