The Viamed Risk Assessment Management Plan

This is carried out in Intrastats

- 1. Icon ISO 13465
- 2. Technical File Links3. Home Page

- 4. Choose a File5. Last column on the Right .
- 6. If OK is Blue if not DUE
- 7. The file guides the user through the requirements Stock references (Stock reference

Comments on supplier

Sales Information (look for falling sales)

Sales Country Risks

Return Information

Return for Re-work

Design Changes

Risks associated with design changes

*See Note 1 Issues raised since last review

Risks associated with issues

- 8. There are steps that can be taken at every step

 - General comments
 Further action required
- 9. Sign Off review

The Viamed Risk Assessment Management Plan

NOTE 1. Importance of the Issue system cannot be understated.

Issues System See Overview Document ${\rm ID}\,12395$

Issues must be attached to a specific header See documentID22167

Issues Are raised Either Manually as a problem/non conformance / customer complaint is located. Appropriate header is selected either manually, or by the system depending where the issue is being raised from.

Automatic Issues are created so functions / processes are carried out,

For Example.

Post Market Surveillance is scheduled to be performed every 2 Months (Task 50), where Technical Files are checked to see if any product ranges require the Yearly PMS.

Many Intrastats pages contain Links to raise non conformances linked to the Page being displayed. And when non conformances should be raised.

The Viamed Risk Assessment Management Plan

Appendix 2. Issue Meeting Header List As per 22 / 09 / 2017, See Intrastats for upto date list

VIAMED Management Meeting VIAMED Management	Meetin	g Name Agenda Name	
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VIAMED	Sales And Marketing	Existing Good Products
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VIAMED	Sales And Marketing	External Sales
VIAMED	Sales And Marketing	External sales companies & Distributors
VIAMED	Sales And Marketing	FrameWork Agreements
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VIAMED	Board Directors Meeting	ISO Issues		
VIAMED	Board Directors Meeting	Loans		
VIAMED	Board Directors Meeting	Matters Arising		
VIAMED	Board Directors Meeting	Minutes of Last Meeting		
VIAMED	Board Directors Meeting	Overdraft		
VIAMED	Board Directors Meeting	Profiability		
VIAMED	Board Directors Meeting	Staff Issues		
VIAMED	Board Directors Meeting			
VIAMED	Board Directors Meeting	Supplier Issues		
VIAMED	Board Directors Meeting	Target for 2nd Year		
VIAMED	Board Directors Meeting	Target for following year		
VIAMED	Board Directors Meeting	Target for next Month		
VIAMED	Board Directors Meeting	Target for Year		
VIAMED	Board Directors Meeting	Turnover and Predicted for Year		
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Bluepoint	Bluepoint Medical	Capnography Monitor		
Bluepoint	Bluepoint Medical	Capnography Sensors		
Bluepoint	Bluepoint Medical	NIBP Cuffs Connectors		
Bluepoint	Bluepoint Medical	NIBP Cuffs Disposable		
Bluepoint	Bluepoint Medical	NIBP Cuffs Hoses		
Bluepoint	Bluepoint Medical	NIBP Cuffs Reusable – Silicone		
Bluepoint	Bluepoint Medical	NIBP Cuffs Reusable – Standard		
Bluepoint	Bluepoint Medical	NIBP Monitor		
Bluepoint	Bluepoint Medical	Oxygen Monitoring Monitor Vandagraph		
Bluepoint	Bluepoint Medical	Oxygen Monitoring Monitor Viandagraphi Oxygen Monitoring Monitor Vianed		
Bluepoint	Bluepoint Medical	SpO2 Oximeters Dolphin OEM Boards		
Bluepoint	Bluepoint Medical	SpO2 Oximeters Dolphin OEM Boards SpO2 Oximeters Dolphin ONE Sensors		
Bluepoint	Bluepoint Medical	SpO2 Oximeters Bolphin ONE Sensors SpO2 Oximeters Hand held – VM 2101		
-	-			
Bluepoint	Bluepoint Medical	SpO2 Oximeters Hand held – VM 2105		



