

VM3COP27.12 Clinical Evaluation Risk assessment Technical Files

Open 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).

Follow Med DEV 2.7.1 Rev 3. Doc ID 8318

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

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