COMPANY OPERATING PROCEDURES

Post Market surveillance

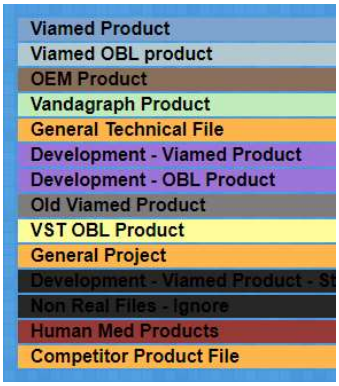
VM3/COP/18

Post Market Surveillance

ISO Menu, Technical File Links

Find the Technical File / Product range Name to be reviewed.
List is Grouped on Technical Family Type.

List Can Be Filtered to Viamed Products by
Clicking the Title Viamed Product in the KEY Listing Box.



Filtered list showing all product ranges:

ID	CE Cert	Family Name	Technical Family Type	Tools	Reviewed
(22)		Apgar Timer 2	Viamed Product (I)		18/11/21
(53)		COT Lids	Viamed Product (I)		18/01/21
(18)		Heat Shields	Viamed Product (I)		18/01/21
(25)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	Microstim MkIII	Viamed Product (IIa)		20/10/21
(8)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	Oxygen Tents/Hoods Nova	Viamed Product (IIa)		18/01/21
(21)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	Oxygen Tents/Hoods Tanda	Viamed Product (IIa)		18/01/21
(19)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	Phototherapy Light Shields	Viamed Product (I)		18/01/21
(13)		Resuscitation Cabinet	Viamed Product (I)		21/10/21
(7)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	T Adaptors	Viamed Product (IIa)		21/10/21
(16)	Viamed CE Certificate CE01389 Internal Use Only Cancellation Letter	Tom Thumb	Viamed Product (IIb)		18/03/21
(20)		Tube Holder	Viamed Product (I)		21/10/21
(66)		V1000 Foetal Heart Simulator	Viamed Product (I)		21/10/21

SELECT the Green or Red PMS Button – the Button will be Red if the Post Market Surveillance is Due. Button will be Green if the last review was within 12 Months.

The Page Takes sometime to load as its gather data from various sections of Intrastats.

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Post Market surveillance

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Section 1. Part numbers and Descriptions

Lists all Part numbers associated with the Technical File / Product range.
Check the Part numbers are still valid , The descriptions are correct and no new ones have been Added that are not on the list

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll Down for Section 2.

Section 2. Supplers and Supplier Reviews

Lists all suppliers associated with all the associated parts in the Technical File.
All suppliers should have upto date supplier review if they are still being used.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll Down for Section 3.

Section 3. Sales Information

Lists Sales Information for all the products and associated products.
If for Example Spare parts suddenly getting larger sales than normal it may indicate there is a problem with the main product.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll Down for Section 4.

Section 4. Location of Sales

Lists unique countries where the products have been sold.
See if any new countries could potentially pose a risk to/from the product based on region.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Questions Sales Country's - New Risks? With a comments box
Add in if there are or are not any risks identified with selling to various countries
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
Scroll down for Section 5.

Section 5.Customer Returns, Product/Component Failures

List out any Customer returns, Parts and Faults, over time.
Number failures , Trends in failures are part of the table.
Any new faults potential problems will be shown in the tables.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question does any returns or re-works pose any risks With a comments box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 6.

Section 6. Design Changes / Product Changes

List out Document design changes, ANY file in red are new to the system since the last review.
After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question does any design changes or product changes require any notifications to external parties such as MHRA/BSI , With a comments/answer box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 7.

Section 7. Current User / Instruction

Lists out User Instructions, any changes since the last review will be highlighted in red,

After the Listing there is a comments box to confirm the manuals are still for for purpose
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question if any risks associated with instruction manuals has been identified With a comments/answer box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 8.

Section 8. Labels

Lists out Labels used, any changes since the last review will be highlighted in red,

After the Listing there is a comments box to confirm the labels are still for purpose

Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question if any risks associated with the current label has been identified With a comments/answer box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 9.

Section 9 All documentation listing
Lists all documents linked in the technical file, with any new documentation highlighted in Red.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question does any documents pose any risks With a comments box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 10.

Section 10 Internal Communications and Issues
Lists all internal Communications that contain/attached/linked to the products and/or components.
The list contains any/all non conformance/ customer complaints / customer returns/ amonst all other areas of the company's processes and systems.

After the Listing there is a comments box, where comments can be logged to the report.
Clicking the Further Action will generate an Issue with the comments box when the form is completed.
There is also a Question Have any risks been identified in the Issues system With a comments box
Clicking the Further Action will generate an Issue with the comments box when the form is completed.

Scroll down for Section 11.

Section 11 Web Search for Clinical Reports
Contains 2 Yes / No Questions based on searching Google for Clinical + Product range.
Do any of the Results indicate a Risk / Problem with .. Product range
Do any of the Results indicate 'Product Range' is outdated Technology
Also a Comments box where any URL links can be pasted

Scroll down for Section12.

Section 12 Web Search for FDA Reports

Contains 2 Yes / No Questions based on searching Google for FDA + Product range.
Do any of the Results indicate a Risk / Problem with .. Product range
Do any of the Results indicate 'Product Range' is outdated Technology
Also a Comments box where any URL links can be pasted

Finally Click Signoff Report.
Print the PDF that is generated.
Find the Previous years version of the file, and upload on top.

If any Further actions were required, they will be in your daily Issues ready to be forwarded / acted upon by the relevant people.