Bluepoi		Bluepoint Medic	
Bluepoi		Bluepoint Medic	
Bluepoi		Bluepoint Medic	
Bluepoi		Bluepoint Medic	•
Bluepoi		Bluepoint Medic	
Bluepoi		Bluepoint Medic	
Bluepoi	nt	Bluepoint Medic	al SpO2 Sensors Reusables – Ear sensor
Bluepoi	nt	Bluepoint Medic	al SpO2 Sensors Reusables – Finger, hard shell
Bluepoi	nt	Bluepoint Medic	al SpO2 Sensors Reusables – Finger, silicone
Bluepoi	nt	Bluepoint Medic	al SpO2 Sensors Reusables – Multi-site 'Y'
Bluepoi	nt	Bluepoint Medic	al SpO2 Sensors Reusables – Wrap sensor
Bluepoi	nt	Bluepoint Medic	al Temperature Monitoring Monitor
Bluepoi	nt	Bluepoint Medic	
Bluepoi		Bluepoint Medic	
Bluepoi		Bluepoint Medic	
ToDo	ToDo	Derek Lamb	
ToDo	ToDo	Helen Lamb	
ToDo	ToDo	Jean Lamb	
ToDo	ToDo	John Lamb	
ToDo	ToDo	Ryan Swaine	
ToDo	ToDo	Steve Hardaker	
ToDo	ToDo	Steve Nixon	
ToDo	ToDo	ToDo	
ToDo	ToDo	ToDo Lists	
		Meeting Ad-Hoc	Meeting
VST	General	-	eneral Issues
VST	General		
VST			Additional Sales Orders
VST		ment Meeting	
VST		ment Meeting ment Meeting	Any Changes in Agenda Audits
	_	•	
VST	_	ment Meeting	Back Order Report
VST		ment Meeting	Banking Issues
VST		ment Meeting	Calibration / P.A.T.
VST		ment Meeting	Debtors
VST		ment Meeting	Fire Alarms
VST	_	ment Meeting	Forward Sales Order Report
VST	_	ment Meeting	Future Reviews - First Aid
VST		ment Meeting	Future Reviews - Internal Audits
VST		ment Meeting	Future Reviews - Risk Assessment HSE
VST		ment Meeting	Future Reviews - Waste
VST	_	ment Meeting	General Issues
VST		ment Meeting	General Maintenance Requirements
VST		ment Meeting	Grants
VST		ment Meeting	Internal Process Verification
VST	_	ment Meeting	Issues for Accountants
VST	Manage	ment Meeting	Members Objections To Meeting
VST		ment Meeting	Minutes From Various Meetings
VST		ment Meeting	Non Conformance Issues
VST	Manage	ment Meeting	Other
VST	Manage	ment Meeting	Passwords Codes other Private information
VST	Manage	ment Meeting	Personnel Holidays and Time Adjustments
VST	Manage	ment Meeting	Personnel Requirements and Training
VST	Manage	ment Meeting	Production
	_	•	



VST	Management Me	eting	Projects
VST	Management Me	eting	Requested Supplier Payments
VST	Management Me		Research and Development rnd
VST	Management Me		Review Accident Book
VST	Management Me		Review Weekly Meeting
VST	Management Me		,
	_	_	Standards up to date
VST	Management Me		Supplier Review
VST	Management Me		Technical Files Review
VST	Management Me		Turnover Report
VST	Management Me		VST Management Meeting
VST	Sales And Marke	-	Any other business
VST	Sales And Marke	eting	Calendar Progress
VST	Sales And Marke	eting	Competitors
VST	Sales And Marke	eting	Customer Database Updates
VST	Sales And Marke	eting	Customer pricing agreements
VST	Sales And Marke	-	Customer Training
VST	Sales And Marke	-	Distributor results
VST	Sales And Marke		Exhibitions
VST	Sales And Marke	-	Existing Good Products
VST	Sales And Marke		Existing Good Froducts Existing Poor Products
		_	_
VST	Sales And Marke	_	External Sales
VST	Sales And Marke	_	External sales companies & Distributors
VST	Sales And Marke		Feedback
VST	Sales And Marke	_	Internal sales
VST	Sales And Marke	eting	Leaflets
VST	Sales And Marke	eting	New Potential Products
VST	Sales And Marke	ting	Next Quarter Total
VST	Sales And Marke	ting	Next Actions
VST	Sales And Marke		Next Month UK
VST	Sales And Marke	-	Next Month Export
VST	Sales And Marke	-	Post Market Surveilance
VST	Sales And Marke	-	Price Lists Export
VST	Sales And Marke	-	Price Lists UK
VST	Sales And Marke	-	Products to be Marketed
VST	Sales And Marke	-	Promotions
VST	Sales And Marke		Results achieved
VST	Sales And Marke		Sales
VST	Sales And Marke	_	Sales
VST	Sales And Marke		Sales Targets
VST	Sales And Marke	-	Search Engine Positions
VST	Sales And Marke	-	Search Engine Positions
VST	Sales And Marke		Service extension
VST	Sales And Marke	eting	Service exisiting
VST	Sales And Marke	eting	Staff
VST	Sales And Marke	ting	VIC - updates needed
VST	Sales And Marke	ting	VST Sales And Marketing
VST	Sales And Marke	_	VST Turnover
VST	Stock Meeting	_	ner Business
VST	Stock Meeting		er Accounts Review
VST	Stock Meeting		er Complaints Review **Mandatory**
VST	Stock Meeting		er or Product Feedback
VST	Stock Meeting Stock Meeting		Courier Cost Request
	_	_	•
VST	Stock Meeting	LOST III	Shipping Claims



