VOP			
Operating sub Process			
Documentation/Records Control			
Created:	27/03/06	VOP 01	**Issue 1**
Revised:	03 September 2018	Viamed Ltd ISO13485:2016: 4.2.4 Control of documents ,4.2.5 ,4.2 , 4.2.1 ,4.1.1 VST Ltd ISO9001:2015: 4.3 ,4.4.2 , 5.2.2 ,8.2.3.2 ,8.2.4 ,7.5.1 ,7.5.2 , 7.5.3	Page 1 of 5

SCOPE

This procedure is established to describe the system used within the company for the control of Documentation and that all significant documents are subject to control and that only correct issues of relevant documents are available and in use. It is used in conjunction with the individual sub procedures, which show the relevant information necessary. The purpose of this document is to describe the system in use at the company in order to ensure Company Operating Procedures are binding instructions, and all members of staff are required to conform to the requirements therein. The requirement for new Procedures, or changes to procedures can originate from any person within the company. These requirements will be discussed and agreed by management before processing

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to and to ensure the origination, upkeep, revision, control and authorisation of documentation, including technical documents, work instructions, specifications, records, forms and procedures.

GENERAL

All Company operating procedures are complementary to, but DO NOT, replace the requirements of the Quality Manual (VOPs).
Company operating procedures are binding instructions and all members of staff are required to conform to the requirements therein.

DOCUMENTATION

Documents such as procedures, instructions, specifications etc. are retained as Word documents, Autocad & PCB documents, and are also stored electronically (Read Only) therefore making them available to all personnel, for information purposes. All documentation including international standards and technical files are now digitally controlled. Internal documents not designated to be used external to the system have a computer controlled revision id, and updated date. A warning on the user view of documentation,
"All Documents While Viewed Live are CURRENT. Printed internal documents should have the date written on them and the Document ID / Version Control #Number and destroyed the next day, or be destroyed immediately after use"

DOCUMENT CHANGE / AMENDMENT

The Managing director will decide when a company operating procedure or top level VOP requires updating.

All essential documents contain a change / revision facility. This is controlled by date revised and last date printed. Printed is either electronic or hard copy. Departmental heads are responsible for ensuring prompt removal of obsolete documents from all points of use. After many revisions, a document may be fully re-issued as the next number status.

Where significant changes have been made to a Company document / management system e.g. new or major modifications to procedures or a reduction in quality surveillance, or to such as the Design / CE Files, then the appropriate Notified Body(s) will be informed in writing, with copies of the changes where required.
It is the responsibility of the originator of any change order to ensure that documents becoming obsolete are promptly destroyed or returned for filing.
After the retention period (as defined in the document register) has expired, the documents may be archived, in various locations, or destroyed, depending on the nature of the document. The Managing Director will take this decision.

Electronic documents that are amended, the new document will get a new document ID, and the obsolete document, will be filed away in the history of the new document only available to the admin panel of the document index limited to directors.
Any users who have use of the obsolete document, will be informed by the Intrastats system, that the document has been updated, or prior to the process being performed.
All documentation in the document index have a request amendment function so end users can request an amendment, this creates an internal issue to log any changes, updates if required, the issue can track the changes of a document until its finally approved and uploaded to the system.

TECHNICAL DOCUMENTATION

When engineering drawings and / or specifications are created for manufacturing purposes, the documents will be authorised by signature on the final draft copy, and computer initialled on the final master copy, as verification of current issue. This authorisation will be vested in a senior person responsible for technical matters. These documents will be controlled in the same manner as previously stated above.
Manufacturers manuals and technical data sheets, British and International standards, together with any regulatory guidance documents are maintained in the library for reference purposes. Where applicable, these documents are also stored electronically (old versions are not removed).
All relevant Standards are filed and indexed in the document system and are allocated a regular document ID and are maintained up to date annually by reference to the BSI guide. European Commission harmonised standards to check documentation up to date https://ec.europa.eu/commission/index_en.

Quality records are electronically stored against the products barcode identifiable to the product.
A network is installed and the central File server holds a master copy of all files, which require shard access. All centrally held files are backed up routinely by the IT Controller.
All CE and Design files are maintained by the Technical engineer and are available for viewing electronically.
All documents are being entered systematically into the Intrastat system.

The Technical files documentation is available in the regular Document Index. However they also have an electronic version, of the original sections of the old paper versions of the technical documentation. Here you can view documentations grouped together per technical files, and files sectioned of into appropriate headers. Where a document applies to more than one header it can be filed in both sections, however both section will refer to the same document ID, and if that document get updated, all 'virtual' documents in the section with that ID will be updated.

OUT OF DATE DOCUMENTS
When a document has an expire date it is set in the document system and is flagged as out of date to the end users. A regular task to check the out of date documents register is performed by the document controller who is responsible for obtaining a new copy of the documentation updating as per 'document change / amendment'.

DUPLICATE DOCUMENTS
The system will automatically flag if possible if a document has been entered into the system twice so they can be merged together and only 1 document becomes available to the end users.

INFORMING EXTERNAL BODIES
It is the responsibility of the Managing Director to inform the external bodies that may need to be informed of any changes to either the Quality Management system or any significance changes to the CE marked products.
E.g. BSI, CMDCAS, MHRA

Document register is available via the Intrastats system.

DOCUMENTS BACKUP

Documents are backup from one building to the next building every evening into the live Backup System.
Off-Site backups are performed every 3 days.

FILE TYPES

In most cases the file types of documents are automatically detected, however in some cases if using less well known software, the File type and version of software should be noted in the 'Document Notes Displays on main Doc View Screen' box of the Admin Document.

EXTRA DOCUMENT OPTIONS

After a document has been uploaded to the system, the document can be linked to various sections of intrastats, i.e.

- Type of documentation
- Owning Company (Viamed / VST / Humanmed / Vandagraph / Viamed Properties)
- Security Level (Internal use only / External use approved / Manager Access only)
- Products
- Contacts
- Technical Files
- Expiry date
- Hidden search terms
- Download name if different to the stored index name
- Linked to a Training Course

Once a document is linked it will present itself as and were appropriate. i.e. a product search it will be available from the Stock/Product screen.
If its updated and a user has been trained and its part of the training program, the user will be alerted the document has been updated.

RETENTION OF RECORDS

Intrastats records are kept indefinitely.
Except upon a GDPR request where any data not legally required for ISO traceability will be removed from the system relating to the GDPR Request.

Account records from Account software periodically cleared out due to size limitations of the accounts databases. However any data removed will still be retained within the Intrastats system.

Sensitive Health Data.

Viamed / VST do not have any products which store patient identifiable information. Should we receive from an outside source any documentation / information which could be classed as sensitive health information. The data shall not be digitised into the system but passed to the MD to Safely lock away, and an Issue generated to the GDPR supervisor to decide how to proceed.