

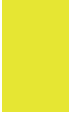

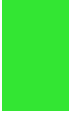











VIA MED

Versastream



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
4421154	VersaStream - Nasal Sampling Line with
4421165	VersaStream - Oral/Nasal Sampling Line
4421171	VersaStream - Airway Adapter Sampling
4421173	VersaStream - Airway Adapter Sampling

Comments on Stock references review:

Part numbers in place

Supplier Review

Comments on Suppliers:

Pre Product sale file no supplier logged yet,
Supplier will be Blue Point medical.

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
4421154	VersaStream - Nasal Sampling Line with							
4421165	VersaStream - Oral/Nasal Sampling Line							
4421171	VersaStream - Airway Adapter Sampling							
4421173	VersaStream - Airway Adapter Sampling							

Comments on Sales Information:

Pre Product sale file No sales yet,

Countries Review

Comments on Sales to Countries:

Pre Product sale file

Comments on Risks with Sales to Countries:

Pre Product sale file

Returns Review

Comments on Returns:

Pre Product sale file

Comments on Risks with Returns and Potential Re-work:

Pre Product sale file

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Pre Product sale file

Comments on Risks with Design Changes:

Pre Product sale file

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Comments on User Instructions:

Pre Product sale file

Comments on Risks User Instructions:

Pre Product sale file

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Comments on Labels:

Pre Product sale file

Comments on Risks Labels:

Pre Product sale file

Documentation Updates / Changes

Comments on Document Changes:

Pre Product sale file

Comments on Risks with Document Changes:

Pre Product sale file

Internal Issues Review

Number of Issues reviewed: 2

Issue ID	Subject
50624	VersaStream Respironics - Usability questionnaire
51519	VersaStream label artwork

Comments on Issues:

Pre Product sale file

Comments on Risks with Issues:

Pre Product sale file

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Risk ISO 14971 : 2012 Review

Full ISO 14971 : 2012 Risk review held off-site at original OEM company