VST	Stock Meeting	Missing Stock or Adjustments
VST	Stock Meeting	Non Conforming Stock Transfers. (QC19)
VST	Stock Meeting	Opera Partnumber / Prices Updates
VST	Stock Meeting	Production Requirements
VST	Stock Meeting	Purchase Back Orders Review
VST	Stock Meeting	Purchase Order Requirements
VST	Stock Meeting	Repairs Review - General
VST	Stock Meeting	Returns Overview
VST	Stock Meeting	Returns Overview - Credits
VST	Stock Meeting	Returns Overview - From Customers
VST	Stock Meeting	Sale or Returns
VST	Stock Meeting	Sales Back Orders Review - By Customer
VST	Stock Meeting	Sales Back Orders Review - By Product
VST	Stock Meeting	Sales Forward Orders Review
VST	Stock Meeting	Sales Order Issues
VST	Stock Meeting	Shipped Order Queries
VST	Stock Meeting	Stock Processing
VST	Stock Meeting	Stock Queries
VST	Stock Meeting	UPS Shipping Fuel Surcharge
VST	Stock Meeting	VST Stock Meeting
VST	Stock Meeting	'Goods In' Review
VST	Stock Meeting	'Goods Out' Review
VST	Calibration	P.A.T. Testing
VST	Calibration	VST Calibration
VST	Audits Calander	
VST		Audit Analysis of Data Audit Calibration
VST	Audits Calander Audits Calander	
VST		Audit Ce Files Audit Contact Review
VST		Audit Contract Review Audit Contract Review
VST		
VST		Audit Customer Complaints
VST	Audits Calander	Audit Design Control
VST	Audits Calander	Audit Devive Classification Now Apart of Audit 12
VST		Audit Documentation Control
VST		Audit Goods Inwards and Product Identity
VST		Audit Handling and Storage
VST		Audit Health and Saftey
VST		Audit Internal Audits
VST		Audit Management Review
VST		Audit Non - Conformances Now apart of Audit 14
VST	Audits Calander	
VST		Audit Organisation and Process Verification
VST		Audit Picking and Packing
VST		Audit Post Marketing Surveillance
VST		Audit Production
VST		Audit Purchasing
VST		Audit Repairs and Service
VST	Audits Calander	
VST		VST Audits Calander
	Compla	
	Old Hea	
		stomer Complaints
VST	Feedback	Customer Feedback Negative



VST	Feedback	Custome	er Feedba	nck Positive
VST	Feedback	Product	Feedbacl	k Negative
VST	Feedback			k Positive
VST	Feedback	VST Fee		
VST	Board Directors	Meeting	Any oth	er Business
VST	Board Directors		Back Or	
VST	Board Directors	_		g fabric Issues
VST	Board Directors	_	-	y Issues
VST	Board Directors		Creditor	
VST	Board Directors		Debtors	
VST	Board Directors		Distribu	tor Issues
VST	Board Directors		ISO Issu	ies
VST	Board Directors		Loans	
VST	Board Directors	_	Matters	Arising
VST	Board Directors	_		of Last Meeting
VST	Board Directors	_		nformities Review
VST	Board Directors	_	Overdra	
VST	Board Directors		Profiabi	
VST	Board Directors	_	Staff Iss	
VST	Board Directors	_	Stock Le	
VST	Board Directors	_	Supplier	
VST	Board Directors	_		or 2nd Year
VST	Board Directors	_		or following year
VST	Board Directors	_		or next Month
VST	Board Directors I	_	Target f	
VST	Board Directors	_	_	er and Predicted for Year
VST	Board Directors 1	_		and Directors Meeting
	GRAPH Manage			Additional Sales Orders
	GRAPH Manage			Any Changes in Agenda
	AGRAPH Manage			Audits
	GRAPH Manage			Back Order Report
	GRAPH Manage			Banking Issues
	GRAPH Manage			Calibration / P.A.T.
	GRAPH Manage			CE Files Review
	GRAPH Manage			CMDCAS Standards up todate
	GRAPH Manage			Customer or Product Feedback
	GRAPH Manage			
	GRAPH Manage			EN Standards up todate Fire Alarms
	_		_	
	AGRAPH Manage			Forward Sales Order Report
	AGRAPH Manage			Future Reviews - First Aid
	GRAPH Manage			Future Reviews - Internal Audits
	AGRAPH Manage			Future Reviews - Risk Assessment HSE
	GRAPH Manage			Future Reviews - Waste
	AGRAPH Manage			General Issues
	AGRAPH Manage			General Maintenance Requirements
	GRAPH Manage			Grants
	AGRAPH Manage			Internal Process Verification
	AGRAPH Manage			ISO Standards up to date
	AGRAPH Manage			Issues for Accountants
	AGRAPH Manage			MDA Recalls
	AGRAPH Manage			Members Objections To Meeting
	AGRAPH Manage			Minutes From Various Meetings
VANDA	AGRAPH Manage	ment Me	eting	Non Conformance Issues



