VM3COP27.12 Clinical Evaluation Risk assessment Technical Files
*Note VM3COP27.12 should be performed by an independent person whom performed VM3COP27.11 on the product range.

Find the previous Clinical Evaluation Risk assessment section (H 3)

Find the Latest Risk Assessment Report section (H 3),

Find the Latest Risk analysis report (E 3).

Find the Latest version(s) of the IFU (F 5)

Follow Med DEV 2.7.1 Rev 3. Doc ID 8318 (or the latest version if it has been superceeded)

Evaluated if the Device(s) benefits still outweigh the residual risks, and that the device is still current and state of the art.

Ensure any related issue IDs are referenced

If Either the risk assessment report or risk analysis report is not in the system Follow VM3COP27.11

Once the new Clinical Evaluation has been performed

If the benefits still outweigh the residual risks, and that the device is still current and state of the art upload the new report on top of the old version .
If the Instruction manual requires updating due to new residual risks find the exisit manual in the technical file and request an amendment, add into the notes what is required.
the review is then complete..

If the device is either outdated or has residual risks that are a cause for concern.
Generate a NEW issue in the management CE Files review section,
subject: Name of the range - Clinical Evaluation Risk assessment
Active user : The Managing Director,
CC the issue to : The Product Manager

If anything has changed
Upload the new Clinical Evaluation Risk assessment report to the issue,