VOP			
Operating sub Process			
Measurement Control , Calibration, QA Stock			
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		Viamed Ltd ISO13485:2016: 7.6, 7.4.3, 7.5.1, 6.3 VST Ltd ISO9001:2015: 7.1.5.1, 7.1.5.2, 8.5.1, 7.1.3	Page 1 of 2
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SCOPE

This procedure is established to describe the system used within the company for the control of measurement control and Calibration. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to.

INSPECTION AND TESTING

This procedure defines the system in use, within the company in, order to ensure that inspection, testing and calibration requirements are planned, controlled and documented. All process and measuring activities are recorded through the use of Intrastats.

It is the responsibility of the Warehouse Controller, to ensure that all inspections and testing is performed correctly. As per the procedures in Intrastats, and that these procedures are strictly adhered to by individuals perform these tasks.

GOODS RECEIVING

Inspection of receipt of purchased goods, proprietary items etc., shall be visually for damage, correctness and completeness to purchase order, including certification where required. Received goods, where appropriate, are then processed through QA systems for testing and inspection.

Goods requiring testing and inspection will have a specific test procedure, in Intrastats, which must be complied with. Goods failing inspection will be dealt with as stated in VOP 05 Supplier Control. Goods accepted will be booked in to Intrastats and transferred to the goods awaiting QA and/ or labelling.

QA SYSTEM

Manufactured items are inspected and / or tested to the relevant operating procedures for each part. Full aesthetic checks are done and should anything be damaged or faulty, then it is processed through in the Supplier Returns System. When items are inspected satisfactory, then they will placed on the Awaiting QA shelves for testing and labelling.

When carrying out QA, the product specific procedures will be followed and readings recorded, in Intrastats. Barcodes and any other labels or instructions, will be added and any further packaging required will be used.

Upon satisfactory testing, labelling and packing. The stock items are now ready to be transferred to the sellable stock shelves. The stock is now scanned to its new location.

Where tested items are found to be electrically faulty then this will be recorded in Intrastats and then processed through in the Supplier Returns System. Repaired items are then re tested to the relevant operating procedures. As with manufactured items they are given a visual inspection first. Testing is to the values stated in Intrastats for each part. Upon satisfactory testing, the items scanned to the sellable stock shelves.

CALIBRATION

This can be found in Intrastats ISO Calibration Index. This is an index of all the items of equipment that require calibration within the company. Including a description, barcode ID, CE number, serial number, the last time it was updated, when it is next due, its location in the company, its status and the ability to request calibration.

Most equipment is Indication Only and is only calibrated before use when the results are critical.

Each piece of equipment will be labelled, either on the equipment itself or on its protective case with a CExxx Barcode, Searching CExxx or barcode in Intrastats serial number search will give link to status of that equipment

Equipment not calibrated by Viamed will be sent to a sub-contract source capable of issuing an approved calibration certificate. These certificates will be stored in Intrastats Document Index.

The intervals between calibration will be set by the Managing Director and will be related to the particular piece of equipment and its frequency of use. Subsequent changes to the calibration interval can only be made by the Managing Director. These will relate to the deviations found from previous calibrations. Normally this will be every two years.

Additional calibration checks will be made if:

a) The equipment has been dropped or damaged,

OR b) The user has reason to suspect the equipment's accuracy,

c) The user needs accuracy beyond indication

Any equipment which cannot be re-calibrated will be withdrawn for repair, and if irreparable will be replaced or scrapped.

If any item of equipment is found to be out of calibration the Managing Director will assess the effect that this could have had on products previously checked by that equipment. He will decide if the customer shall be informed that he has received suspect products or if a recall is necessary. A non conformance issue should be raised to log the assessment of risks and potential recalls.