The Viamed Risk Assessment Management Plan

VANDAGRAPH Management Meeting Other VANDAGRAPH Management Meeting Passwords Codes other Private information VANDAGRAPH Management Meeting Personnel Holidays and Time Adjustments VANDAGRAPH Management Meeting Personnel Requirements and Training VANDAGRAPH Management Meeting Production VANDAGRAPH Management Meeting Projects VANDAGRAPH Management Meeting Requested Supplier Payments Research and Development rnd VANDAGRAPH Management Meeting Review Accident Book VANDAGRAPH Management Meeting Review Weekly Meeting VANDAGRAPH Management Meeting VANDAGRAPH Management Meeting Supplier Review VANDAGRAPH Management Meeting Turnover Report VANDAGRAPH Management Meeting VANDAGRAPH Management Meeting VANDAGRAPH Sales And Marketing Any other business VANDAGRAPH Sales And Marketing Calendar Progress VANDAGRAPH Sales And Marketing Competitors VANDAGRAPH Sales And Marketing Customer Database Updates Customer pricing agreements VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing **Customer Training** VANDAGRAPH Sales And Marketing Distributor results dont use VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing E.Commerce VANDAGRAPH Sales And Marketing **EBay Exhibitions** VANDAGRAPH Sales And Marketing **Existing Good Products** VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing **Existing Poor Products** VANDAGRAPH Sales And Marketing Export Sales Catalogue - Updates needed VANDAGRAPH Sales And Marketing **External Sales** VANDAGRAPH Sales And Marketing External sales companies & Distributors Feedback VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing FrameWork Agreements Internal sales VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing Kingfisher Leaflets VANDAGRAPH Sales And Marketing Mailshots Export VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing Mailshots UK VANDAGRAPH Sales And Marketing Medica Exhibitions post show reports VANDAGRAPH Sales And Marketing **New Potential Products** Next Quarter Total VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing **Next Actions** VANDAGRAPH Sales And Marketing Next Month UK Next Month Export VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing NHS Supplies Future Technology VANDAGRAPH Sales And Marketing Post Market Surveilance VANDAGRAPH Sales And Marketing Price Lists Export VANDAGRAPH Sales And Marketing Price Lists UK Products to be Marketed VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing **Promotions** VANDAGRAPH Sales And Marketing Report on Export trip Results achieved VANDAGRAPH Sales And Marketing Sales VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing Sales Targets VANDAGRAPH Sales And Marketing Sales Viamed Automotive Export



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VANDAGRAPH Sales And Marketing Sales Viamed Automotive UK VANDAGRAPH Sales And Marketing Sales Viamed Medical Export VANDAGRAPH Sales And Marketing Sales Viamed Medical UK VANDAGRAPH Sales And Marketing Search Engine Positions VANDAGRAPH Sales And Marketing Search Engine Positions Service extension VANDAGRAPH Sales And Marketing Service exisiting VANDAGRAPH Sales And Marketing Staff VANDAGRAPH Sales And Marketing Telesales VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing UK Sales Catalogue - Updates needed VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing Viamed Turnover VANDAGRAPH Sales And Marketing VIC - updates needed VANDAGRAPH Sales And Marketing VANDAGRAPH Sales And Marketing Website VANDAGRAPH Stock Meeting Any Other Business VANDAGRAPH Stock Meeting Customer Accounts Review VANDAGRAPH Stock Meeting Customer Complaints Review **Mandatory** Customer or Product Feedback VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting Freight Courier Cost Request VANDAGRAPH Stock Meeting Lost in Shipping Claims VANDAGRAPH Stock Meeting Missing Stock or Adjustments VANDAGRAPH Stock Meeting Non Conforming Stock Transfers. (QC19) VANDAGRAPH Stock Meeting Opera Partnumber / Prices Updates VANDAGRAPH Stock Meeting **Production Requirements** Purchase Back Orders Review VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting Purchase Order Requirements VANDAGRAPH Stock Meeting Repairs Review - General VANDAGRAPH Stock Meeting Repairs Review - Pulse Oximetry Sensors VANDAGRAPH Stock Meeting Returns Overview Returns Overview - Credits VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting Returns Overview - From Customers VANDAGRAPH Stock Meeting Sale or Returns Sales Back Orders Review - By Customer VANDAGRAPH Stock Meeting Sales Back Orders Review - By Product VANDAGRAPH Stock Meeting Sales Forward Orders Review VANDAGRAPH Stock Meeting Sales Order Issues VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting Shipped Order Queries VANDAGRAPH Stock Meeting **Stock Processing** Stock Queries VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting UPS Shipping Fuel Surcharge VANDAGRAPH Stock Meeting VANDAGRAPH Stock Meeting 'Goods In' Review VANDAGRAPH Stock Meeting **VANDAGRAPH Stock Meeting** 'Goods Out' Review VANDAGRAPH Calibration P.A.T. Testing VANDAGRAPH Calibration VANDAGRAPH Calibration Audits Audits Calander Audit analysis Audits Audits Calander Audit Analysis of Data Audits Audits Calander Audit Calibration Audits Audits Calander Audit CE Files Audits Audits Calander Audit Contract Review Audits Audits Calander Audit Customer Complaints Audits Audits Calander Audit Design Control

Audits Audits Calander Audit Device Classification Now Apart of Audit 12



Human Human Med

Human Human Med

Human Human Med

Human Med

Human Med general Issues

Human Med Non Conformances

The Viamed Risk Assessment Management Plan

Audits Audits Calander Audit Documentation Control Audits Audits Calander Audit Goods Inwards and Product Identity Audits Audits Calander Audit Handling and Storage Audits Audits Calander Audit Health and Safety Audits Audits Calander Audit Internal Audits Audits Audits Calander Audit Management Review Audits Audits Calander Audit Non - Conformances Now apart of Audit 14 Audits Audits Calander Audit of Audits Audits Audits Calander Audit Organisation and Process Verification Audits Audits Calander Audit Picking and Packing Audits Audits Calander Audit Post Marketing Surveillance Audits Audits Calander Audit Production Audits Audits Calander Audit Purchasing Audits Audits Calander Audit Repairs and Service Audits Audits Calander Audit Training Audits Audits Calander Audits Calander VANDAGRAPH Customer Complaints VANDAGRAPH Customer Complaints VANDAGRAPH Feedback Customer Feedback Negative VANDAGRAPH Feedback Customer Feedback Positive VANDAGRAPH Feedback Product Feedback Negative VANDAGRAPH Feedback Product Feedback Positive VANDAGRAPH Feedback VANDAGRAPH Feedback VANDAGRAPH Board Directors Meeting Any other Business VANDAGRAPH Board Directors Meeting Back Orders VANDAGRAPH Board Directors Meeting Building fabric Issues VANDAGRAPH Board Directors Meeting Company Issues VANDAGRAPH Board Directors Meeting Creditors VANDAGRAPH Board Directors Meeting Debtors VANDAGRAPH Board Directors Meeting Distributor Issues VANDAGRAPH Board Directors Meeting ISO Issues VANDAGRAPH Board Directors Meeting Loans VANDAGRAPH Board Directors Meeting Matters Arising VANDAGRAPH Board Directors Meeting Minutes of Last Meeting VANDAGRAPH Board Directors Meeting Non Conformities Review VANDAGRAPH Board Directors Meeting Overdraft VANDAGRAPH Board Directors Meeting **Profiability** VANDAGRAPH Board Directors Meeting Staff Issues VANDAGRAPH Board Directors Meeting Stock Levels VANDAGRAPH Board Directors Meeting Supplier Issues VANDAGRAPH Board Directors Meeting Target for 2nd Year VANDAGRAPH Board Directors Meeting Target for following year VANDAGRAPH Board Directors Meeting Target for next Month VANDAGRAPH Board Directors Meeting Target for Year VANDAGRAPH Board Directors Meeting Turnover and Predicted for Year VANDAGRAPH Board Directors Meeting VANDAGRAPH Board Directors Meeting Marketing Job Logger Marketing Job Logger General General Contacts General General General General Stock Upgrading Upgrading Intrastats ISO Quality system Upgrading Intrastats ISO Quality system

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Office Office Meeting Office followups
Office Office Meeting Office Health safety
Office Office Meeting Office Meeting
Office Office Meeting Office Procedures
Office Office Meeting Office requirements
Office Office Meeting Office Training